

Sunset 2020 Review
Meeting 1 - Request for Public Comment
Livestock Substances §205.603, §205.604
April 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 2020. 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. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through www.regulations.gov by April 4, 2018 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic livestock production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with livestock production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

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

Sunset 2020 Review Summary
Meeting 1 - Request for Public Comment
Livestock Substances §205.603, §205.604
April 2018

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](#)

[Glycerine](#)

[Phosphoric acid](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Sucrose octanoate esters](#)

Alcohols

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

(1)(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

Background from Subcommittee:

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.

Additional information requested by Subcommittee:

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

Alcohols

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

(1)(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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:**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 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).

Additional information requested by Subcommittee:

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

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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:**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 ($R-OH \rightarrow R-OCOCH_3$). 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 has annotation restricting its withdrawal time. A second pain medication approved for pain relief in organic livestock is butorphanol (21 CFR 603(a)(5)). 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.

Additional information requested by Subcommittee:

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

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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

In addition to the allowance of this category of synthetic materials on the National List, there are other areas that address “biologics—vaccines” in the NOP Final Rule.

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);

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

- (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).

Excerpts from NOSB meeting notes of April 2013:

In the Vaccine Working Group's interim report, we see challenges with changing technology, lack of disclosure, and verifying supply chains. Any expectation of verifying vaccines made with excluded methods will need a clear and practical framework of how to determine compliance. Also, even with a

stricter rule regarding GM vaccine use, exceptions may be needed for critical vaccines that are only available from GM sources. *The interim report states:*

....because there's a considerable amount of manufacturer confidential business information, the working group could not end up with getting this list that we would like to have for producers that would allow them to easily identify which vaccines to use and which not. We then explored it further... as to what in fact constitutes an excluded method.

Current situation in 2017

The NOSB has improved and clarified their working definition of what methods would be considered genetic modification and therefore excluded from use under the USDA organic regulation. This work should aid the NOSB in moving ahead in looking at the issue of use of vaccines produced through the use of excluded methods.

The NOSB could propose to begin reviewing the known vaccines produced through excluded methods as listed in the TR from 2011, to place them individually on the National List as required in the regulation, 2015.105 (e). The NOSB could also propose to approve all vaccines produced through excluded methods as a "class" of vaccines, as suggested by the National Organic Program in the April 2013 NOSB meeting transcript. The NOSB could also choose to do nothing and maintain the current status quo of not addressing this issue, at this time.

The use of vaccines as a preventative measure to promote health in livestock is a necessary tool in organic livestock production. The Livestock Subcommittee does not want to lessen access to vaccines, both for routine maintenance of health, as well as in response to emergency situations. The allowance or prohibition of vaccines produced through the use of genetic engineering, or excluded methods, is not addressed in other organic standards around the world. As a result, all types of vaccines are allowed in various international organic standards.

NOSB members are aware that there is a great lack of consistency between certifiers when addressing the issue of GMO vaccines. Some require documentation that every vaccine used is not a GMO. Others do not require that documentation. Some require documentation and allow the use of the GMO vaccine. Inconsistency in implementation of the organic regulations leads to lack of trust in the certification system, as well as in the marketplace. Since the NOSB is now in review of vaccines for their sunset listing, we believe it is the time to address this problem of regulatory inconsistency.

The NOSB understands that livestock diseases can happen anywhere in the world and can quickly become a problem for all types of producers. At times, a GMO vaccine may be the only available solution to the problem, and the NOSB does not want to constrict the options available to producers. The NOSB is aware of GMO vaccines that are currently being used on organic livestock operations. Some may not have a non-GMO equivalent and some may. The NOSB could begin review of these individual GMO vaccines now for placement on the national list, to bring these operations using them into compliance with the full regulation as currently written.

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.

Manufacturing Process:

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, addition of other materials that may enhance the efficacy of the vaccine. These methods will result in a live, modified live or killed vaccine.

Specific Use:

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.

Additional information requested by Subcommittee:

1. Should individual genetically modified vaccines be listed on the National List, or should all genetically modified vaccines be allowed as a class, perhaps with a commercial availability clause such as "use of GE vaccines as a class is allowed with documentation that no GE version of the specific vaccine is commercially available".
2. What type of documentation are certification agencies currently requesting to determine non-GMO status for the vaccines used on organic livestock? How is this verified? Are they denying the use of GMO vaccines on organic livestock operations?
3. Is the current system where GMO vaccines are sometimes reviewed and either allowed or not, acceptable to the organic industry, and should it remain in place with no changes?
4. Are there alternative methods or materials that make vaccines no longer an essential material on the National List of approved synthetics?

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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

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 the 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.

Manufacturing Process:

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

Specific Use:

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, and 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.

Additional information requested by Subcommittee:

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

Glycerine

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable
(12) Glycerine - 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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

Glycerin, or glycerol, 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 the annotation for glycerin at § 205.603(a)(11) that requires production through hydrolysis of fats or oils. 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.

Specific Uses: Glycerin has over 1,000 uses; however, glycerin is limited to being used as an ingredient in teat dips for the addition to § 205.603(a), 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 detrimentally affect chemical interactions with other substances. Glycerin remains inert and does not change the properties of substance in which it is used. Furthermore, it acts as an emollient, reducing moisture evaporation of the skin.

OFPA: Glycerin falls under section 6517(1)(B)(i) of the OFPA code that describes livestock medicines.

INTERNATIONAL: The 2010 TAP review stated that livestock materials have not been addressed by Codex and that IFOAM Basic Standards do not mention glycerin, or other synthetics used as teat dips, but it does not appear to be prohibited.

Effects on Human Health: Glycerin mist can act as an inhalation irritant. It is easily digested with the same metabolism as the carbohydrates.

Effects on the Environment: Glycerol can never be sorted or come into direct contact with strong oxidizers such as potassium chlorate or potassium permanganate because it may produce an explosion.

Alternatives:

Synthetic Alternatives: Isopropyl Myristate, Isopropyl Palmitate, Polypropylene Glycol, Other Glycol Derivatives, Petroleum Fractions, High Molecular-Weight Alcohol, Allantoin, Synthetic Glycerin from petrochemicals.

Natural Alternatives: Castor and Vegetable Oil.

Management tools: Some management tools for controlling mastitis 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.

Additional information requested by Subcommittee:

1. In April 2015, the NOSB Handling Sub-committee recommended listing of glycerin at §205.606 and removal of glycerin from §205.605(b) after review of the manufacturing methods and sources. Are there non-food grade agricultural sources of glycerin produced by microbial fermentation of carbohydrate substances, and/or are there sources of glycerin produced from hydrolysis of fats and oils using mechanical/physical methods that are readily available as an ingredient for teat dips?
2. If there are non-food agricultural sources of glycerin available, should synthetic glycerin be removed from 205.603(a)?
3. Have there been updates in the International status for approval of synthetic glycerin used as livestock teat dips since the 2010 TAP was published?
4. How are certifiers tracking that the glycerin used as a teat dip is being produced through the hydrolysis of fats or oils?

Phosphoric acid

Reference: **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable
(20) 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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

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?

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](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for external pest control (7 CFR 205.603(b)(5)). Regarding livestock applications, the National List states that hydrated lime may not be used to cauterize physical alterations 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. The USDA organic regulations currently permit 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)).

Manufacturing Process:

According to USDA organic regulations, “synthetic” is defined as “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...” (7 CFR 205.2). Hydrated lime [Ca(OH)₂] is produced through two sequential reactions: thermal decomposition of ground limestone (CaCO₃) to quicklime (CaO) followed by hydration of quicklime at elevated temperatures and/or pressures. The limestone starting material is a naturally derived, non-synthetic substance. However, the NOSB classified calcium oxide (quicklime) as a synthetic substance due to the chemical change that occurs during the thermal reaction of natural limestone. Hydrated lime is therefore produced through chemically changing a synthetic substance (quicklime). Based on the “synthetic” definition, it is reasonable to conclude that hydrated lime used as an external parasiticide in organic livestock production is a synthetic substance. The NOSB has classified hydrated lime as synthetic since initially recommending addition of the substance to the National List for organic livestock production.

Specific Use:

The USDA organic regulations currently permit the use of hydrated lime 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)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations or deodorize animal wastes.

Additional information requested by Subcommittee:

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?

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](#)

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

Background from Subcommittee:

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 former 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 for organic production, but a proposed rule published by NOP on January 17, 2018 ([83 FR 2498](#)) would add mineral oil to the National List for relief of intestinal impaction (as recommended by the NOSB in 2002).

Mineral oils used in organic livestock production are hydrocarbon molecules containing 15 to about 50 carbon atoms (U.S. EPA, 2007; EFSA, 2012). Crude, untreated mineral oil mixtures consist of three major classes of compounds: paraffins (linear and branched alkenes), naphthenes (alkyl-substituted cyclo-alkanes) and aromatics (including polynuclear aromatic hydrocarbons (PAHs)), which are generally alkyl-substituted. These untreated mineral oils may also contain small amounts of nitrogen- and sulfur-containing compounds (EFSA, 2012).

Manufacturing Process:

The composition of mineral oil is dependent upon the crude petroleum oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. In the 2007 risk assessment for mineral oils, U.S. EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds (U.S. EPA, 2007). Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components from compounds of varying carbon chain length to isomers of the same carbon chain length - are constituents of crude and refined mineral oil mixtures (EFSA, 2012).

Specific Use:

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 former use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites.

Additional information requested by Subcommittee:

1. Is this an essential material?
2. Is mineral oil being used orally?
3. Are organic farmers using mineral oil as a lubricant?

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

Background from Subcommittee:

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SFAEs are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. 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* (wild tobacco) and other *Nicotiana* species. In addition to the tobacco plant, insecticidal sugar esters have been found in wild tomato and wild potato species and in the petunia plant (Chortyk et al., 1996). The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids. SOEs are listed at §205.601(e) as an insecticide (including acaricides or mite control), but the listing at §205.603(b) specifically addresses the petitioned use for livestock (i.e., honey bees).

Specific Uses of the Substance:

Sucrose octanoate esters (SOEs) are an EPA-registered biopesticide. SOEs are permitted by EPA for use as a biopesticide for foliar spray in field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals), as well as on mushroom growing media and on adult honey bees. (U.S. EPA, 2002a).

Effect on the Environment:

SOEs are an effective adult miticide (as well as controlling other pest types); they can be used at all plant growth stages; is not harmful to fish; it is not a hazard to bees (it is registered for use on bees to control *Varroa* mites); and it is not phytotoxic. When applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOE is expected (U.S. EPA, 2002a).

In addition, 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 exists to insects, fish, and other non-target wildlife. U.S. EPA, 2002a). 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 TAP review states that no sub-chronic, chronic, immune, endocrine issues have been identified. An ocular risk exists but is unlikely if product is used according to label.

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 spray. Should there be further information requested about the toxicity of SOEs to non-target organisms?
2. Is this product still being used, or are there other synthetic products that are more effective?
3. If SOEs are not being used, do we need it to keep in the livestock toolbox to be rotated with other products?