Sunset 2025
Meeting 2 - Reviews
Livestock Substances § 205.603 & § 205.604
October 2023

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 must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
Written public comments will be accepted through September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Public 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: (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 clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant 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 (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that <u>Support</u> the Continued Use of §205.603 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.603, 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 the Continued Use of §205.603 Substances in Organic Production:
If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. 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/or
3. inconsistent with organic livestock production.

For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic livestock production.

For Comments Addressing the Availability of Alternatives:
Comments may include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

1. Alternative management practices or natural substances that would eliminate the need for the specific substance;
2. Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
3. 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 organic operations 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 September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:

- Alcohols: Ethanol
- Alcohols: Isopropanol
- Aspirin
- Biologics—Vaccines
- Electrolytes
- Glycerin
- Phosphoric acid
- Lime, hydrated
- Mineral oil

§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:

- None

Alcohols: 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
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The following is from the 2014 Technical Report (TR), line 118-123:

> "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 (RED) 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:
The following is from the 2014 TR, line 43-48:

> "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 (Merck, 2006; Logsdon, 2004). Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene ($H_2C=CH_2$), and as a by-product of certain industrial operations."

International Acceptance:
Canadian General Standards Board Permitted Substances List
The following is from the 2014 TR, line 204:

> "Canadian organic production standards permit the use of ethanol for a number of agricultural applications."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The following is from the 2014 TR, line 222-223:

> "Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils…"

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The following is from the 2014 TR, line 215-216:

> "Ethanol is allowed… when mechanical, physical and biological methods are inadequate for pest control."

International Federation of Organic Agriculture Movements (IFOAM)
The following is from the 2014 TR, line 242-243:

> "…synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available."

Japan Agricultural Standard (JAS) for Organic Production
The following is from the 2014 TR, line 229-231:

> "…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."

Environmental Issues:
The following is from the 2014 TR, line 586-594:

> "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."

Discussion:
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of this material further confirms it as being aligned with OFPA.

Questions to our Stakeholders:
None.

Justification for Vote:
The Subcommittee finds alcohols: ethanol compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove alcohols: ethanol from the National List
Motion by: Nate Powell-Palm
Seconded by: Brian Caldwell
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Alcohols: 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
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The following is from the 2014 Technical Report (TR), line 54-63:

> "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:
2014 TR, line 37-44:

> "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 Acceptance:
Canadian General Standards Board Permitted Substances List
2014 TR, line 195-196:

> "Canadian organic production standards permit the use of isopropanol for a number of agricultural applications."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
\Isopropanol is not an allowed synthetic substance for organic production within the European Union. However, Commission Regulation (EC) No 889/2008 provides rules for two different uses of ethanol in organic production in European Union member states. Alcohol, likely referring to ethanol alone, may be used for cleaning and disinfecting livestock building installations and utensils under Annex VII of the

regulations. In addition, Annex VIII stipulates the use of ethanol (not isopropanol) in Section B—Processing aids and other products, which may be used in the processing of ingredients of agricultural origin from organic production. This regulation specifically allows the use of ethanol as a solvent in the preparation of foodstuff of both plant and animal origin..

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

The Codex Guidelines do not provide any allowable uses for isopropanol in the production or processing of organically produced foods. However, ethanol is allowed under Annex 2 (table 2) of the Guidelines when mechanical, physical and biological methods are inadequate for pest control. Further, the Guidelines require that an organic certification body or authority recognize the need for any pest control treatments using ethanol. Ethanol is also listed as an allowed processing aid "which may be used for the preparation of products of agricultural origin." Specifically, ethanol may be used as a solvent in these preparatory operations (Codex, 2013)..

International Federation of Organic Agriculture Movements (IFOAM)

2014 TR, line 239-241:

> "…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 (IFOAM, 2012)."

Japan Agricultural Standard (JAS) for Organic Production

Japanese organic standards do not directly permit the use of isopropanol for any purpose in organic production or processing. In contrast, ethanol is allowed for use in several areas of organic production/processing. In lieu of information related to the use of isopropanol, technical information for ethanol is compiled in the following paragraph. __According to the Japanese standards for organic plant production, ethanol may be used in the processing, cleaning, storage, packaging and other post-harvest processes when physical or methods utilizing biological function are insufficient. The specific crop uses of ethanol are for (1) controlling noxious animals and plants, and (2) quality preservation and improvement (JMAFF, 2005a). Likewise, ethanol may also be used in the manufacturing, processing, packaging, storage and other processes associated with organic livestock feed when physical or methods utilizing biological function are insufficient for disease and pest control (JMAFF, 2005b). Similar provisions exist for the use of ethanol in the slaughter, dressing, selection, processing, cleaning, storage, packaging and other processes associated with organic livestock products. "Alcohols" are listed as allowed cleaning and disinfection agents for livestock housing; however, it is unclear whether isopropanol is allowed under this listing (JMAFF, 2005c). It should be noted that ethanol use is not permitted for the purpose of pest control for plants and agricultural products. For processed foods, ethanol may be used as an additive in the processing of meat products only (JMAFF, 2005d).

Environmental Issues:

2014 TR, line 362-364:

> "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."

2014 TR, line 366-367:

> "Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses."

2014 TR, line 413-415:

> "According to US EPA, isopropanol is slightly toxic (Category III) to practically non-toxic (Category IV) based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995)."

Discussion:
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of isopropanol further confirms it as being aligned with OFPA.

Questions to our Stakeholders:
None.

Justification for Vote:
The Subcommittee finds alcohols: isopropanol compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove alcohols: isopropanol from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 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: 1994 TAP; 2017 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 347-348); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
There was no additional discussion aside from the review of Spring 2023 meeting comments.

Use:
The following information and data was taken from the 2017 TR.

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. Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effects. 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.

Manufacture:
The most prevalent method of synthesizing aspirin is via 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 → R-OCOCH3; 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 CO2 to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from an 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.

International Acceptance:
Canadian General Standards Board Permitted Substances List
The Canadian General Standards Board includes aspirin as a permitted substance for organic production 82 systems under CAN/CGSB-32.311-2015 for pain mitigation and inflammation reduction in livestock 83 84 Aspirin was not found to be listed under any other international standard for organic livestock production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Aspirin was not found to be listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Aspirin was not found to be listed under CODEX for organic livestock production.

International Federation of Organic Agriculture Movements (IFOAM)
Aspirin was not found to be listed under IFOAM for organic livestock production.

Japan Agricultural Standard (JAS) for Organic Production
Aspirin was not found to be listed under JAS for organic livestock production.

Environmental Issues:
Due to the rapid biodegradation/hydrolysis of aspirin and its active metabolite, salicylic acid, and the effectiveness of sewage treatment, there are no known reports of aspirin causing appreciable harm to surface or groundwater, soil, or agro-ecosystems. The background levels present in drinking water would result in the average exposure of approximately 0.05% of a typical daily dose over an average 70-year lifetime in humans. There is some evidence that acetylsalicylic acid (and/or active metabolites) can be toxic to aquatic invertebrates; however, current research into the impact of aspirin and pharmaceuticals in wastewater and aquatic ecosystems is not sufficient for definite conclusions.

Discussion:
Aspirin 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.

Questions to our Stakeholders:
None

Justification for Vote:
The Subcommittee finds aspirin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove aspirin from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 1

Biologics—Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(4) Biologics - Vaccines.
Technical Report: 2014 TR2011 TR (GMO vaccines); 2014 TR (§205.611 aquaculture)
Petition(s): 2012 (§205.611 aquaculture)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 3-4); 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation (§205.105 excluded methods); 10/2010 NOSB sunset recommendation; 10/2014 NOSB recommendation (§205.105 excluded methods); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation; 10/2019 NOSB recommendation (§205.105 excluded methods)
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290);

Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The Organic Foods Production Act (OFPA) specifically allows vaccines to be used in the absence of illness, while prohibiting all other medications from this use (7 U.S.C. 6509(d)(1)(C)). 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. In the case of a disease outbreak, administration of vaccines may be required by government agencies.

Manufacture:
Vaccines are produced through a variety of methods that use natural pathogens, parts of pathogens, or genetically modified organisms grown in a culture (yeast, bacteria or cell), separation and purification of the vaccine, and addition of other materials that may enhance the efficacy or stability of the vaccine. In mRNA vaccines, the final production of the antigen occurs in cells of the vaccinated person or animal via the action of introduced modified mRNA.

International Acceptance:
Canadian General Standards Board Permitted Substances List
It appears that GMO vaccines are allowed in organic agriculture in Canada if other vaccines are not commercially available or are ineffective (CAN/CGSB-32.311-2020 table 5.3).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
EU standards (EU 2018/848) do not explicitly discuss GMO vaccines. GMOs are not allowed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
2011 Technical Report (TR), which focuses on GMO vaccines, says this in lines 153-158:

> According to the Codex Alimentarius Commission's guidelines for organic agriculture, *"where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."* The standards do not clarify whether vaccines should be free of GMO organisms; however, it is noted in the guidelines that anything contained in animal feed must be from non-biotechnology-derived sources (Codex Alimentarius Commission, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms
2011 TR, line 164-167 says:

> According to the International Federation of Organic Agriculture Movements (IFOAM) draft 2010 standards, while *"the deliberate use or negligent introduction of genetically engineered organisms or their derivatives is prohibited"* for animals, seeds, fertilizers, and other materials, IFOAM makes an exception for vaccines (IFOAM, 2010).

Japan Agricultural Standard (JAS) for Organic Production

2011 TR, line 169-171 says:

> Recombinant technology is generally prohibited in the production of livestock products under the Japan Agricultural Standard (JAS) for Organic Production; however, a discussion of vaccines derived with GMO organisms is not provided (JMAFF, 2005).

Environmental Issues:

The Subcommittee has structured this sunset review of Biologics-Vaccines based on the substance evaluation criteria in the OFPA (7 U.S.C. 6518). 7 U.S.C. 6518 (National Organic Standards Board) paragraph "m" (Evaluation) lists seven items that the Board shall consider when evaluating National List substances. The Subcommittee pulled responses to items 1-6 from the 2011 TR. The Subcommittee response to item 7 is based on the NOSB 2019 formal recommendation to the NOP.

§6518(m)(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.

> The 2011 TR, lines 261-265, indicates:
> Vaccine additives may interact with other additives/adjuvants; however, reactions are limited due to the generally small amounts of chemical constituents present in vaccines. Furthermore, preservative/adjuvant combinations such as thimerosal [a mercury-based preservative] and aluminum salts are common, and generally any vaccines causing adverse reactions would not be allowed on the market unless risks were mitigated (Roth and Henderson, 2001).

§6518(m)(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

> The 2011 TR, lines 236-243, indicates:
> All vaccines (conventional and GMO) can be shed in the animal's feces and other secretions, although not all animals will shed vaccine DNA. This shed DNA could potentially infect other animals and spread the virus or bacteria in the environment. However, … vaccines cannot survive in the environment for long periods of time. Vaccines contain aluminum salts and other chemical adjuvants or additives; however, it is unclear if these substances are released in high quantities or whether they may impact the environment. Moreover, for both conventional and GMO vaccines, regulatory authorities consider additives when licensing them, establishing residue limits and withdrawal periods (required time between vaccination and slaughtering or milking) when necessary (OIE, 2010).

§6518(m)(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance.

> The 2011 TR, lines 248-255, indicates:
> Although accidental spills may occur during vaccination and some environmental contamination may occur during proper use (e.g., in coarse spray vaccine administration),… extensive contamination of the environment with vaccine organisms is not anticipated due to low rates of shedding and the low survival rate of many pathogens in the environment (CFIA 2007 and 2008a). If manufacturers/livestock farmers do not correctly dispose of unused or expired vaccine materials, there is a potential for contamination of the environment with vaccine additives such as mercury-containing thimerosal (MDH, 2011). The impact of this contamination would depend on the specific circumstances of the manufacturing process or disposal.

§6518(m)(4) the effect of the substance on human health.

> The 2011 TR, lines 307-323, indicates:

Regulators have noted that farmers or vaccine applicators could become infected during care of vaccinated animals that shed viral or bacterial organisms (CFIA, 2007 and 2008a). However, many of the diseases for which food animals are vaccinated cannot reproduce in either the target animal or humans (CFIA, 2007 and 2008a). For example, the vector for the porcine circovirus vaccine is Baculovirus, which is an insect virus not associated with disease in humans or animals. Risk assessments for GMO vaccines conducted by the Canadian Food Inspection Agency (CFIA) predicted that human health effects in workers would be minimal, as long as handlers took the necessary safety precautions to protect themselves (e.g., safety equipment such as gloves).

Some regulators and scientists have questioned whether the meat from GMO vaccinated animals may be harmful to humans who consume it (CFIA, 2006; Traavik, 1999). This issue is examined before licensure of a GMO vaccine. For example, the risk assessment report from the CFIA (2006) indicates that the Salmonella typhurium vaccine (live culture GMO vaccine) has a low health risk to humans exposed through spills or shedding by vaccinated animals. The vaccine strain is entirely eliminated before the broiler chickens are sold, so salmonella exposure to humans consuming vaccinated animals is unlikely. If any viral DNA is left in meat from vaccinated animals, it is expected to be broken down in the human gastrointestinal tract, thus, health problems are not anticipated from consumption (CFIA, 2010).

§6518(m)(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.

The 2011 TR, lines 283-290, indicates:
GMO vaccines are meant to improve immunity to disease in vaccinated livestock animals…. All vaccines, including GMO vaccines, can cause unwanted side effects in vaccinated animals including swelling and irritation at the site of injection, fever, coughing (after nasal administration), respiratory distress, and reduced fertility (Morton, 2007). However, there is no difference in these symptoms between GMO and traditional vaccines, and all vaccines are evaluated for side effects by manufacturers.

§6518(m)(6) the alternatives to using the substance in terms of practices or other available materials.

The 2011 TR, lines 340-346, indicates:
Homeopathic remedies may be used to supplement or replace vaccines. For example, nosodes are a homeopathic remedy made from a pathological product (e.g., blood, saliva, or diseased tissue) that are administered orally (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. However, some studies have indicated that nosodes are not highly efficacious in preventing disease (McCroy and Barlow, in Morris and Keilty, 2006). Nosodes may be more effective if combined with conventional vaccines or if other homeopathic remedies are used. Natural herbal supplements like dandelion and chicory may also be used, but these are usually used to treat infection once it occurs, rather than to prevent infection (Morris and Keilty, 2006).

The 2011 TR, lines 423-431, also indicates:
According to the European Council for Classical Homeopathy (ECCH), nosodes are “homeopathic remedies of biological origin that are derived from pathologically modified organs or parts of organs that are of human or animal origin, or from cultured micro-organisms that have been killed, or from products of the decomposition of animal organs, or from body liquids containing

pathogens or pathological products" (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. Nosodes have been used to treat bovine mastitis, or inflammation of the mammary glands, in dairy cows. This condition is usually caused by bacteria entering the udder. Vaccines have been shown to be ineffective in preventing most cases of mastitis.

Finally, the 2011 TR, lines 441-451, indicates:
A study by Werner et al. (2010) found no difference between the cure rates of homeopathic treatments versus antibiotic treatments (allowed in conventional livestock only) for mild to moderate mastitis at the end of a 56-day treatment period. However, authors reported that the homeopathic remedy significantly increased the cure rate compared to placebo treatments…. Despite the improvements compared to placebo-treated animals, authors noted that both homeopathic and antibiotic treatments had a relatively low cure rate, suggesting low efficacy for these two treatments Werner et al., 2010).

§6518(m)(7) its compatibility with a system of sustainable agriculture.

The NOSB recognizes that vaccines play an important role in a sustainable agriculture system, from animal health to farm financial viability. The 2019 NOSB recommendation states the following:
"The [NOSB] recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal's production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, 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."

Discussion

The Livestock Subcommittee recognizes that use of vaccines can be critical to the success of organic livestock farms. Two areas in the organic regulations address use of vaccines; one on the National List of Allowed and Prohibited substances at §205.603(a)(4), and one in the section that details excluded methods at §206.105 (e). In 2019, the NOSB issued a formal recommendation to the NOP. In this, the NOSB recommended that the NOP change the USDA organic regulations at §205.105(e), from:

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

to:

(e) Excluded methods, except for vaccines: Provided, That, **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.**

The 2019 NOSB recommendation also included proposed instructions on how to determine whether a vaccine was produced with excluded methods. The recommendation included a list of vaccines produced with and without excluded methods (from the 2011 TR), that the NOSB asked the NOP and stakeholders to use and update. As of the writing of this subcommittee sunset review for the October 2023 NOSB meeting, the 2019 NOSB recommendation has not been adopted by the NOP and the NOSB Recommendations Library (July 2023 version) indicates that this recommendation is "On Hold".

For Spring 2023 stakeholder comments, the Livestock Subcommittee posed several specific questions:

1. What are the most up to date organic regulations on GMO vaccines in other countries?
2. Are there concerns about components of vaccines besides the active ingredients?
3. Are certifiers interpreting the provisions at §205.603(a)(4) and § 205.105(e) consistently, even though the 2019 NOSB recommendation has not been officially adopted?
4. Is the wording in italics below an acceptable interpretation of § 205.105(e)?

This sunset review encompasses the entire class of synthetic livestock vaccines, including those made with excluded methods. The NOSB encourages the NOP to adopt the 2019 recommendation. In the meantime, our interpretation is that this listing fulfills the requirement at §206.105 (e) for all livestock vaccines.

The Subcommittee received one answer to #1, saying that to their knowledge, all vaccines are allowed in Canada and the EU and #2, that other components are present in minute quantities. Responses to #3 and #4 indicated that in practice, certifiers follow the italicized approach above. One consumer group opposes that interpretation, saying that since no vaccines have been individually reviewed, no GMO vaccines should be allowed. One farmer organization opposes the implementation of the 2019 recommendations because they felt that it would present practical difficulties and be a barrier to farmers. Eight other stakeholders supported the implementation of the 2019 recommendations.

In spite of important concerns over non-active ingredients and the GMO status of many livestock vaccines, the Livestock Subcommittee feels that the need for effective vaccines is critical for livestock production. Since the 2019 recommendations have not been implemented at this time, the Livestock Subcommittee has adopted the following interpretation:

> This sunset review encompasses the entire class of synthetic livestock vaccines, including those made with excluded methods. The Livestock Subcommittee encourages the NOP to adopt the 2019 NOSB recommendation. In the meantime, our interpretation is that this listing fulfills the requirement at §206.105 (e) for all livestock vaccines.

Justification for Vote
The Livestock Subcommittee finds biologics - vaccines compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove biologics - vaccines from the National List
Motion by: Brian Caldwell
Seconded by: Amy Bruch
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(11) Electrolytes - without antibiotics.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Electrolytes are more properly called "veterinary electrolyte formulations". They are mixtures of multiple synthetic ingredients used to restore ionic balance, especially in oral rehydration solutions to correct dehydration and in oral and injectable formulations for correction of milk fever. Key electrolyte ingredients include calcium, potassium, magnesium, and sodium salts plus phosphates, dextrose and other additives.

Use:
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 electrolytes to restore health and well-being to the animal.

Manufacture:
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.

International Acceptance:
Canadian General Standards Board Permitted Substances List
In Canada, the Permitted Substances List for Organic Animal Production allows electrolytes as part of Table 5.3 'Health Care Products and Production Aids.' Calcium borogluconate is specifically permitted as a treatment for milk fever. 'Electrolytes without antibiotics' are permitted, and electrolyte solutions 'with no added active ingredients' are permitted (Canadian Standards 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Electrolytes are not specifically mentioned. However, under Health Care, Section 22 “where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted.” However, veterinary drugs are not permitted to be used for preventive purposes (Codex 2001).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Electrolytes are not mentioned specifically in 834/2007. However, Article 14 Section 1 (e) (ii) states “chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions” (EU EEC 2007).

In 889/2008 many of the electrolyte salts are permitted as feed additives. The list is in Annex V, Feed Materials of Mineral Origin (EU EEC 2008).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005). Later revisions included livestock. A summary in 2007 mentions that organic livestock must be fed organic feed, have exercise and access to pasture, and must not be fed antibiotics or GMOs. Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

International Federation of Organic Agriculture Movements (IFOAM)
In the IFOAM NORMS for organic production and processing version 2012, electrolytes are not specifically mentioned for organic animal production. In Section III (5) on Animal Husbandry, only natural sources are permitted for vitamins, trace elements, and supplements. Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status (IFOAM 2012). But many of the electrolyte substances are mentioned in Appendix 4 as additives and processing aids.

Environmental Issues:
Environmental impacts are thought to be low. Since electrolytes are usually added to correct deficiencies, concentrations in the environment due to excretion would be no more than a normal untreated animal with normal electrolyte balances. Also, usually only a small number of animals are treated at a time. Production of electrolytes does have environmental effects, but quantities used for this purpose are relatively small.

Discussion:
There was agreement among all Spring 2023 written commenters to retain electrolytes on the National List, with no changes to the annotation. One commenter requested that the allowed uses be specified, but this is accomplished via the listing at 205.603(a) As disinfectants, sanitizers, and medical treatments as applicable. Electrolytes are used regularly and found to be essential by a large number of organic livestock producers. Environmental and consumer groups supported electrolytes, as well as companies that market organic livestock products.

Questions to our Stakeholders:
None.

Justification for Vote:

The Livestock Subcommittee finds electrolytes compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove electrolytes from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Glycerin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(14) Glycerin - allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
Technical Report: 2010 TAP
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Technical correction (changed to "glycerine") published 12/12/2007 (72 FR 70479); Sunset renewal notice published 06/06/2012 (77 FR 33290); Technical correction (changed back to "glycerin") published 02/05/2015 (80 FR 6429); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Glycerin has over 1,000 uses; however, its use in organic livestock is limited to an ingredient in teat dips (§205.603(a)(11)). As an ingredient in teat dips, glycerin prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990) [2010 TAP p. 1].

Manufacture:
Glycerin is a byproduct of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats and 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 [2010 TAP pgs. 1, 3].

International Acceptance:

Canadian General Standards Board Permitted Substances List
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

International Federation of Organic Agriculture Movements (IFOAM)
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Japan Agricultural Standard (JAS) for Organic Production
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Environmental Issues:
Glycerin breaks down to glucose, which in turn readily breaks down in the environment to carbon dioxide (CO_2) and water (H_2O); there are no concerns with persistence or toxicity in the environment [2010 TAP pg. 2].

Discussion:
Spring 2023 comments were supportive of relisting glycerin. A few commentors noted that manufacturer documentation can validate hydrolysis process.

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

Questions to our Stakeholders:
None

Justification for Vote:
The Subcommittee finds glycerin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove glycerin from the National List
Motion by: Kim Huseman
Seconded by: Amy Bruch
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(25) Phosphoric acid - allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
Technical Report: 1999 TAP (pg. 25-34); 2003 TAP (pg. 21-24); 2021 TR (handling); 2023 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Phosphoric acid (H_3PO_4) 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.

From the 2023 Limited Scope Technical Report (TR), line 63-66:

> "In livestock facilities, phosphoric acid is used in Clean-In-Place (CIP) and non-CIP systems[2] to remove encrusted surface matter and mineral scale found on metal equipment. The chemical reaction of the acid with minerals found in deposits makes them water soluble and thus easier to remove. For cleaning purposes, phosphoric acid is often combined with a surfactant, usually a detergent….
>
> [2] Clean-in-Place refers to cleaning the interior surfaces of pipes and equipment without dismantling them first. NonCIP would involve at least some dismantling of the equipment before cleaning."

From the 2023 Limited Scope TR, line 70-73:

> "Phosphoric acid is sometimes used to remove resistant biofilms, colonies of microorganisms that attach to a surface and are protected by a self-generated protective film of polysaccharides (Muhammad et al., 2020). Surfaces covered with mineral scale are particularly susceptible to biofilm attachment. It is important to note that when the mineral scale is dislodged, the biofilm is also dislodged."

Manufacture:
There are two ways to create phosphoric acid (2003 Technical Advisory Panel (TAP), pg. 21).

1. Wet Process – Mined phosphate ore is treated with sulfuric acid, and the resulting phosphoric acid is separated from the calcium sulfate crystals produced. Many ore impurities exist; therefore, they can be further purified to obtain technical or food-grade phosphoric acid.

2. Thermal (furnace process) – Pure phosphorus is burned in excess air, and the resulting phosphorus pentoxide is then hydrated, cooled, and the acid mist is collected. It is considered purer than phosphoric acid achieved via the wet process and is considerably more expensive.

International Acceptance:

Canadian General Standards Board Permitted Substances List

2021 TR for Handling, line 349-351:

> "Phosphoric acid is… listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." "

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

2021 TR for Handling, line 358:

> Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

2021 TR for Handling, line 358:

> "Phosphoric acid is not listed in the CODEX."

International Federation of Organic Agriculture Movements (IFOAM)

2021 TR for Handling, line 365-367:

> "Phosphoric acid is listed in the IFOAM NORMS for organic production and processing as an "equipment cleanser and equipment disinfectant only for dairy equipment" and as a "substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment." "

Japan Agricultural Standard (JAS) for Organic Production

2021 TR for Handling, line 361:

> "Phosphoric acid is not listed in the JAS."

Environmental Issues:

The 2021 TR (handling) indicates that if stored, used, and disposed of properly, phosphoric acid utilized as a cleaning agent for livestock equipment and facilities will not interact very much with the agroecosystem nor come into direct contact with livestock. The acid will dilute quickly in the environment, and there are no toxicity issues directly from its breakdown products.

Effects on Human Health – The exact dangers depend on the solution's concentration strength, 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.

Discussion:

The Subcommittee conducted a thorough discussion of phosphoric acid and reviewed extensive public comments at the Spring 2023 Board meeting. Public comments indicated consensus in relisting, as phosphoric acid is used extensively to remove deposits on equipment, such as milk lines and bulk tanks, that cannot be removed with other detergents and acids. The Board reviewed concerns from stakeholders regarding the need for clarity on several fronts, including the following:

1. **Rinse or No Rinse:** Clarity is needed regarding phosphoric acid's classification as a sanitizer or a cleaner. Use as a cleaner requires a rinse post-use. The Board discussed the legal requirement to not rinse phosphoric acid, per the United States Public Health Service/Food and Drug Administration (USPHS/FDA) Grade "A" Pasteurized Milk Ordinance (PMO).
2. **Downstream equipment**: Clarity is needed surrounding the bulk tank, located downstream of the milking system equipment, about whether it is included in this scope. If the bulk tank does get rinsed, can the rinsate, that is combined with manure, be applied onto farm fields?
3. **Livestock and Handling:** Stakeholders believe that the livestock listing for phosphoric acid is clearer than the handling listing, and requested that the handling listing (§205.605) be updated to mimic the listing in livestock (§205.603).
4. **Material Review:** This is outside of the purview of the NOSB, but it is important to capture within the sunset review. Some certifiers, but not all, require that all ingredients in a cleaner/sanitizer product must be allowed on the National List for the product to be allowed without a rinse. Most phosphoric acid products will require a rinse because they contain inactive (inert) ingredients not on the National List. Should the multi-ingredient material contain only phosphoric acid and water, according to these certifiers, it would be allowed without a rinse. This should be clarified in an annotation or in guidance.

In summary, the Subcommittee is asking that action be taken to clarify the use of phosphoric acid. The Subcommittee is also seeking clarification and confirmation that the Accredited Certifiers Association (ACA) has a working taskforce reviewing these issues.

Justification for Vote:
The Subcommittee finds phosphoric acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove phosphoric acid from the National List
Motion by: Amy Bruch
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Lime, hydrated

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(6) 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: 11/1995 NOSB minutes and vote (pg. 24); 04/2006 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Information and data was taken from the 2015 TR.

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parasiticide. Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes.

This NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle, and other livestock. Mange caused by parasitic mites is highly irritating for animals and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (McNeal, 1999). Sheep scab—caused by the parasitic mite *Psoroptes ovis*—is a contagious, highly pruritic (i.e., itching) disease that results in the development of large, yellowish, scaly, crusted lesions, accompanied by damage to wool and hide. Sarcoptic and demodectic mange are problematic for producers of sheep and goats (CFSPH, 2009). In U.S. cattle production, sarcoptic mange (scabies), psoroptic mange, chorioptic mange, demodectic mange and psorergatic mange (itch mite) continue to be problematic skin diseases. Dips consisting of 2% hot lime sulfur (i.e., hydrated lime, elemental sulfur, and water) are recommended as treatments for parasitic mites associated with these diseases (Losson & Mignon, 2011).

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.

Manufacture:
The industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum, and iron oxide compounds—is thermally transformed into quicklime. Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 degrees Celsius results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (2015 TR, line 236). This thermal transformation occurs with liberation of carbon dioxide (CO2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [Ca(OH)2] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC. A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After

hydration, the hydrated lime product is dried, milled, and air classified. Equations 1 and 2 below provide molecular depictions of the overall synthetic process.

	heat		
$CaCO_3$	→	$CaO + CO_2$ (g)	(2015 TR, line 245)
$CaO + H_2O$	→	$Ca(OH)_2$	(2015 TR, line 246)

International Acceptance:

Canadian General Standards Board Permitted Substances List

Canadian organic regulations permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated lime is also listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Organic regulations from the European Union do not permit the use of hydrated lime/calcium hydroxide as an external parasiticide in livestock production. However, Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control Nectria galligena in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM Norms permit the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (IFOAM, appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (IFOAM, appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (IFOAM, appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM.

Japan Agricultural Standard (JAS) for Organic Production

According to Table 4 of the Japanese Agricultural Standard (JAS) for organic livestock products, slaked lime (calcium hydroxide) is an approved agent for cleaning or disinfecting of housing for livestock. Calcium hydroxide derived from calcium oxide (slaked lime) is also listed in Table 1 of JAS as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations.

Environmental Issues:
Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production (2015 TR, line 399-400). Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters (2015 TR, line 401); therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise the pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH (2015 TR, line 406). While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0 (2015 TR, line 408). Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients (2015 TR, line 409-410). It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process (2015 TR, line 414-415).

Treatment and disposal is a potential complication associated with the use of hydrated lime and other miticide treatments in large volumes. In some cases, operators have discharged spent dip directly into watercourses or allowed the chemicals to soak into the ground near the dip facility (PAN-UK, 1997). Livestock operators using hydrated lime dipping stations for external parasite control should ensure that the resulting highly alkaline waste solutions are properly treated and disposed of to minimize the likelihood of environmental contamination.

Discussion:
Comments from the Spring 2023 meeting were mostly supportive of relisting hydrated lime. It was mentioned by a few that the actual use of hydrated lime may not be as intended, and rather it may be used more as a white-wash or in bedding. Many of the 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.

Questions to our Stakeholders:
None

Justification for Vote:
The Subcommittee finds hydrated lime compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove hydrated lime from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Mineral oil

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Mineral oil - for topical use and as a lubricant.
Technical Report: 2002 TAP; 2015 TR; 2021 Limited Scope TR
Petition(s): 2002 (medical treatment and feed additive)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 24); 05/2003 NOSB recommendation (feed additive, not recommended) (pg.1443-1444); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

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)(7). Regarding this use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice, and other parasites. External parasites such as lice, mange mites, and various insects can adversely impact the health of individual animals and lead to economic losses for livestock producers. These parasites do not generally kill their hosts, but they can weaken the animal and, in some cases, transmit diseases to the host animals. Mineral oil is also used as a lubricant during artificial insemination.

In a separate listing (§ 205.603(a)(20)) that is not the subject of this sunset review, mineral oil is administered internally to lubricate the intestinal tract to treat bloat and dislodge intestinal obstructions in cattle and other ruminants.

Manufacture:
From the 2015 Technical Report (TR), line 55-60:

> "Crude petroleum oil is the predominant source of mineral oils used in organic and conventional agriculture, as well as food for human consumption, cosmetic products, and drugs… Refined mineral oils are obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations."

2015 TR, line 38-40:

> "The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions."

2015 TR, line 61-63:

> "As complex mixtures, refined mineral oils are identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product."

2015 TR, line 33-38:

> Mineral oils used in organic livestock production are hydrocarbon molecules containing 15 to about 50 carbon atoms (US EPA, 2007; EFSA, 2012)… These untreated mineral oils may also contain small amounts of nitrogen- and sulfur containing compounds (EFSA, 2012)."

Crude, untreated mineral oil mixtures also include aromatics, including polycyclic aromatic hydrocarbons (PAHs). PAHs may be toxic, and some are carcinogenic in long-term exposures. [2015 TR]

2015 TR, line 423-435:

> "The industrial production of highly refined, food-grade mineral oils involves chemical processing and refinement using various chemical reagents and/or catalysts. Specifically, crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen and sulfur atoms) as well as PAHs and other aromatic compounds (EFSA, 2012; Wright, 2012). Crude oil is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. To produce mineral oil, the chemical composition of natural crude oil is altered through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids and/or catalysts). Mineral oil is therefore considered a synthetic material. As such, the NOSB classified mineral oil as "synthetic" since initially recommending addition of the substance to the National List (USDA, 2002)."

International Acceptance:

Canadian General Standards Board Permitted Substances List

2015 TR, line 273-275:

> Canadian regulations permit numerous uses for mineral oils of varying purity. Mineral oils are allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011)."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

2015 TR, line 287-288:

> "According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas)."

Mineral oils are not mentioned specifically in 834/2007 for the use in livestock. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states:

> "chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007).

While there is no specific listing for mineral oils in livestock, Article 14 notes that:

> "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter."

The regulation further notes:

> "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phyto-therapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Part B, Section 22, The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Mineral oils are not specifically mentioned for livestock applications. However, under Health Care, Section 22:

> "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

International Federation of Organic Agriculture Movements (IFOAM)

2015 TR, line 299-301:

> The IFOAM Norms permit the use of "light mineral oils (paraffin)" under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oils or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005) with later revisions including livestock. 2015 TR, line 294-297:

> "Japanese regulations for the organic production of livestock only mentions the use of "petroleum oil aerosol" and "petroleum oil emulsion" for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012)."

Environmental Issues:

2015 TR, line 481-490:

> "Mineral oils may be classified as highly refined or mildly treated/untreated. The white mineral oils that are likely to be used for lubrication and external parasite control in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants *[such as PAHs]* compared to untreated and mildly treated oils.
>
> Testing in laboratory animals has demonstrated that mineral oils are slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oils are mild irritants, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation (US EPA, 2007). Highly refined "white" mineral oils produced no sensitization reactions in guinea pigs repeatedly exposed to the substance…"

2015 TR, line 518-521:

> "The carcinogenicity and genotoxicity potential for mineral oils is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oils—which have

undergone the most severe acid, solvent or hydrocracking treatment—showed no activity in a series of skin-tumor bioassays (IARC, 2012)."

2015 TR, line 534-535:

"Much like the mammalian studies, the results of avian and honeybee studies suggest that refined mineral oils are practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively."

2015 TR, line 548-549:

"Refined mineral oils are generally characterized as minimally toxic to aquatic organisms on an acute exposure basis."

Discussion:

White mineral oil for veterinary uses including for treatment of external parasites, appear to have little negative effect on the animal or the environment, while being critical for humane treatment of some serious animal health issues. Public comments submitted to the Board prior to the Spring 2023 meeting were strongly in favor of relisting. Mineral oil is shelf stable and very widely used.

This listing covers its use as a topical parasiticide and external lubricant. Other veterinary uses are covered separately at §205.603(a).

Justification for Vote:

The Subcommittee finds mineral oil compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:

Motion to remove mineral oil from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 1