Sunset 2026
Meeting 2 - Reviews
Livestock Substances § 205.603 & § 205.604
October 2024

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. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
Written comments should be submitted via Regulations.gov at www.regulations.gov on or before September 30, 2024, as explained in the meeting notice published in the Federal Register.

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 Support the Continued Use of Substances in Organic Production at § 205.603:
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 Substances in Organic Production at § 205.603:
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 at § 205.604, 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 Substances in Organic Production at § 205.604:
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 at § 205.604 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:

- Alternative management practices that would eliminate the need for the specific substance;
- Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- 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 30, 2024 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:

Atropine
Hydrogen peroxide
Iodine (a)(16)
Iodine (b)(4)
Magnesium sulfate
Fenbendazole
Moxidectin
Peroxyacetic/peracetic acid
Tolazoline
Xylazine

Oxalic acid dihydrate
DL-methionine
Trace minerals
Vitamins

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

None

Atropine

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

(3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 TR

Petition(s): 2002

Past NOSB Actions: 05/2003 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

Use

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by the plants in the nightshade family (EFSA 2008, Timberlake 2015). Atropine is primarily isolated from *Atropa belladonna* (also known as deadly nightshade) and is a component in both human and veterinary medicines for a range of treatments. Although, it is most widely used in both human and veterinary practices as a treatment for organophosphate poisoning. [2019 TR 35-39]

Atropine is currently allowed by the United States Department of Agriculture (USDA) organic regulations as a medical treatment for organic livestock production (7 CFR 205.603(a)). USDA organic regulations restrict atropine to "use by or on the lawful written or oral order of a licensed veterinarian," and it must be followed by "a meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals. [2019 TR 24-28]

Manufacture

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by plants in the nightshade family (EFSA 2008, Timberlake 2015). The primary source of atropine is accessed by extraction from *Atropa belladonna*, which yields the racemic mixture of (+)-hyoscyamine and (-)-hyoscyamine (atropine) (Figure 1). Atropine may also be synthesized in an acid-catalyzed esterification reaction in between tropine and tropic acid, although the primary source of atropine is from plant extracts (PubChem 174174, Karkee 1980, Merck 2001, USDA 2002, EFSA 2008). [2019 TR 51-56]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed as a health care product and production aid. Botanical preparations (such as atropine, butorphanol, and other medicines from herbaceous plants) shall be used according to label specifications. Substances containing petroleum-derived formulants (such as propylene glycol) shall not be fed to livestock. (Table 5.3, Botanical compounds listing, CAN/CGSB-32.311-2020, page 26)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances
None

Human Health and Environmental Issues
Atropine alkaloids are naturally produced by plants in the nightshade family, which exists exclusively (pre-extraction) as L-hyoscyamine (PubChem 174174, Bunke et al. 1996, Reist et al. 1997, EFSA 2008). Because L-hyoscyamine is the lone enantiomer that is biologically produced, atropine does not exist naturally, but rather is formed during the racemization. [2019 TR 343-347]

There are no reported studies on the persistence or concentration of atropine (neither D-hyoscyamine nor L-hyoscyamine) or the metabolized products tropine and tropic acid, although tropine has been identified as "readily biodegradable" (Sigma-Aldrich 2018b). [2019 TR 371-373]

Due to the limited application of atropine (for veterinary medicine, approved for use only when used or ordered by a veterinarian), and the small quantities administered (milligrams), atropine is unlikely to be a source of environmental contamination (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). Moreover, the L-hyoscyamine enantiomer is largely degraded to tropine and tropic acid prior to excretion, further reducing the likelihood of environmental persistence and concentration build-up (Sigma-Aldrich 2018b). [2019 TR 375-380]

The metabolism of atropine in humans is like that of most animal species. Atropine is both readily absorbed and distributed within the human body and readily excreted in urine (EMEA 1998, Williams et al. 2000, Aardema et al. 2008, EFSA 2008). Similar to the metabolic pathways in veterinary applications, humans also metabolize L-hyoscyamine (one enantiomer of the racemic atropine mixture) to tropine and tropic acid (Equation 2), which are excreted in urine along with the non-metabolized D-hyoscyamine enantiomer present in atropine (EMEA 1998, EFSA 2008). The short biological half-life of atropine (2-5 hours), and incorporation of the substance in human medical applications makes negative health effects from the approved usage of atropine unlikely (Williams et al. 2000, Aardema et al. 2008, Mayo Clinic 2017, MedlinePlus 2017). Moreover, atropine is approved for use only when used or ordered by a veterinarian coupled with the withdrawal restrictions placed on animals receiving atropine treatments, makes human health effects unlikely (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). [2019 TR 544-555]

Discussion
Both written and oral comments submitted at the Spring 2024 NOSB meeting were in support of relisting Atropine as essential product for use in organic animal production. One certifier stated that it did not have any livestock clients using products containing atropine. There were comments that emphasized the

importance of atropine for treating organophosphate poisoning, treatment of cardiac arrest, and its function as a bronchodilator. One commenter mentioned the negative effect of atropine on the vagal nerve thereby causing bloating if proper dosing of atropine was not ensured. Commenters generally referred to atropine as an emergency and potentially lifesaving drug that should be available to organic livestock producers. The withdrawal periods of 56 days for livestock intended for slaughter and 12-day milk discard period were mentioned as additional reasons for the strong endorsement among commenters. No commenters expressed opposition to relisting.

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

Subcommittee Vote
Motion to remove atropine from the National List
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Hydrogen peroxide

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(15) Hydrogen peroxide.
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Historically, agricultural disinfectants containing hydrogen peroxide have been used for the disinfection of livestock housing surfaces and production equipment. Synthetic hydrogen peroxide is permitted for use in organic livestock production as a disinfectant, sanitizer, and medical treatment [7 CFR 205.603(a)]. It is also permitted for use in or on processed products labeled as “organic” or made with organic (specific ingredient or food group(s)) per 7 CFR 205.605(b), and for various uses in organic crop production per 7 CFR 205.601.

Manufacture
Commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. This is followed by the autoxidation of the hydroquinone in air to regenerate the anthraquinone and release hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H2) and oxygen (O2). Almost all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. [2015 TR 34-39]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a health care product and production aid. Pharmaceutical grade hydrogen peroxide is allowed for external use as a disinfectant. Food-grade hydrogen peroxide is allowed for internal use (for example, added to livestock drinking water). (Table 5.3, CAN/CGSB-32.311-2020, page 27)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

Japan Agricultural Standard (JAS) for Organic Production
Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house)

Ancillary Substances

Water is the primary inert ingredient in hydrogen peroxide formulations. Some product labels list salicylic, phosphoric acid, benzyl alcohol, acetic acid, citric acid, butoxy-propan-2-xyloxy- propan-2-ol [2015 TR 170-173]

Human Health and Environmental Issues

Hydrogen peroxide is inherently unstable due to the weak peroxide (O–O) bond. At typical pesticide concentrations, hydrogen peroxide is expected to degrade rapidly to water and oxygen (US EPA, 2007). [2015 Crops TR, lines 316-317]

When used as a fungicide, hydrogen peroxide is likely to contact soils under a variety of environmental conditions. Hydrogen peroxide degrades with an anaerobic (without oxygen) soil half-life of four hours in soils containing petroleum (US EPA, 2007). [2015 Crops TR, lines 320-322]

Since the substance has physical properties like those of water, hydrogen peroxide is unlikely to preferentially bind to soils when used in agricultural production (US EPA, 2007). [2015 Crops TR, lines 325-327]

Research data indicates that volatilization of the substance from moist soils and surface water is expected to be low (EC, 2003). [2015 Crops TR, lines 328-330]

When released to water, hydrogen peroxide should be rapidly consumed through biodegradation and photolysis. The half-life of hydrogen peroxide metabolism in water generally decreases with increasing size of the microbial populations in the receiving water. Consequently, hydrogen peroxide degradation half- lives in natural waters range from a few hours to several days. [2015 Crops TR, lines 331-334]

Hydrogen peroxide is not expected to bioaccumulate in aquatic organisms due to its low octanol-water partition coefficient (K_{ow}) of 0.032 (US EPA, 2007). [2015 Crops TR, lines 340-341]

Degradation of hydrogen peroxide released to the atmosphere is primarily a result of indirect photolysis reactions with smaller contributions from direct photolysis and chemical reaction with organic substances. [2015 Crops TR, lines 342-343]

Light, oxygen, ozone, hydrocarbons and free radicals in the atmosphere mediate hydrogen peroxide formation and release to the atmosphere, likely at a significantly greater rate than the agricultural uses of the substance (Goor, 2007; Eul, 2001). Considering the various atmospheric degradation pathways, the overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (Goor, 2007; EC, 2003). [2015 Crops TR, lines 347-351]

Multiple EPA terrestrial effects characterizations have evaluated the toxicity of hydrogen peroxide and other "peroxy compounds" to mammals and birds. Studies submitted by the registrants indicate that hydrogen peroxide solutions used in pesticide products are corrosive to washed and unwashed eyes, as well as exposed skin (i.e., Toxicity Category I for eye and skin irritation). [2015 Crops TR, lines 355-358]

The EPA reported in 2009 the results of a skin sensitization study which suggests that Hydrogen peroxide is not likely to be a sensitizer to mammals. The compound is considered slightly toxic to practically non-toxic to birds on an acute oral basis. [2015 Crops TR, lines 363-371]

Hydrogen peroxide is an unstable inorganic compound and is expected to degrade rapidly to water and oxygen in the environment. The half-lives for aerobic and anaerobic degradation of hydrogen peroxide in various soils are between 1-7 hours. Hydrogen peroxide is mobile in soils but does not readily volatilize from moist soils and surface waters (EC, 2003; US EPA, 2007). When released to water, hydrogen peroxide is rapidly consumed through biodegradation and photolysis. The half-life for biodegradation of hydrogen peroxide in water generally ranges from minutes to several hours (Goor, 2007; US EPA, 2007). Light, oxygen, ozone, hydrocarbons, and free radicals contribute to hydrogen peroxide formation in the atmosphere, likely at significantly greater rates than the agricultural uses of the substance. The overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (EC, 2003; Eul, 2001; Goor, 2007). Under typical use conditions, diluted and pure forms of hydrogen peroxide are reactive with transition metals (e.g., iron, copper, chromium) and organic materials (US EPA, 2007; ATSDR, 2014). [2015 Crops TR, lines 480-490]

Sensitivity of ecological receptors to hydrogen peroxide solutions range from insensitive to moderately sensitive. [2015 Crops TR]

- Hydrogen peroxide is considered slightly toxic to practically non-toxic to birds on an acute oral basis.
- Likewise, aquatic toxicity studies indicate that hydrogen peroxide is slightly toxic to aquatic invertebrates and practically non-toxic to fish on an acute exposure basis.
- In contrast to birds and aquatic animals, microorganisms are particularly sensitive to various concentrations of hydrogen peroxide.
    - The scientific literature and agricultural experience have demonstrated that hydrogen peroxide is toxic to pathogenic soil organisms, such as the downy mildew fungus *Pseudoperonospora cubensis* and pink rot of potato fungus *Phytophthora erythroseptica* (Kuepper, 2003; Al-Mughrabi, 2006).
    - Considering the oxidizing mode of action for hydrogen peroxide, it is likely that the substance is also toxic to beneficial soil organisms, including *Mycorrhizal* fungi and nitrogen-fixing bacteria.

- This non-target effect is most relevant for spray drift and soil drench scenarios and should not present a population-level concern for controlled hydrogen peroxide applications.

Environmental contamination is not expected when purified forms of hydrogen peroxide are released to the environment. [2015 Crops TR]

- At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007).
- The toxic solvents and reagents used in the manufacture of hydrogen peroxide are removed prior to product formulation and, in many cases, are reused in subsequent synthetic reactions (Eul, 2001; Goor, 2007). As such, it is unlikely that these chemicals are readily introduced into the environment because of hydrogen peroxide production.

Hydrogen peroxide is generally considered safe for human exposure at **low doses.** Indeed, the US Food and Drug Administration (FDA) affirmed hydrogen peroxide as Generally Recognized as Safe (GRAS) when used as a direct food additive with certain limitations (see "Approved Legal Uses of the Substance" for details). [2015 Crops TR, lines 512-515]

Acute irritation and systemic toxicity are possible in humans exposed to moderate to high doses of hydrogen peroxide. Systemic effects of the substance generally result from the release of oxygen gas and water as the enzyme catalase decomposes available hydrogen peroxide. [2015 Crops TR, lines 515-517]

- Specifically, venous embolism (gas bubble in bloodstream) may occur when the amount of oxygen gas produced exceeds its blood solubility (ATSDR, 2014). Inhalation or ingestion of hydrogen peroxide at high concentrations may lead to seizures, cerebral embolism or even tissue death (infarction).

The most common symptoms reported were acute symptoms based on acute corrosion and irritation effects. The symptoms include eye irritation, skin burns, esophageal burns, nausea, dizziness, rash, and headaches. Inhalation effects include chest congestion, respiratory irritation, coughing of blood, tightness of chest and shortness of breath. Dermal effects include edema, erythema, skin burns, blistering, and swelling. These cases led to hospitalization in some cases. It is important to stress the following facts [2015 Crops TR, lines 536-543]:

- Hydrogen peroxide is unlikely to cause chronic toxicity in humans because it is rapidly decomposed in the body.
- The available toxicity and epidemiology studies provide no evidence of reproductive or developmental toxicity in experimental animals and humans (ATSDR, 2014).

On the other hand, hydrogen peroxide is a known mutagen and is associated with genotoxicity in mammalian and human cell lines (IARC, 1999; Driessens, 2009). In 2014, the International Agency for Research on Cancer (IARC) determined that there is *inadequate evidence* in humans and *limited evidence* in experimental animals for the carcinogenicity of hydrogen peroxide, classifying the substance as *Group 3 – Not classifiable as to its carcinogenicity to humans.* [2015 Crops TR, lines 549-553]

POSITIVE ATTRIBUTES/USES

- Moderate spills of hydrogen peroxide to marine and estuarine environments are unlikely to adversely affect the receiving water bodies. [2015 Crops TR, lines 417-418]
- On the contrary, a method describing the addition of hydrogen peroxide to natural waters as an oxidizing agent for oil spill remediation was published in patent literature (Hoag, 2014). [2015 Crops TR, lines 418-420]

- Hydrogen peroxide has been used to treat wastewater, and aids in the removal of soil contaminants, including creosote, polycyclic aromatic hydrocarbons (PAHs), and other inorganic and organic substances (Atagana, 2003; Conte, 2001; US EPA, 2007). [2015 Crops TR, lines 420-422]

Toxic substances used in the manufacture of hydrogen peroxide, including alkyl anthraquinones, aromatic solvents and transition metal catalysts (e.g., Raney nickel and palladium), are generally removed from hydrogen peroxide prior to formulation of commercial pesticide products. Further, certain fractions of these reagents, catalysts and solvents are often returned to the reactors for use in subsequent synthetic reactions (Goor, 2007; Eul, 2001). [2015 Crops TR, lines 423-429]

- Therefore, the chemicals used in the production of hydrogen peroxide should not be released to the environment when manufacturers adhere to standard operating procedures for safe handling and disposal of toxic substances.

Populations of beneficial soil fungi, such as *Mycorrhizal* fungi, and nitrogen-fixing bacteria may be negatively impacted by large-scale soil treatments of fungicides containing hydrogen peroxide. [2015 Crops TR, lines 456-458]

Overall, the available information suggests that large volumes of concentrated hydrogen peroxide solutions will adversely affect the viability and reproduction of non-target microorganisms, including beneficial soil fungi and nematodes. [2015 Crops TR, lines 472-474]

Discussion
During the Spring 2024 NOSB meeting, the Livestock Committee received comments in favor of relisting Hydrogen Peroxide and no comments against relisting. Some commenters mentioned the importance of hydrogen peroxide and the fact that it is a fairly common input in livestock production. Commenters listed their use in footbaths, to clean wounds, for cleaning to combat hard water as well as serving as ingredients in pre-dips. Some comments in support of relisting hydrogen peroxide focused on its minimal health and environmental concerns. Some proponents described hydrogen peroxide as a safer alternative to chlorine-based and other toxic sanitizers. The fact that the product breaks down quickly to oxygen and water which do not cause adverse residual effects was another positive factor that commenters listed for their support for relisting of Hydrogen peroxide. Additional comments include the fact that Hydrogen peroxide is relatively nontoxic in low concentrations. Some commenters talked stated that hydrogen peroxide may damage soil biota and exposure to its vapor may be harmful. Comments received were in support of relisting this product.

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

Subcommittee Vote
Motion to remove hydrogen peroxide from the National List
Motion by: Franklin Quarcoo
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Iodine §205.603(a)(16) and §205.603(b)(4)

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (16) Iodine.
§ 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (4) Iodine.
Technical Report: 1994 TAP; 2015 TR; 2024 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre-milking and post- milking. Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor, and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus antimicrobial teat dips used in pre- and post-milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine-based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

Manufacture
Molecular iodine (I_2) production processes generally utilize raw materials containing iodine, including seaweeds, mineral deposits, and oil well or natural gas brines [2015 TR, lines 310-311]. Various chemical substances are added in the production of commercially available teat dip products. Many of the iodophors commonly used for disinfection in the dairy industry consist of iodine mixed with polymeric nonionic surfactants, such as the polyalkylene glycol and polyvinylpyrrolidone carriers. The nonylphenol ethoxylates (NPEs), polyoxyethylene nonylphenol (CAS# 9016-45-9) and ethoxylated nonylphenol (CAS# 26027-38-3), as well as polyvinylpyrrolidone (CAS# 9003-39-8) and other potential polymeric carriers are US EPA List 4 Inerts (US EPA, 2004a) when used in pesticides, including antimicrobial sanitizers. When used in animal drugs (*e.g.,* teat dips), these substances are considered excipients, and are subject to restrictions at section 205.603(f). This rule states that a given excipient may be used in the manufacture of drugs used to treat organic livestock when the excipient is: (1) identified as GRAS by FDA, (2) approved by FDA as a food additive, (3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application, [2015 TR, lines 209-219] or (4) approved by APHIS for use in veterinary biologics.

Manufacturers commonly incorporate conditioners into iodine teat dip products to replace the protective oils that polymeric surfactants (*i.e.,* detergents) used as complexing agents remove from animal skin during treatment. Moisturizers such as glycerin and propylene are normally added at concentrations ranging from two to ten percent of the product formulation (Universal, 2011; Nickerson, 2001). Further, glycerin

produced through the hydrolysis of fats or oils is allowed as a livestock teat dip on the National List [7 CFR 205.603(a)(12)]. Lanolin may also be added to iodophor teat dip products as an emollient to replace natural oils lost from the affected skin of dairy cows (Nickerson, 2011) [2015 TR, lines 222-228].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a topical disinfectant. Allowed iodine sources include potassium iodide and elemental iodine. If used as a cleaning agent, non-elemental iodine shall be used. Iodine shall not exceed 5% solution by volume (example: iodophors). Use shall be followed by a hot-water rinse (Table 5.3, CAN/CGSB-32.311-2020, page 27).

Substances such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations (Table 5.3, Teat dips and udder wash listing, CAN/CGSB-32.311-2020, page 29).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)
Allowed (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; iodine agent).

Japan Agricultural Standard (JAS) for Organic Production
Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house).

Ancillary Substances

Excipients are almost always used in iodine sanitizing products, and the review of these substances is outlined above in manufacturing. One class of excipients, NPEs, has been identified as hazardous to the environment and potentially no longer necessary in manufacturing.

Human Health and Environmental Issues

A limited scope TR for iodine was requested for this sunset review of the substance. One of the questions explored by the TR was the impact that NPEs (an excipient used in combination with iodine) has on the environment and human health.

NPEs have long been known to be toxic to aquatic organisms, they bioaccumulate in plants, and they have been shown to exhibit estrogenic properties in human studies. Their use in cleaning and sanitizing products has slowly been phasing out. However, they remain in use in dairy iodine teat dips, and the residues of these substances can find their way into milk bulk tanks, equipment, and manure lagoons where they will likely be applied to the soil. The TR identifies iodine teat dips as the largest potential contributing source of NPEs on dairy operations.

Discussion

NOSB acknowledges that iodine sanitizers remain necessary to livestock operations as a sanitizer for medical procedures as well as for topical use, particularly as a teat dip for dairy animals. NOSB has also

heard from numerous stakeholders that it is time to ensure that iodine products used on organic farms are free from NPEs. A limited scope TR was conducted to evaluate the availability of NPE-free iodine products and their suitability, the potential for NPEs contained in iodine products to contaminate organic products and the environment, and what detrimental effects may occur should NPEs enter the supply chain or be applied to soil.

The Livestock Subcommittee believes iodine continues to meet National List criteria and should not be removed. The LS would like to consider an annotation to prohibit NPEs in iodine products used on organic livestock operations, and we have made a recommendation to that effect in a separate annotation change proposal document.

Questions to our Stakeholders

1. Based on the feedback received at previous reviews of iodine and the recently conducted limited scope TR of iodine, it appears that there is a significant supply of NPE-free iodine formulas for numerous types of iodine products, and a prohibition on NPE containing formulas would not have significant impact on the industry. Is this analysis correct? Are there specific types of iodine products where NPE-free formulas are not available?
2. For certifiers and MROs: Would an annotation restricting iodine formulas to those that are free of NPEs pose significant challenges to the review of iodine products in organic system plans?
3. What specific language should NOSB consider for a proposed annotation in order to fully restrict NPEs from iodine products used on organic livestock operations?

Commenters generally expressed support for the phase out of iodine formulas that contain NPEs. Environmental groups applauded the idea that organic farmers would lead the way in removal of these harmful substances from their system plans. Certifiers and Material Review Organizations (MROs) indicated that there are numerous formulations available on the market and approved for use in organic system plans (OSPs) that do not contain NPEs. Dairy producers indicated support for the additional restriction, as it would better support organic goals of minimizing impact to the environment while allowing options for iodine products. Commenters suggested that the annotation prohibiting NPEs include language that clearly prohibits all alkylphenol ethoxylates. The Subcommittee agrees with this and is proposing a proposal to amend the annotation in parallel with this sunset review.

Justification for Vote

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

Subcommittee Vote

Motion to remove iodine from § 205.603(a) and§ 205.603(b) of the National List
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

Magnesium sulfate

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Magnesium sulfate.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Magnesium sulfate has a number of veterinary uses. It acts as an anticonvulsant, laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically, in swine, magnesium sulfate is administered to treat malignant hypothermia. [2011 TR, lines 78-81]

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed. [2011 TR, lines 83-89]

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium. If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously. [2011 TR, lines 91-95]

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle‘s use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium. [2011 TR, lines 97-100]

Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation. [2011 TR, lines 102-104]

Manufacture
Magnesium sulfate can be obtained from naturally-occurring sources or manufactured by a chemical process. [2011 TR, lines 312-313]

Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate

monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite and epsomite, respectively (Kawamura and Rao, 2007). [2011 TR, lines 316-319]

The synthetic form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (containing MgCO3), or magnesium hydroxide (Mg[OH]2) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. To produce a high grade of purity, the magnesium sulfate is re-crystallized and separated from the parent solution (Kawamura and Rao, 2007). [2011 TR, lines 321-325]

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as an animal health care product and production aid; origin must be mined sources. Usage includes being a source of magnesium and sulphur. (Table 5.3, CAN/CGSB-32.311-2020, page 27)

Non-synthetic chelated or sulphated minerals are allowed for use as an animal health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex III, Part A(1), 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Human Health and Environmental Issues
Magnesium and sulfur are ubiquitous in the natural environment. According to the 2011 TR, if used in accordance with 7 CFR 205.603, it is unlikely that magnesium sulfate will cause harm to the environment.

Magnesium sulfate is considered by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) when used as a nutrient or dietary supplement (21 CFR 184.1443). The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population (FAQS, 2010). [2011 TR, lines 116-121]

Multiple products containing magnesium sulfate are approved by the FDA for medicinal use in humans. Magnesium sulfate can be administered via injection or can be orally ingested (U.S. FDA, 2010). In 2010, the FDA approved a product containing magnesium sulfate, which acts a colon cleanser in preparation for a colonoscopy (Braintree Laboratories, 2010). [2011 TR, lines 123-126]

If large quantities of magnesium sulfate are ingested by or injected into humans, blood electrolyte balance can be disturbed, resulting in circulatory collapse and death. However, this is far beyond the bounds of veterinary use.

Discussion
Written and verbal comments at the Spring 2024 meeting were unanimously in favor of relisting magnesium sulfate, with one commenter requesting that natural sources be used if available. This material has important veterinary uses and has little negative environmental or heath impact. Stakeholders were unaware of non-synthetic magnesium sulfate products.

Subcommittee Discussion
Magnesium sulfate satisfies the OFPA evaluation criteria, and the Livestock Subcommittee supports relisting.

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

Subcommittee Vote
Motion to remove magnesium sulfate from the National List
Motion by: Brian Caldwell
Seconded by: Nate Lewis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

Parasiticides, Fenbendazole

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

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Technical Report: 1999 TAP (parasiticides: fenbendazole, ivermectin, levamisole); 2015 TR (parasiticides: fenbendazole, ivermectin, moxidectin); 2020 TR
Petition(s): 03/2007; 07/2019 (annotation change)
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 recommendation – annotation change; 10/2019 sunset recommendation; 10/2020 NOSB recommendation to not amend listing
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 (82 FR 14420); Annotation change effective 01/28/2019 (83 FR 66559); Renewed 08/03/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

In veterinary medicine the term parasiticide refers to anthelmintic drugs (medicines used to destroy parasitic worms) [2015 TR 148 - 150]. Anthelmintics are medications capable of causing the evacuation of parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]) [2015 TR 233-235]. The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state does not include the routine use of parasiticides [2015 TR, lines 382-383]. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed herds. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected and without treatment parasite infestation can lead to disease and potentially death (Stockdale, 2008) [2015 TR 394-398].

The 2020 Technical Report discussed the use of fenbendazole in chickens, which was the subject of a 2019 petition to change the allowance on the National List. The 2020 TR summarized fenbendazole as follows:

> The target organisms of the parasiticide fenbendazole are the roundworms *Ascaridia galli* and *Heterakis gallinarum*. These nematodes, along with *Capillaria spp*., are recognized as the principal helminthic parasites of chickens, with *A. galli* by far the most common. The life cycles of both target nematodes are simple and direct, transmitted bird-to-bird via fecal droppings. Infected chickens are unthrifty, weak, and emaciated, and have weight loss proportional to the parasite burden. Young birds are particularly susceptible. Although mature hens are less susceptible, their egg productivity may drop, and death may occur in severe cases. Because chickens raised as broilers have a much shorter lifespan than laying hens, parasiticides are generally not required to treat them. Turkeys have a longer grow-out than broilers and are subject to additional helminthic parasite pressure, particularly the roundworm parasite *Ascardia dissimilis* [2020 TR 25-37].
>
> Fenbendazole is a benzimidazole veterinary anthelmintic – i.e., an antiparasitic drug (US NLM 2020). The mode of action works at the sub-cellular level, preventing cell division. Benzimidazoles bind to β-tubulin, inhibiting the cell's microtubule assembly responsible for intracellular transport and required for mitotic cellular division… The ultimate effect on nematodes is starvation caused by intestinal cell disruption and inhibition of nematode egg production. The late-stage (L5) larvae and adult stages of *A. galli* and *H. gallinarum* are susceptible. Efficacy studies reported that fenbendazole increased mortality of *A. galli* larvae and adult, but did not report any reduction in the number of viable parasite eggs [2020 TR 67-76].

Manufacture

The fenbendazole is manufactured using a condensation of o-phenylenediamine or o-nitroaniline with a carboxylic acid derivative. N-arylamide hydrochlorides can also be transformed to benzimidazoles with sodium hypochlorite and base. (Brown et al., 1961; Grenda et al., 1965; Loewe et al, 1976) [2015 TR Table 4].

Fenbendazole is approved as a New Animal Drug Application (NADA) by the U.S. Food and Drug Administration's Center for Veterinary Medicine (U.S. FDA CVM) … The FDA has established a tolerance of 1.8ppm fenbendazole in 93 eggs, using the predominant metabolite fenbendazole sulfone as a marker [21 CFR 556.275]. This effectively provides a maximum residue limit (MRL) of 2.4 ppm total fenbendazole, including its metabolites fenbendazole sulfone and oxfendazole. In addition to poultry, the FDA has

approved fenbendazole for use in cattle, swine, sheep, horses and turkeys, as well as zoo and wildlife animals [21 97 CFR 520.905, 21 CFR 558.258]. Fenbendazole is also approved for use as an anthelminthic for laying hens in the European Union (EMA 2011) and Canada (Health Canada 2020) [2020 TR 89-98].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

5.2.2(b) Shall respect requirements set out in 6.6 of CAN/CGSB-32.310 with regard to the use of internal parasiticides. Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

As per the 2015 TR - Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas (2015 TR 461-467]

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

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

International Federation of Organic Agriculture Movements (IFOAM)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year

Japan Agricultural Standard (JAS) for Organic Production

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

Ancillary Substances

Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

Human Health and Environmental Issues

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. All FDA livestock approved parasiticides are synthetically produced substances shown by experimental and clinical studies to be safe for application to food animals. The excipients are usually United States Pharmacopoeia (USP) grade chemicals and also subject to FDA approval [2015 TR 379-381].

Discussion
Parasiticides are used in acute, emergency cases and should be administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc. According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that pasture height above six inches results in lower pest loads as the cows don't graze low enough to where the parasites are typically located. Additionally, it was anecdotally noted during Subcommittee discussion that calves allowed to nurse experience lower pest loads than calves that are bottle fed.
The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

Written comments for the Spring 2024 NOSB meeting were strongly in favor of relisting fenbendazole, as was the NOSB.

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

Subcommittee Vote
Motion to remove fenbendazole from the National List
Motion by: Nate Powell-Palm
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Parasiticides, Moxidectin

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

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Technical Report: 2003 TAP; 2015 TR (Parasiticides: Fenbendazole, Ivermectin, Moxidectin)
Petition(s): 2003
Past NOSB Actions: 05/2004 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 NOSB recommendation - annotation change; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review
Subcommittee review was brief; spring meeting was recapped with public comments and board dialogue. Full support from the subcommittee to relist this essential tool.

Use
In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites [2015 TR, lines 148-149]. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]) [2015 TR, lines 233-235]. The use of moxidectin in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state that does not include the routine use of parasiticides [2015 TR, lines 382-384]. Routine management of parasiticides should include proper grazing management (rotating pastures when the grass is less than 6" tall), herbal and natural remedies, and selective breed genetics.

Manufacture
Moxidectin, a derivative of nemadectin, is a chemically modified *Streptomyces cyanogriseus* fermentation product (Asato and France, 1990) [2015 TR, lines 224-225]. The synthesis of moxidectin involves protecting the 5-hydroxy group of nemadectin with p-nitrobenzoyl chloride to give the corresponding 5-O(p-nitrobenzoyl)- nemadectin, which is then oxidized to give a 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative in a crystalline state. The 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative is then reacted with methoxylamine to give the 23-(methyloxime)5-O(p-nitrobenzoyl)- nemadectin intermediate in a crystalline state. This intermediate is then deprotected in the presence of base to give the desired 23-(methyloxime)-nemadectin. These reactions take place in the presence of various organic solvents (U.S. Patent Number 4,988,824). [2003 TAP, page 2]

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas [2015 TR 461-467].

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

International Federation of Organic Agriculture Movements (IFOAM)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times

documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Japan Agricultural Standard (JAS) for Organic Production
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

Ancillary Substances
Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

Human Health and Environmental Issues
The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. Moxidectin is excreted in feces but is both microbially and photo-degraded in dung pats in the soil. It is the least toxic to dung beetles of the macrocyclic lactone anthelmintics. Moxidectin peaks in 2 days in feces after treatment and decreases to less than 10 ppb by 37 days after treatment. The half-life for degradation of moxidectin in the environment may be up to 130 days [2015 TR Table 5 and 575-577].

Discussion
During the Spring 2024 board meeting, public comment and board discussion were favorable for the relisting of moxidectin citing the need for organic livestock to uphold the highest standards for animal welfare. It was noted that creating robust organic system plans (OSPs) and maintaining accurate records are essential to monitoring the care of livestock. Although natural forms of pest management and prevention are encouraged, the use of parasiticides on the National List in acute, emergency cases should be allowed and administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc.

According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that herds who keep pasture height above 6” experience lower pest loads as the cows don’t graze low enough to where the parasites are typically located on the pasture plants. Additionally, it was anecdotally noted during discussion that calves allowed to nurse on their mother experience lower pest loads than calves that are bottle fed.

The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

History of Moxidectin
The NOSB recommended adding moxidectin to the National List in 2004 with the restriction that it only be allowed for use to control internal parasites. But NOSB October 2019 proposals and discussion documents Page 212 of 230 in the proposed rule published on July 17, 2006, USDA announced its decision that

moxidectin would not be proposed for inclusion on the National List because of its macrolide antibiotic classification.

Based upon the public comments received at the NOSB meeting July 17, 2006, the NOP verified the information supplied by commenters, and subsequently concurred that moxidectin does not function as an antibiotic when used as a parasiticide. In the Final Rule in 2012 NOP added moxidectin to National List.

Questions to our Stakeholders

1. How do certifiers mitigate consistent repeat use of parasiticides?
2. Are there suggestions to improve annotation?
3. Which age/class of animal do certifiers see their client's requesting approval for emergency parasiticide use?
4. How often do certifiers request fecal samples to confirm the parasite load in a herd prior to allowing an emergency treatment with parasiticides?

Justification for Vote

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

Subcommittee Vote

Motion to remove moxidectin from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Peroxyacetic/peracetic acid

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008
Past NOSB Actions: 11/2000 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Peracetic acid (PAA) is listed in the National List as allowed for use in organic livestock production for sanitizing facilities and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment, and hard surfaces. 2016 Technical Report (TR) line 99 states, peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment.

Beginning at 2016 TR line 288: The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture
Solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid."

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not explicitly mentioned for livestock use.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed for cleaning and disinfection (Annex IV, Part D, 2021/ 1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)
Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; peracetic acid, page 83).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard for Organic Livestock Products, Table 4, lists "Agents for cleaning or disinfecting of housing for livestock." Included on this list are "Hydrogen Peroxide Solution" and "Cleaning agents and disinfectants for milking equipment, rooms and buildings." Peracetic acid is not specifically mentioned.

Ancillary Substances
Peracetic acid is a sanitizer regulated by the FDA and EPA, and a number of additional substances are allowed in peracetic acid formulations. These additional substances are necessary to stabilize the formulations and do not meet the NOSB's definition of an ancillary substance.

Human Health and Environmental Issues
Peracetic acid is considered an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain.[2016 TR 544-547]

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that

ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain.

[2016 TR lines 615-618] Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(a)pyrene and methylnaphthalene in lake sediments through oxidation of the parent compound.

Discussion
The importance of producers to have access to sanitizers in livestock operations cannot be understated. To maintain efficacy, producers must also have access to substances with multiple modes of action to prevent resistance to a single sanitizer. PAA functions as an effective sanitizer and poses little risk to human health or the environment. There is no new information available to the NOSB that would lead to recommending removal of this substance from the National List at 7 CFR 205.603(a).

Questions to our Stakeholders
None

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

Subcommittee Vote
Motion to remove peracetic acid (PAA) from the National List
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

Tolazoline

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

(29) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian, and;
(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and,
(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 TR
Petition(s): 2002
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 10/30/2029

Subcommittee Review

Use
In organic livestock production, tolazoline is limited to use only by a veterinarian prescription and is further restricted for "use only to reverse the effects of sedation caused by xylazine." Xylazine is primarily used in veterinary medicine as a sedative, tranquilizer, and analgesic. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent pain and suffering and injury to the veterinarians performing the procedures. Tolazoline is commonly used as a reversal agent for xylazine by competing for the α2-adrenergic receptors, blocking binding events for xylazine. Structural similarities with xylazine allow tolazoline to compete with xylazine for biological binding sites, providing the mode of action for its approved use in organic livestock production as a reversal agent for xylazine [2019 TR 116-118].

Tolazoline is used only for veterinary applications, with no natural or USDA-approved synthetic alternatives. There are no alternative practices that would make the anesthetic agent unnecessary. Tolazoline may be made unnecessary by allowing the veterinary subject to recover from the effects of xylazine by natural metabolism of the substance, rather than its active reversal. However, the rate of xylazine metabolism is species-dependent; therefore, this may prove problematic in species with slower metabolic rates (e.g., cattle) [2019 TR 658-665].

Manufacture
Tolazoline is a synthetic substance produced by a one-pot process (i.e., no intermediates are isolated) by the reaction of phenylacetaldehyde with ethylene diamine, with the incorporation of an iodine-based oxidation process.

International Allowance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Although xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances listed in Table 5.3 "health care products and production aids," as a "sedative," tolazoline (the most commonly used substance for a reversal agent for sedatives, including xylazine) is not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Tolazoline is not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Tolazoline is not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Tolazoline is not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Tolazoline is not explicitly mentioned.

Environmental Issues
Tolazoline is a synthetic α2-adrenergic antagonist that also interacts with histamine and cholinergic receptors temporarily and reversibly. Tolazoline affords several physiological effects, including vasodilation (increasing arterial oxygenation), transient hypotension, and histaminic gastrointestinal effects. There are no published toxicity or carcinogenicity studies on tolazoline's toxicity or lethal dosages.

Neither xylazine nor tolazoline are listed by the EPA as an inert ingredient of toxicological concern [2019 TR 398]. There are no studies on tolazoline's environmental toxicity, persistence, or concentration.

Discussion
The Livestock Subcommittee (LS) finds that xylazine and tolazoline are critical tools for farmers and veterinarians. These two materials enable humane veterinary care. They are used together during both planned and emergency surgeries, sedating the animal to allow effective procedures. There are no equally effective synthetic or natural alternatives, and these two materials pose little environmental or health hazards. The subcommittee is reviewing xylazine and tolazoline together, updating their sunset schedule, as they are consistently used together.

Questions to our Stakeholders
None

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

Subcommittee Vote
Motion to remove tolazoline from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Xylazine

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

(30) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian, and;

(ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP (xylazine, tolazoline); 2019 TR (xylazine, tolazoline)
Petition(s): 2002
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420) Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Xylazine is essential for use in veterinary surgical procedures for livestock, especially cattle.

Manufacture
Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture, which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine. Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water-based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures. Xylazine is commonly used in conjunction with tolazoline, which is a reversal agent for sedatives such as xylazine. According to information posted on the FARAD (Food Animal Residue Avoidance Databank) website (http://www.farad.org/amduca-law.html), extra label use (i.e., off label use) of xylazine is permissible under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) only if such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. According to the FARAD Digest (published in JAVMA, Vol. 223, No. 9, Nov. 1, 2003), xylazine is used as a medical treatment in livestock intended for food production as well as in dairy cows.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a health care product and production aid (Table 5.3, Sedatives listing, CAN/CGSB-32.311-2020, page 28).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Human Health and Environmental Issues
Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrythmias, which has resulted in its lack of approval for human medical applications (Green et al. 1981, EMEA 1999, Reyes et al. 2012). Due to the lack of approval for use in human medical applications, information on the mode of action and toxicity of xylazine is limited. [2019 TR 610-614]. Reported cases of xylazine in humans have shown physiological effects like those seen in veterinary applications (Samanta et al. 1990, JECFA 1998a). Upon absorption of xylazine, patients were difficult to rouse and showed signs of confusion (indicative of central nervous system and neuropathic depression) and expressed symptoms of bradycardia, hypotension (respiratory depression), and hyperglycemia (Gallanosa et al. 1981, Spoerke et al. 1986, Samanta et al. 1990). With regard to human carcinogenicity, no studies of direct effects have been published; however, the International Agency for Research on Cancer (IARC) has designated the xylazine metabolite, xylidine, as potentially carcinogenic to humans based on studies with

laboratory animals (NTP 1990, IARC 1993, JECFA 1998a). The lethal dosage of xylazine in humans is not well known and appears to vary dramatically between individuals (Spoerke et al. 1986, Ruiz-Colon et al. 2014). Fatal doses of xylazine recorded have been as low as 40 mg, while other individuals have survived exposure to levels as high as 2400 mg (Spoerke et al. 1986, Ruiz-Colon et al. 2014) [2019 TR 616-628].

Discussion
The Livestock Subcommittee (LS) finds that xylazine and tolazoline are critical tools for farmers and veterinarians. These two materials enable humane veterinary care. They used together during both planned and emergency surgeries, sedating the animal to allow effective procedures. There are no equally effective synthetic or natural alternatives, and these two materials pose little environmental or health hazards. The subcommittee is reviewing xylazine and tolazoline together, updating their sunset schedule, as they are consistently used together.

Questions to our Stakeholders
None

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

Subcommittee Vote
Motion to remove xylazine from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Oxalic acid dihydrate

Reference: § 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(8) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.
Technical Report: 2018 TR
Petition(s): 2017
Past NOSB Actions: 04/2019 NOSB recommendation to add
Recent Regulatory Background: Added to NL 07/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review
As a varroa mite treatment, having oxalic acid dihydrate as a tool in the beekeeper toolbox is essential; subcommittee dialogue was brief but supportive of relisting.

Use
Oxalic acid is used as a parasiticide specifically for apiculture. Oxalic acid is currently labeled and approved by the EPA for use in beehives (Registration #91266-1). It is used both in the hive and during transport of honeybees in cages when sold as “bee packages”. It can be used in rotation with formic acid, currently on the National List, to control varroa mites and is a useful tool for beekeepers to manage honeybee parasites. Oxalic acid can be applied to a hive in two ways: In a sugar syrup to be trickled between frames, and as a vapor treatment. There are numerous types of equipment, both home-made and commercially available,

that provide the beekeeper the means of heating the oxalic acid and filling the hive with this vapor. In addition, oxalic acid is used to treat packaged bees before they are shipped to customers. Packaged bees with infestations of varroa mites have been a problem for beekeepers and the use of a sugar/oxalic acid syrup spray is a useful method to address this issue. Varroa mites, an invasive pest, are one of the many production problems affecting the livelihood of beekeepers. Numerous chemical varroa mite treatments have been used over the years in nonorganic operations. Many of these treatments are no longer effective due to the development of resistance by the varroa mite. Formic acid has been used for many years in honeybee hives, with no varroa mite resistance. It is considered unlikely that resistance will occur. Similar to formic acid, it is unlikely that varroa mites will develop resistance to oxalic acid.

The mode of action of this substance is not clearly understood, but it appears to be attributed to its acidity (pH near 0.9). Oxalic acid will cross the exoskeleton of the mites in a few hours of application and cause death. Oxalic acid vapor can enter the mite through the soft pads of its feet, enter the mite's blood stream and kill it. When mites parasitize and suck on the bee, it can kill the mite through this method as well. There is no clear research to determine if one or all of these are the main modes of action. Current research does indicate that the amount of oxalic acid typically applied to the honeybee hive is not toxic to the bees and is sufficient to kill varroa mites.

Manufacture
Oxalic acid is a dicarboxylic acid, which is in a crystalline form when solid, but loses this structure when dissolved in water. Commercial oxalic acid is produced through a variety of chemical reactions that include oxidation of carbohydrates or alkenes as well as synthesis from carbon monoxide and water. Oxalic acid crystals are produced through precipitation of the crystals from the mother liquor. Oxalic acid can also be produced through microbial fermentation of products such as citric acid, but these are not the typical method for commercial production.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
CAN/CGSB-32.310-2015 Clause 6.6.10: "The use of veterinary medicinal substances shall comply with the following: (a) if no alternative treatments or management practices exist, veterinary biologics, including vaccines, parasiticides or the therapeutic use of synthetic medications may be administered, provided that 408 such medications are permitted by this standard and Table 5.3 of CAN/CGSB-32.311 or are required by law."

Allowed as a health care product and production aid for mite control in honeybee colonies. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed 2018/848 Annex 2, Part II 1.9.6.3 Health Care of Bees (e)
Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with Varroa destructor."

OR 2021/1165 PART D Products referred to in Article 12(1) of this Regulation The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products: — caustic soda; — caustic potash; — oxalic acid

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

Allowed for pest and disease control in beekeeping. (72, B. livestock & livestock products; page 17)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed for pest and disease control in beekeeping. (5.8.7, page 52 and Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

Japan Agricultural Standard (JAS) for Organic Production
Japan does not have apiculture standards and oxalic acid is not present on their list of approved materials.

Ancillary Substances
None identified.

Human Health and Environmental Issues
Since it is an acid, it is considered hazardous in cases of skin contact, eye contact, ingestion, or inhalation. Handling instructions include use of protective equipment, such as long sleeves and pants, chemical resistant gloves, goggles, and a respirator.

There are no concerns of environmental contamination during manufacture or disposal. The amount used for honeybees is fairly small and does not add to concentrations of greenhouse gases in the atmosphere, and it would not have widespread negative impacts due to its biodegradability. Misuse of higher-than-recommended concentrations of oxalic acid could result in killing honeybees.

Discussion
In previous years' Board discussions, it was debated whether apiculture materials should be reviewed and approved only after there are NOP apiculture standards. It was noted that the NOP currently allows for organic honeybee products to be sold with the USDA organic seal, and honeybee products are certified organic by numerous NOP accredited certifiers. At the time, all Livestock Subcommittee members supported the implementation of the 2010 NOSB recommendation for organic apiculture standards. Beekeepers have expressed support in prior public comments noting some benefits over formic acid. During the Spring 2024 meeting, written comments and board discussion were limited but generally supportive of relisting.

Questions to our Stakeholders
What factors are weighed when determining to use sucrose octanoate esters, formic acid or oxalic acid dihydrate for varroa mite control?

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

Subcommittee Vote
Motion to remove oxalic acid dihydrate from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

DL methionine

Reference: § 205.603(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

Technical Report: 2001 TAP; 2011 TR

Petition(s): 2005; 2007; 2009; 2011

Past NOSB Actions: 10/2001 NOSB recommendation; 03/2005 NOSB recommendation; 05/2008 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012; 04/2010 sunset recommendation; 08/2014 Organic poultry feed proposal; 04/2015 NOSB Formal recommendation to amend; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

Use

Methionine is an essential amino acid for poultry since it cannot be produced biologically by the birds and is necessary for proper cell development for the growing chicks and for proper feathering. The USDA organic standards require that all agricultural ingredients for livestock feed be certified organic, and prohibit feeding meat by-products to organic poultry. This restriction narrows the options for natural sources of methionine.

Manufacture

Methionine is a sulfur-containing amino acid. The 2011 Technical Report lists these various methods of manufacture:

1. L-methionine may be isolated from naturally-occurring sources, produced from genetically engineered organisms, or synthesized through many processes. While methionine has been produced by fermentation in the laboratory, racemic mixtures of D- and L-methionine (i.e., DL-methionine) are usually produced entirely by chemical methods (Araki and Ozeki, 1991) [2011 TR 238-240]. Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:
    a. Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);
    b. Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);
    c. Use of the Strecker synthesis method with α-methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or
    d. Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998) [2011 TR 242-248].
2. In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and Lenantiomers (Ajinomoto Corporation, 2012) or by acetylation of synthetic DL-methionine and subsequent enzymatic selective deacetylation of the N-acetylated L-

methionine (Usuda and Kurahashi, 2010). Because much of the DL-methionine supply is synthesized using chemical methods, the L methionine produced from it is also synthetic. While nonsynthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005) [2011 TR 479-480].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed for use in feed, feed additives, and feed supplements. Organic sources, such as fishmeal, insect meal, brewer's yeast, potato protein, corn gluten and distillers' grains, shall be the first preference. When these organic sources does not meet amino acid requirements to produce a balanced feed, then:

a) amino acids derived from biological sources by biofermentation and extracted/isolated by hydrolysis, by physical, or other non-chemical means may be used;

b) when such forms of lysine and methionine are not commercially available for use in monogastrics feeding, all sources of lysine and methionine may be used.

This annotation will be reviewed at the next revision of the standard. (Table 5.2, Amino acids listing, CAN/CGSB-32.311-2020, page 23).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

The European Economic Community (EEC) Council Regulations state that "growth promoters and synthetic amino acids shall not be used" in animal feed in organic production.

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

Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)

Not allowed (3.2 Organic animal management does not use any of the following synthetic feed rations: amino acids (including isolates), page 16).

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Human Health and Environmental Issues

Synthetic methionine used as a nutritional supplement in livestock production can enter the environment through waste streams from its production, use, and disposal. Methionine has a relatively low vapor pressure, indicating that methionine present in soil or water is not likely to evaporate into air. Methionine is highly mobile in soil, and research has shown that most of the methionine in soil breaks down in about 16 days. Methionine can exist as a vapor or particulate in the air. Airborne methionine vapor will be degraded in the atmosphere with a half-life of about 7.5 hours. Methionine is also found naturally in water from metabolism of proteins. The potential for bioconcentration of methionine in aquatic organisms is considered low due to its high water solubility [2011 TR 729-286].

Discussion

The Livestock Subcommittee continues to see a need for synthetic DL-methionine in the organic poultry diet. Poultry are naturally omnivorous. Wild birds obtain sulfur containing essential amino acids (methionine and lysine) in their diet by eating insects, carrion, and other types of animal protein found in nature. Since USDA organic regulations prohibit the feeding of mammalian or poultry slaughter byproducts, the sulfur containing amino acids necessary for balanced poultry diets must come from other sources including agricultural products, nonsynthetic substances, and synthetic amino acids when permitted on the

National List at 205.603. Neglecting to supplement methionine in organic poultry diets results in serious health concerns including nervousness, feather picking, cannibalism and death. Organic poultry producers have struggled to find agricultural or nonsynthetic feed ingredients that adequately address methionine deficiencies without impacting bird health in other ways from overfeeding protein or introducing new feed ingredients that cause adverse health effects (e.g. Brazil nuts).

The feeding of synthetic methionine to organic poultry has been a contentious practice over the years, with some stakeholders opposed to any synthetic feed component. In contrast, comments from organic producers at the last review tended to strongly support the use of synthetic methionine under the current annotation. Commenters who identified as poultry producers all emphasized the essentiality of methionine to their operations. Specifically, commenters cited the animal welfare impact of methionine on their poultry including reduced pecking, improved feathering, and consistent, correct bird development. Research and innovation on this issue continues, but in the meantime the inclusion of DL-methionine on the National List appears warranted.

Questions to our Stakeholders

1. Is there a need for changes to the USDA organic regulations to align with either Canadian (unrestricted amino acid are allowed in organic feed) and/or EU (non-organic feeds containing methionine are allowed) organic regulations? If so, what changes to the USDA organic regulatory text should be made?

2. What other nutritional barriers to organic poultry production do producers face when formulating well balanced rations for all poultry in the organic sector?

3. Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?

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

Subcommittee Vote
Motion to remove DL-methionine from the National List
Motion by: Nate Powell-Palm
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Trace minerals

Reference: § 205.603(d) As feed additives.
(2) Trace minerals, used for enrichment or fortification when FDA approved.
Technical Report: 2013 TR (aquatic trace minerals); 2019 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 09/2014 subcommittee proposal - aquatic trace minerals; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Minerals are required in animal nutrition for their vital roles in various metabolic, enzymatic, and biochemical reactions in the animal body. Forages and grains are good sources of calcium and phosphorus, respectively. Minerals may be provided through the intake of plant matter feedstuffs and through synthetic supplements. Several factors directly or indirectly influence the levels of minerals in plants, including location, nature, and chemical composition of the soil; level of fertilization; and the presence of anti-nutritional factors that may reduce mineral bioavailability. Bioavailability is defined as the total proportion of the nutrient in a feedstuff that is available for use in normal body functions. As a result, the amounts of minerals for animals that depend on plants as feedstuffs will vary.

The dietary importance of each micro-mineral will depend on the animal species in question. When diet is insufficient to meet an animal's nutrient requirements, supplementation of minerals is typically done through inclusion in the diet either as an individual substance or as part of a trace mineral premix. NOP Guidance 5030 *Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed* spells out in more detail which minerals are covered under this listing.

It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock Subcommittee acknowledges this listing also includes macro minerals. The 2019 TR addresses macro minerals that are included in animal diet, though not in great detail as they are outside the focus of trace minerals.

Manufacture
Because this is a broad categorical listing, manufacture varies. In most cases, biologically active forms of trace minerals cannot be obtained by mining, so many trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. More recently, organic forms have become available. This would include the various chelates and complex forms. One of the limiting factors to the use of chelated minerals has been high cost. At the time of the 2019 review, chelated minerals cost 10 to 15 times more per milligram of mineral supplied, compared to inorganic sources.

Descriptions of the common processes used to manufacture many of the trace minerals in use are included in the 2019 TR. This level of detail is not provided for the class of substances called metal amino acid chelates since the processes used to manufacture those materials are largely the same.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed for use in feed, feed additives, and feed supplements. Unprocessed rock dusts; ground animal or plant material (other than blood or bone meal); and seawater are preferred sources. Chelated and sulphated forms are allowed. If none of these sources are commercially available, other versions are allowed, except for forms containing or produced with EDTA or EDDHA. (Table 5.2, CAN/CGSB-32.311-2020, page 24)

Non-synthetic chelated or sulphated minerals are allowed for use as a health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may

be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed when used in preference to veterinary drugs or antibiotics, needs to be recognized by the certification body or authority, and can only be used if they are of natural origin. In case of shortage of these substances, synthetic substances may be used.

International Federation of Organic Agriculture Movements (IFOAM)
Allowed. Animals may be fed vitamins, trace elements, and supplements from natural sources unless they are not available in sufficient quantity and/or quality.

Japan Agricultural Standard (JAS) for Organic Production
Allowed for therapeutic purposes and mineral supplementation.

Human Health and Environmental Issues
Based on information presented in the 2019 TR, the hazards associated with the use of the trace minerals are primarily associated with dust irritation of the skin and eyes.

When used as petitioned, trace minerals from unconsumed feed have the potential to be transferred to ground or surface waters. While trace minerals are essential dietary components for animal feeds, some are considered heavy metals with strong toxic potential. When included in animal feeds above required amounts, trace elements accumulate in urine and feces in low concentrations. In many cases, these may serve to increase deficient soil levels. The environmental risks of overly high micronutrient applications include impairment of plant production, accumulation in edible animal products, and contamination of the water supply. Concerns regarding specific minerals are included in the 2019 TR.

Discussion
The NOSB received 5 comments in spring 2024 supporting the relisting of trace minerals, and none opposed. They noted the essentiality of trace minerals to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Some commenters noted organic production should not be dependent on synthetic nutrients and that the current annotation is not restrictive enough to prevent reliance on synthetic materials. These commenters recommend adding “when forage and available natural feeds are poor quality” to the annotation. However, according to the 2019 TR, forages alone do not always satisfy the mineral requirements of grazing cattle. Mineral deficiencies and imbalances in grazing ruminants have been reported in almost all regions of the world. The choice of forage crop; the part of the plant consumed, and the plant’s state of maturity; the soil type and condition; and climatic conditions and seasons when plant material is eaten/gathered are all factors in determining the level and availability of trace minerals in feeds, and thus the need for trace mineral supplements.

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

Subcommittee Vote
Motion to remove trace minerals from the National List
Motion by: Brian Caldwell
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Vitamins

Reference: § 205.603(d) As feed additives.
(3) Vitamins, used for enrichment or fortification when FDA approved.
Technical Report: 1995 TAP (Folic Acid); 2013 TR (aquaculture); 2015 TR; 2024 Limited Scope TR
Petition(s): 2012 (aquaculture)
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) ; Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
The National Organic Program (NOP) currently allows the use of vitamins as feed additives in organic livestock production under 7 CFR 205.603, "Synthetic Substances Allowed for Use in Organic Livestock Production" for enrichment or fortification when FDA approved in amounts needed for maintenance (7 CFR §205.237) and for adequate nutrition and health. Further, the USDA organic regulations require producers to meet certain standards for livestock health care practices. As part of this requirement, livestock feed rations must meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants) (7 CFR 205.238(a)(2)).
The addition of vitamins directly or indirectly into animal food falls under the regulatory oversight of the U.S. Food and Drug Administration (FDA). According to FDA regulations, the addition of vitamins must be used according to the relevant food additive regulation, unless the substance is generally recognized as safe (GRAS) under 21 CFR 582/584 for that use pattern (FDA, 2014a) [2015 TR 234-236]. Vitamins may be added to mineral mixes and fed free choice or incorporated into rations.

Depending on the raw nutrients available, vitamins are combined in livestock feed rations of grains, beans, oilseeds, and other meals along with minerals and amino acids. There are 15 essential vitamins currently allowed for use in organic livestock production for fortification and enrichment: Vitamin A (vitamin A acetate), Vitamin B1 (thiamine hydrochloride), Vitamin B2 (riboflavin), Vitamin B3 (niacin, nicotinic acid), Vitamin B5 (calcium pantothenate), Vitamin B6 (pyridoxine hydrochloride), Vitamin B7 (biotin), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Choline chloride, Vitamin D3 (cholecalciferol), Vitamin E (α-Tocopherol acetate), and Inositol. The scope of vitamin compounds is reflective of vitamins defined as "required nutrients" by the National Research Council's (NRC's) Nutrient Requirements for cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well- being of all animals, including livestock. Most vitamins aid in the metabolism of proteins, carbohydrates, and fats while some vitamin compounds have important antioxidant properties. Common signs of vitamin deficiency include anorexia, poor growth, reduced feeding efficiency and, in some cases, mortality.

Manufacture
Individual vitamin compounds are normally produced on an industrial scale by chemical synthesis or partial synthesis. While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production. Many recently developed fermentation methods for manufacturing vitamins utilize excluded methods. They use genetically engineered (GE) microorganisms, generating concerns over the use of these vitamin sources in organic food production. The Technical Review conducted in 2015 stated that fermentation production using genetic modification may be commonly used in production of vitamins A, B2, B5, B6, C, E, and B12. A new limited technical review was requested to update which vitamins are produced with excluded methods and the availability of other sources. The authors indicated that this was difficult because much of the information was proprietary and held by foreign companies outside the jurisdiction of US requirements. The new 2024 TR indicated that vitamins B2, B12, and C have a high probability of being produced with use of a GE microorganism, from a GE feedstock. In addition, vitamins B8 and E are likely made from a GE feedstock (corn and soybeans) with non-GE microbes.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Biological and mineral sources of all vitamins are allowed. Non-biological and non-mineral sources of vitamins B1, C (ascorbic acid) and E are allowed. (Table 4.2, CAN/CGSB-32.311-2020, page 21)

Allowed in feed, feed additives, and feed supplements as a concentrated mixture of minerals and vitamins, from organic sources if commercially available. Allowed for enrichment or fortification. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of CAN/CGSB-32.311 are allowed. (Table 5.2, Pre-mixes listing, CAN/CGSB-32.311-2020, page 25)

Allowed for use as a health care product and production aid. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of this standard are allowed. Orally, topically, or by injection. (Table 5.3, CAN/CGSB-32.311-2020, page 29)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Vitamins, pro-vitamins and chemically well-defined substances having similar effect allowed; agricultural derivatives preferred (Annex III, Part B, 3(a), 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Vitamins or provitamins are allowed if they are of natural origin. In case of shortage of these substances or in exceptional circumstances, synthetics may be used. (page 13)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed from natural sources unless they are not available in sufficient quantity and/or quality. (3.2-page 16; 5.5.6-page 48)

Japan Agricultural Standard (JAS) for Organic Production
Allowed for therapeutic purposes.

Human Health and Environmental Issues
In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for livestock and human consumption at levels typically ingested through the diet and dietary supplements. When given

according to label directions, supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans.

No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Strong acids and bases are used in the synthetic or extraction process of vitamin compounds. Improper use or disposal of these chemicals during the production of vitamins could affect both the pH and chemical composition of the soil, potentially resulting in physiological effects on soil organisms. Accidental release of chemical reagents during the production process may lead to ecological impairment.

Discussion

Public Comments

During the Spring 2024 NOSB review the Livestock Subcommittee received 5 comments in favor of relisting vitamins at §205.603, and none to delist. One said that only vitamins A, C, and D, when feeds are insufficient, should be relisted. Vitamins are widely used. B and K vitamins were not considered essential for ruminants [and are thus not commonly included in mineral mixes for these species]. B vitamins were considered essential for poultry. Certifiers commonly use affidavits to determine excluded method status.

Vitamins satisfy the OFPA evaluation criteria and the Livestock Subcommittee supports relisting. However, the use of excluded methods in the production of some vitamins, and the lack of transparency regarding production methods is problematic. The NOP has issued a guidance (NOP 5030, in 2013) and a "response to comments" document (NOP 5030-1) which include discussions of this issue.

- In NOP 5030 guidance document, NOP is clear that proteinated minerals produced with excluded methods are not allowed in organic livestock feed, however, it is silent on the review and approval of vitamins which may be produced using excluded methods.
- In NOP 5030-1 document, the NOP observes "a lack of technical review or specific recommendation from the National Organic Standards Board (NOSB) to clarify this issue regarding sources of livestock mineral and vitamins…."
- It further specifies that "FDA and AAFCO listed vitamins and minerals meet the specifications of the National List at § 205.603(d)(2) and § 205.603(d)(3)."
- Finally, NOP 5030-1 states, "The USDA organic regulations also prohibit use of excluded methods at § 205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods."
- Currently, citing the absence of a clear directive in NOP 5030, the Accredited Certifiers Association Best Practice for GMO Vitamins in Livestock Feed vitamins states that the GMO status of AAFCO-listed vitamins used in certified organic livestock feed does not need to be verified.

Technical Reviews from 2015 and 2024 address this issue in depth and indicate that some FDA and AAFCO listed vitamins are highly likely to be produced with excluded methods.

Vitamins themselves are not GMO's. The NOP regulation states that to be sold as organic, the product must be produced and handled without the use of excluded methods (7 CFR 205.105(e)). This raises the question, if an animal was fed vitamins manufactured with GMO's, does that mean that the animal was produced using excluded methods?

We request advice from the organic community as to whether an annotation is needed, requiring that vitamins fed to livestock be produced without excluded methods. We recognize that this would entail additional work from certifiers and materials review organizations. Further, for the production of some synthetic vitamins such as vitamin C, it might be impossible to verify that excluded methods have not been used. If those synthetic vitamins are disallowed, organic livestock producers could be disadvantaged.

Questions to our Stakeholders

1. If an animal was fed vitamins manufactured with GMO's, does that mean that the animal was produced using excluded methods?
2. How far back in the manufacturing process of a vitamin would a certifier need to verify in order to conclude that the vitamin was produced without excluded methods?
3. How might an annotation be used to ensure that vitamins fed to livestock are produced without excluded methods?

Justification for Vote

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

Subcommittee Vote

Motion to remove vitamins from the National List
Motion by: Brian Caldwell
Seconded by: Nate Lewis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1