

Sunset 2021
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2019

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic livestock production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2019 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2019 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 4, 2019, as explained in the meeting notice published in the Federal Register.

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances under Review:

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

- (1) not harmful to human health or the environment;

- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic livestock production.

For Comments That Do Not Support Substances under Review:

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

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

For Comments Addressing the Availability of Alternatives:

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

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

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

Written public comments will be accepted through April 4, 2019, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

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

[Atropine](#)

[Hydrogen peroxide](#)

[Iodine \(§205.603\(a\)\)](#)

[Iodine \(§205.603\(b\)\)](#)

[Magnesium sulfate](#)

[Parasiticides: Fenbendazole](#)

[Parasiticides: Moxidectin](#)

[Peroxyacetic/Peracetic acid](#)

[Xylazine](#)

[DL-Methionine](#)

[Trace minerals](#)

[Vitamins](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Atropine

§205.603 Synthetic substances allowed for use in organic livestock production.

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 Technical Report](#)

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

Past NOSB Actions: [05/2003 sunset recommendation](#); [04/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

Atropine is an anti-cholinergic derived from *atropa belladonna* (deadly nightshade) roots; it is isolated via various synthetic extraction processes. It is a highly controlled substance, administered under orders of a veterinarian; its primary use is as an antidote for organophosphate poisoning, which most commonly occurs through ingestion of pesticides. The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI). According to the 2019 TR, atropine is itself toxic, with the risk of toxicity dependent on the relative ability of various species to metabolize atropine (cattle and pigs are the agriculturally most sensitive to atropine toxicity).

Range of uses. According to the 2019 TR: “Within the context of livestock veterinary applications, atropine has been used in a variety of ways...a treatment for organophosphate poisoning by reversibly blocking acetylcholine receptors; a preanesthetic for veterinary surgical procedures due to its ability to reduce secretions and relax muscles; a bradycardia treatment to raise heart rates following anesthesia in surgical procedures; a veterinary ophthalmological treatment as it relaxes ocular muscles, relieves pain, dilates pupils, and affects iris permeability for glaucoma treatments....”

International allowance for use. According to the 2019 TR, atropine is listed on the Canadian General Standards Board Permitted Substances List. However, it is not listed for use under:

- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods;
- European Economic Community (EEC) Council Regulations;
- Japan Agricultural Standard (JAS) for Organic Production; or
- International Federation of Organic Agriculture Movements (IFOAM).

Environmental contamination. According to the 2019 TR, “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....” The 2019 TR also states that “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' Tropine has also been identified as toxic to aquatic invertebrates, including *Daphnia magna* (water fleas) at concentrations of 54.7 mg/L...."

Effect on human health. According to the 2019 TR, "Atropine is most commonly administered intravenously, although it may also be applied via ingestion, or ocular absorption (applied directly to the eye) Intravenous administration of the substance using proper medical protocols (e.g., gloves, premeasured doses) makes inadvertent human absorption unlikely. Due to the neurophysiological profile of atropine, its absorption also poses toxicological concerns. Atropine intoxication is associated with symptoms including abdominal pain, confusion and disorientation, hallucinations, urinary retention, hypothermia and tachycardia Atropine toxicity can be lethal in humans, however, the level of toxicity and its relationship to fatal outcomes is not well defined."

Natural (non-synthetic) alternatives. According to the 2019 TR, "Atropine is recognized as the most efficient treatment option for organophosphate poisoning within both human and veterinary medicine...." The TR also states that "Magnesium sulfate ($MgSO_4$) is approved for use in organic livestock production at 7 CFR 205.603, and is being studied as a potential alternative or additional treatment to atropine administration for organophosphate treatment protocols...." However, this substance "has seen little clinical applications, and more studies are required to evaluate its effectiveness compared to traditional atropine and atropine oxime combination treatments...."

Additional information requested by the Subcommittee:

1. For what veterinary medical purposes, if any, is this substance currently being used in organic production?
2. How widely used and essential is this substance by organic producers?
3. Are there alternative substances, whether natural or synthetic, considered preferable for use in organic production? If so, what are these substances?

Hydrogen peroxide

§205.603 Synthetic substances allowed for use in organic livestock production.

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](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from subcommittee:**Use:**

Hydrogen peroxide is used as a readily available disinfectant and broad-spectrum germicide. It is an important cleaning agent for use on contact surfaces, such as equipment, calf pails, bottles, and utensils. The material is used to clean wounds and was first registered with the EPA in 1977.

Manufacture:

Hydrogen peroxide is a very simple molecule with a formula of H₂O₂. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H₂) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

International Acceptance:

The 2015 TR notes that a subset of the international organizations surveyed have provided guidance on the application of hydrogen peroxide for disinfection and plant disease control in organic crop production.

Canadian General Standards Board: allows numerous uses of hydrogen peroxide in organic production. Section 5.3: "Health care and production aids for livestock production" lists pharmaceutical grade hydrogen peroxide for external use as a disinfectant, and food-grade hydrogen peroxide for internal use (e.g., livestock drinking water). Hydrogen peroxide is also listed in Section 7.3: "Food-grade cleaners, disinfectants and sanitizers" that are allowed without mandatory removal of residues, and 7.4: "Cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production" (CAN, 2011).

European Union: According to Annex VII of EU regulation 889/2008, hydrogen peroxide is allowed for cleaning and disinfection of buildings and installations for animal production. Specifically, hydrogen peroxide can be used to satisfy Article 23 (4), which states that "housing, pens, equipment and utensils shall be properly and disinfected to prevent cross-contamination and the buildup of disease carrying organisms." Hydrogen peroxide is also permitted for use in the production of gelatin under Section B of Annex VIII: and substances for use in production of processed organic food (EC, 2008).

International Federation of Organic Agriculture Movements (IFOAM): Hydrogen peroxide is permitted under Appendix 4 – Table 2 of the IFOAM Norms as an equipment cleanser and disinfectants. In addition, Appendix 5 lists hydrogen peroxide as an approved substance for pest and disease control and disinfection in livestock housing and equipment (IFOAM, 2014). The Norms make not mention of hydrogen peroxide for plant disease control and prevention.

UK Soil Association: Standards permit the use of hydrogen peroxide only as a cleaning product for livestock housing areas. No conditions are provided allowing the use of hydrogen peroxide for plant disease control and prevention (Soil Association, 2014).

Environmental Issues (could include human health issues):

Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

Discussion:

Hydrogen peroxide is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995 (Crops), the technical review of October 2015, the unanimous NOSB 2017 support of this material, and no new scientific or meritorious information.

Additional information from Subcommittee:

Is this synthetic material a necessary input in organic livestock production?

Iodine—§205.603(a)

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. **(16) Iodine.**

Technical Report: [1994 TAP](#); [2015 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](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

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.

Additional information requested from Subcommittee:

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so, what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Iodine—§205.603(b)

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (3) Iodine.

Technical Report: [1994 TAP](#); [2015 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](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

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.

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Additional information requested from Subcommittee:

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so, what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Magnesium sulfate**§205.603 Synthetic substances allowed for use in organic livestock production.**

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](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from subcommittee:**Specific Uses:**

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.

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.

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.

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.

Magnesium sulfate, or Epsom salt, 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.

Additional information requested from Subcommittee:

Is this material essential for organic livestock production?

Parasiticides, Fenbendazole

§205.603 Synthetic substances allowed for use in organic livestock production.

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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(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](#) (Fenbendazole, Ivermectin); [2015 TR](#)

Petition(s): [03/2007 Fenbendazole](#)

Past NOSB Actions: [05/2008 NOSB recommendation](#); [10/2015 sunset recommendation](#); [04/2016 recommendation – annotation change](#)

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](#))

Sunset Date: pending

Background from subcommittee:

In veterinary medicine the term parasiticide refers to anthelmintic drugs. 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)]). 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. 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 flocks. 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).

A petition for inclusion of fenbendazole on the National List was received by the NOP, March 23, 2007. Fenbendazole was added to the National List effective May 12, 2012. A technical review was completed in 2015 to review fenbendazole, ivermectin, and moxidectin as one group. The technical review documented that parasiticide resistance management has become an important issue in animal health and that increased use of anthelmintics in livestock production may lead to subsequent selection and

increased parasiticide resistance (Xu et al., 1998; James et al., 2009). As a result, if resistance to one drug occurs, then other drugs with the same mode of action or binding site will also be ineffective.

Fenbendazole and moxidectin are the only anthelmintics approved for use in organic livestock production. Fenbendazole works very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β -tubulin and ion channel proteins targeted by these anthelmintics. This allows the worms in subsequent generations to avoid drug binding and enables drug resistance. Fenbendazole acts selectively by binding to nematode β -tubulin. Binding β -tubulin disrupts the nematode digestive system and prevents egg formation, while potentiating the GLUCL channel causes spastic paralysis.

Fenbendazole is sold as Panacur and Safe Guard. The orally administered product contains polysorbate 80, simethicone emulsion 30%, benzyl alcohol and purified water. Fenbendazole paste contains the excipients carbome homopolymer type B (Allyl pentaerythritol crosslinked), propylene glycol, glycerin, sorbitol, sodium hydroxide, water, methylparaben and propylparaben.

Risks with the use of Fenbendazole:

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). 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.

Fenbendazole is insoluble in water and excreted in feces after administration. Because it is not soluble, there is little mobility of fenbendazole in soils, and low risk of groundwater contamination. Laboratory tests show that radiolabeled fenbendazole is degraded with a half-life of 54 days. Although photodegradation plays a role, degradation of fenbendazole in soil appears to be microbially dependent rather than photodegradative (Kreuzig et al., 2007).

The fate of fenbendazole in manure and manured soils has been studied under laboratory and field conditions. After a 102-day incubation period, 80% of fenbendazole remains. The latter was accompanied by 4% of the corresponding metabolite fenbendazole-sulfoxide. Fenbendazole-sulfoxide remains in clay soil samples after 54 days (Kreuzig et al., 2007). Fenbendazole toxicity was demonstrated in pigeons and doves, leading the authors of the study to suggest a toxic etiology for fenbendazole in birds of the order Columbiformes treatment (Howard et al., 2002).

International Status:

Review of the International Organic Standards- The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production- all shows a commonality: 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. The International Federation of Organic Agriculture Movements (IFOAM) has 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.

Additional information requested by Subcommittee:

- 1). Do livestock producers still have a necessity for the usage of fenbendazole for emergency treatment of parasites when good pasture management techniques are being used?

Parasiticides, Moxidectin

§205.603 Synthetic substances allowed for use in organic livestock production.

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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock

(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 \(Moxidectin\)](#); [2015 TR](#)

Petition(s): [Moxidectin](#)

Past NOSB Actions: [05/2004 NOSB recommendation](#); [10/2015 sunset recommendation](#); [04/2016 NOSB recommendation - annotation change](#)

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](#))

Sunset Date: pending

Background from Subcommittee:

In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites. 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)]). The use of parasiticides 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. 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 flocks. 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).

Moxidectin, a derivative of nemadectin is a chemically modified *Streptomyces cyanogriseus* fermentation product (Asato and France, 1990). 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 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, which was inconsistent with NOP policy prohibiting the use of antibiotics in organic livestock production.

Based upon the evidence received through public comments on the July 17, 2006 proposed rule, the NOP verified the information supplied by commenters and, subsequently, concurred that moxidectin, though categorized as a macrolide antibiotic, does not function as such when used as a parasiticide. In a final rule ([72 FR 70479](#)) published in the Federal Register on December 12, 2007, USDA announced that moxidectin would be added to the National List through a future rulemaking action, and in 2011 NOP proposed to add moxidectin. The Final Rule in 2012 added moxidectin to National List for the first time.

The NOSB received a technical review (TR) in 2015 for Moxidectin, along with Fenbendazole and Ivermectin. The TR documented that parasiticide resistance management had become an important issue in animal health and that increased use of anthelmintics in livestock production may lead to subsequent selection and increased parasiticide resistance. As a result, if resistance to one drug occurs, then other drugs with the same mode of action or binding site will also be ineffective. Fenbendazole, ivermectin and moxidectin individually work very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β -tubulin and ion channel proteins targeted by these anthelmintics, allowing worms in subsequent generations to avoid drug binding and enables drug resistance. Moxidectin, the only milbemycin approved for use in organic livestock production, selectively binds to nematode β -tubulin and potentiating the glutamate-gated chloride (GLUCL) channel. Binding β -tubulin disrupts the nematode digestive system and prevents egg formation, while potentiating the GLUCL channel causes spastic paralysis.

Risks with the use of Moxidectin:

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). Moxidectin is an FDA-approved livestock parasiticide that is a synthetically produced substance which has been shown by experimental and clinical studies to be safe for application to food animals.

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.

International Status:

Review of the International Organic Standards- The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production- all shows a commonality: 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. The International Federation of Organic Agriculture Movements (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.

Additional information requested by Subcommittee:

- 1). Do livestock producers still have a necessity for moxidectin for emergency treatment of parasites when good pasture management techniques are being used?

Peroxyacetic/peracetic acid

§205.603 Synthetic substances allowed for use in organic livestock production.

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 Petition](#)

Past NOSB Actions: [11/2000 NOSB recommendation](#); [04/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from subcommittee:

Specific Use:

According to TR line 88, peracetic acid is listed for use in organic livestock production for sanitizing facility 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. 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 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:

The March 2016 TR outlines the following guidelines from international organizations regarding the use of peracetic acid as a disinfectant, sanitizer and medical treatment.

Canada: Peracetic acid does not appear in paragraph 5.3 (Health Care Products and Production Aids) of the CAN/CGSB-32.311-2015 Permitted Substances List. It is, however, listed at paragraph 7.3 as a food-grade cleaner, disinfectant and sanitizer permitted with a mandatory removal event, with the following annotation: "On food and plants: peracetic acid may be used in wash or rinse water. Peracetic acid may also be used on food contact surfaces." This allowance is consistent with the NOP regulations at 7 CFR 205.603.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (GL 32-1999): The Codex Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) do not mention any permitted sanitizers. Peracetic acid also does not appear on Annex 2 (Permitted Substances for the Production of Organic Foods) in the guidelines.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008: Peracetic acid is a permitted product for cleaning and disinfection of buildings and installations for animal production (EC No 889/2008 - Annex VII - Products for cleaning and disinfection referred to in Article 23). Peracetic acid and peroctanoic acid are permitted materials for cleaning and disinfection of equipment and facilities in the presence as well as in the absence of aquaculture animals (EC No 889/2008 - Annex VII point 2.2).

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.

International Federation of Organic Agriculture Movements (IFOAM): The IFOAM norms permit use of peracetic acid for cleaning equipment and disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), and for disinfection of livestock housing and equipment (IFOAM

Environmental Issues:

Peracetic acid is considered to be 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.

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.

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 National Organic Standards Board (NOSB) previously reviewed peracetic acid as a disinfectant, sanitizer, and medical treatment in accordance with 7 Code of Federal Regulation (CFR) § 205.603(a). Recently, peracetic acid also has been used to clean stalls and to disinfect livestock, particularly dairy cattle. Acetic acid and hydrogen peroxide both have a longer history of use in livestock production than commercial preparations of peracetic acid, but the substance has, in effect, been used by farmers who combine vinegar and peroxide in a cleaning solution.

Peracetic acid is recommended for relisting based on the available 2000 technical advisory panel (TAP), the technical review of March 2016, the unanimous NOSB 2017 support of this material, and no new scientific or meritorious information.

The NOSB has reviewed few materials for use in barns, stalls, stables and milking parlors, leaving relatively few options for producers.

Additional information from Subcommittee:

Is peracetic acid still necessary for organic livestock production?

Xylazine

§205.603 Synthetic substances allowed for use in organic livestock production.

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](#); [2019 Technical Report](#)

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

Past NOSB Actions: [09/2002 NOSB recommendation](#); [04/2010 sunset recommendation](#); [10/2015 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](#))

Sunset Date: pending

Background from subcommittee:

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.

International allowance:

- **Canadian General Standards Board Permitted Substances List**

Xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list in Table 5.3 “health care products and production aids,” as a “sedative.”

Tolazoline (most commonly used as a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list.

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**
Neither xylazine nor tolazoline are listed in the CODEX.
- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**
Neither xylazine nor tolazoline are listed in the EEC EC No. 834/2007 or 889/2008.
- **Japan Agricultural Standard (JAS) for Organic Production**
Neither xylazine nor tolazoline are listed in the JAS for Organic Production.
- **International Federation of Organic Agriculture Movements (IFOAM)**
Neither xylazine nor tolazoline are listed in IFOAM.

Persistence/concentration of xylazine or its by-products in the environment.

According to the 2019 TR: Environmental studies on xylazine...highlight the possible persistence of the substance and its accumulation in soil systems as well as its role as an aquatic pollutant (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017). Reports of xylazine environmental contamination on the Iberian Peninsula may be linked with xylazine manufacturing, resulting in high contributions to water pollution in Iberian river systems (Fabrega et al. 2013, Pugajeva et al. 2017). The leaching ability of xylazine and its reported slow degradation in aquatic systems make wastewater pollution a concern in cases of improper use or disposal (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017).

Effects on human health. According to the 2019 TR:

Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrhythmias, 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.

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 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).

Natural (non-synthetic) alternatives. According to the 2019 TR, “No natural alternatives are common for either [xylazine or tolazoline] (i.e., a sedative alternative for xylazine or a xylazine-reversal agent as a

tolazoline alternative). Moreover, while there are several synthetic alternatives for both substances, no other synthetic alternatives have been approved by the USDA for use in organic agricultural production.”

Additional information requested by the Subcommittee:

1. For what veterinary medical purposes, if any, is this substance currently being used in organic production?
2. How widely used and essential is this substance by organic producers?
3. Are there alternative substances, whether natural or synthetic, that are considered preferable for use in organic production? If so, what are these substances?

DL-Methionine

§205.603 Synthetic substances allowed for use in organic livestock production.

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 Methionine](#); [2007 Methionine](#); [2009 Methionine](#); [2011 Methionine](#)

Past NOSB Actions: [10/2001 NOSB recommendation](#); [03/2005 NOSB recommendation](#); [2008 NOSB recommendation](#); [04/2010 NOSB recommendation on Methionine annotation through October 2012](#); [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](#); [10/2015 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](#))

Sunset Date: pending

Background from subcommittee:

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, which require all agricultural ingredients for livestock come from an organic source, as well as the prohibition of feeding poultry or mammalian by-products to organic poultry or mammals, narrow the options for natural sources of methionine.

Manufacture:

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

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). Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:

- *Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);*
- *Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);*
- *Use of the Strecker synthesis method with α -methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or*
- *Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998). In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and L-enantiomers (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).*

International:

The European Union does not allow synthetic methionine in livestock feed. EU regulations do allow for some use of nonorganic non-GMO agricultural ingredients when organic forms are not available, and these ingredients (e.g., nonorganic corn gluten meal) could provide natural methionine. In 2015, there was non-organic corn gluten meal available in the United States, and a recent review of the NOP organic integrity database noted 12 sources of organic corn gluten meal, with one located in the U.S. and the others in China. Canadian standards allow the use of DL-methionine with no restrictions. However, there is a notation in the current list of allowed materials under the Canadian Organic Standard, that this use of synthetic methionine will be under review in the near future.

Background from Subcommittee:

A petition to allow use of this synthetic amino acid in organic poultry rations was presented to the NOSB in 1999. In 2001, a Technical Advisory Panel analyzed the use of the synthetic DL-methionine and determined that feed supplementation with this material is compatible with an organic system of agriculture, since it is essential to maintain the health of the birds. Synthetic amino acids are not specifically listed as a category of approved synthetics in the Organic Food Production Act.

For almost two decades this material has been present on the National List of approved synthetics, resulting in many written and oral public comments both for and against its allowance in organic poultry production. Those against its allowance state synthetic methionine in the poultry ration enables high concentrations of organic birds to be raised in confinement, with minimal access to the outdoors. In addition, they state that birds who have access to vegetation and bugs on a healthy organic pasture can obtain methionine from these sources and do not suffer negative health effects when there is insufficient methionine (natural or synthetic) in their ration.

Those in favor of synthetic methionine have stated that natural sources of methionine are difficult to provide in sufficient quantities. Crops, such as soybeans, are a source of methionine, but when sufficient soybean meal is fed to meet methionine levels, other levels of amino acids become too high which results in a poorly balanced ration. Excess protein in the ration causes a significant rise in the ammonia levels from manure in the chicken houses, resulting in a lower quality of life for the birds.

Natural sources of methionine have a variety of issues. There are no organic sources of fish meal, crab meal or blood meal. Black soldier larvae would need to be fed in very large quantities, making it impractical since there are no sources producing enough dried larvae to feed the current flocks of organic poultry in the U.S. Algae is another promising area, but has not been developed to determine its acceptability. Items such as whey powder, nonfat dry milk and potato proteins have been tried, but were not fully digestible by the birds. These items and more have been researched by the Methionine Task Force, an ad-hoc citizen group that has provided information to the NOSB over the years, whose members consist of organic poultry operations and animal nutrition specialists.

A final rule published on December 27, 2018, and effective on January 28, 2019, incorporated the NOSB recommendation of April 2015 to adjust the amount of methionine in the feed ration to meet the demands of the birds at different stages of life, while still limiting the total amount of methionine that can be fed over the lifetime of the birds. This change allowed for a specific amount of methionine over the life of the bird rather than how much would be allowed per ton of feed prepared for the organic flock. Typically, a higher percentage of methionine is needed in the ration when the birds are young and growing. Organic poultry producers, through public comment, stated the previous annotation requiring a specific amount of methionine in each ration led to poor immune system development, poor feathering, feather pecking and cannibalism in their flocks. The new annotation, noted above, effective January 28, 2019, will be the listing that the NOSB will vote upon in Fall 2019. The previous annotation was as follows:

Synthetic substances allowed for use in organic livestock production.

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 maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

In addition to the 2015 NOSB recommendation to modify the annotation for DL-Methionine, the following resolution was passed unanimously by the Livestock Subcommittee.

Resolution: The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

Additional information requested by Subcommittee:

1. What types of ingredients have been tested in feed ration trials with the goal of developing acceptable sources of natural methionine, and what were the results?
2. Are there new options being trialed to find natural and/or organic agricultural sources of methionine that meet the needs of organic poultry?
3. Has there been any research to determine if pastured poultry that has access to growing vegetation, have less of a need for synthetic methionine than poultry that does not have access to living plants, bugs and biologically active soils?

Trace minerals

§205.603 Synthetic substances allowed for use in organic livestock production.

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 (pending) to be available at <https://www.ams.usda.gov/rules-regulations/organic/national-list/m>

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB recommendation](#); [11/2005 sunset recommendation](#); [04/2010 sunset recommendation](#); [09/2014 aquatic trace minerals subcommittee proposal](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from subcommittee:

Use:

Trace mineral elements, whether naturally occurring in the diet or provided in supplements, are important for the maintenance, growth, and reproduction in the healthy production of beef cattle, swine, and poultry. In beef cattle production, minerals needed in larger amounts include calcium, phosphorus, magnesium, potassium, sodium, chlorine, and sulfur, while iron, zinc, manganese, copper, cobalt, and selenium are needed only in trace amounts (2013 TR Line 178). Forages and grains are good sources of calcium and phosphorus, respectively. However, the bioavailability of minerals in forage may vary depending on the mineral content of the soil and the level of pasture fertilization. Mineral premixes are therefore widely used for livestock feed fortification to ensure the adequate intake of minerals (Hale, 2001). Likewise, poultry and swine production uses dietary supplementation of trace mineral compounds (Richards, 2010). (TR lines 173-180). The NOP has issued a guidance document for the use of minerals in livestock feed, which 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.

Manufacture:

Because this is a broad categorical listing, manufacture varies. According to the 2013 TR, individual mineral compounds are produced on an industrial scale through chemical synthesis and extraction from either natural or reclaimed sources. Selection of the manufacturing processes typically depends on the available technology, cost of raw materials/chemical feedstocks, availability of mineral containing reclaimed materials, market prices and size, cost of implementing extraction versus chemical synthetic processes and, to a lesser extent, the overall environmental impact of the production method. For a representative sample of common production methods, please refer to the 2013 TR, lines 563 to 631.

International:

Canadian General Standards Board

As included in the 2013 TR, according to the Canadian General Standards Board General Principles and Management Standards (CAN/CGSB-32.310-2006), organic operators may not use “feed and feed additives, including amino acids and feed supplements that contain substances not in accordance with CAN/CGSB-32.311, Organic Production Systems - Permitted Substances Lists” (CAN, 2011a). Minerals are included in the definition of feed additives and therefore subject to regulation. However, the Permitted Substances List (CAN/CGSB 32.311-2006) allows the use of synthetic minerals under certain circumstances: “minerals, trace minerals, elements” may be used for enrichment or fortification of livestock feed, and synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Under no circumstances should minerals be used to stimulate growth or production (CAN, 2011b).

Codex Alimentarius

The specific criteria for feedstuffs and nutritional elements section of the standards set forth by the Codex Alimentarius Commission (2012) pertaining to livestock production states that “feedstuffs of mineral origin, trace minerals, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used” (Codex Alimentarius Commission, 2012).

European Union

The European Economic Community (EEC) Council Regulations, EC No. 834/2007 and 889/2008, state that “feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production.” Specifically, the following trace elemental compounds are allowed as nutritional additives in the organic production of livestock under Annex VI:

- Iron – Ferrous (II) carbonate, ferrous (II) sulfate, monohydrate and/or heptahydrate, ferric (III) oxide; Iodine – Calcium iodate (anhydrous and hexahydrate), sodium iodide;
- Cobalt – Cobaltous (II) sulfate monohydrate and/or heptahydrate, basic cobaltous (II) carbonate monohydrate;
- Copper – Copper (II) oxide, basic copper (II) carbonate monohydrate, copper (II) sulfate pentahydrate;
- Manganese – Manganous (II) carbonate, manganous oxide and manganic oxide; manganous (II) sulfate mono and/or tetrahydrate;
- Zinc – Zinc carbonate, zinc oxide, zinc sulfate mono and/or heptahydrate;
- Molybdenum – Ammonium molybdate, sodium molybdate;
- Selenium – Sodium selenate, sodium selenite.

Japan Ministry of Agriculture, Forestry and Fisheries (MAFF)

The Japan Ministry of Agriculture, Forestry, and Fisheries Standard for Organic Feed do not specify the allowed or prohibited status of trace minerals in organic livestock or aquatic animal feed. However, the standard permits natural feed additives:

Feed additives (except for those produced by using antibiotic and recombinant DNA technology), which are natural substances or those derived from natural substances without being chemically treated. In case of a difficulty to obtain feed additives listed in 8, the use of

similar agents to the described food additives are permitted only for supplementing nutrition and effective components in feeds.

This statement suggests that synthetic minerals may be allowed if naturally derived substitutes are not available (JMAFF, 2005).

International Federation of Organic Agricultural Movements (IFOAM)

Within their norms, the International Federation of Organic Agricultural Movements (IFOAM) allows vitamins, trace elements and supplements from natural sources in animal feed. An exception to this rule states that “synthetic vitamins, minerals and supplements may be used when natural sources are not available in sufficient quantity and quality” (IFOAM, 2012).

Ancillary substances:

See the questions below.

Human Health and Environment:

According to the 2013 TR, at excessive levels of exposure, many of the trace minerals have the potential for toxicity toward humans, aquatic animals, and terrestrial animals. As a result, the U.S. EPA has established maximum contaminant levels for some minerals due to human toxicity concerns (U.S. EPA, 2012). The TR provides further detail regarding toxic effects related to excessive amounts of selected trace mineral elements, lines 704-713.

Discussion:

The NOSB has continually received comments from the organic community supporting the continued use of trace minerals, noting their essentiality to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Additional information from Subcommittee:

- 1) Are trace minerals still essential to the production of organic livestock?
- 2) Can trace minerals be produced from agricultural sources that have been produced through excluded methods?
- 3) Are there ancillary substances used in the production of trace minerals?

Vitamins

§205.603 Synthetic substances allowed for use in organic livestock production.

Reference: 205.603(d) As feed additives. (3) Vitamins, used for enrichment or fortification when FDA approved.

Technical Report: [2015 TR](#)

Petition(s): N/A

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

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)) ; Renewed 03/15/2017 ([82 FR 14420](#))

Sunset Date: 3/15/2022

Background from Subcommittee:

The National Organic Program (NOP) final rule currently allows the use of vitamins 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. The U.S. Food and Drug Administration (FDA) enforces provisions of the Federal Food, Drug and According to the FFDCa, any substance that is added or expected to directly or indirectly become a component of animal food must be used according to the relevant food additive regulation unless the substance is generally recognized as safe (GRAS) under 21 CFR parts 582 and 584 for that use pattern (FDA, 2014a). In addition, substances listed as FDA-approved food additives (21 CFR parts 570, 571, and 573) may also be incorporated into animal feeds.

In organic livestock production, vitamins are combined in feed rations of grains, beans, oilseeds, and other meals with minerals, amino acids, and vitamins (Pond et al., 1995). Depending on the raw nutrients available to the animal, individual vitamins or a premix of multiple vitamins may be added to feed rations (Sewell, 1993.)

The National Organic Program (NOP) final rule currently allows the use of vitamins, as feed additives, in organic livestock production under 7 CFR §205.603(d)(3) in amounts needed for adequate nutrition and health maintenance (7 CFR §205.237). 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)).

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 of cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well- being of all animals, including livestock. In particular, 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.

Individual vitamin compounds are produced on an industrial scale by chemical synthesis or partial synthesis, fermentation and/or by extraction from natural material sources. Selection of the manufacturing processes typically depends on available technology, cost of raw materials/chemical feedstocks, market prices and size, cost of implementing fermentation versus chemical processes (synthesis or extraction) and, to a lesser extent, the overall environmental impact of the production method.

While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production (Festel, 2005). Fermentation is an enzymatic process whereby microorganisms convert natural carbon-based nutrients (e.g., glucose, molasses, etc.) to desired compounds. Many recently developed fermentation methods for manufacturing vitamins utilize genetically engineered microorganisms, generating concerns over the use of these vitamin sources in organic food production (Roseboro, 2008). As of 2015, when the last technical review (TR) was received, fermentation production using genetic modification was commonly being used in production of vitamins A, B2, B5, B6, C, E, B12.

Accordingly, NOP published Guidance 5030 “Guidance Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed”, which instructs certifiers to be diligent in reviewing vitamins for the presence of excluded methods. Specific to excluded methods in vitamins, NOP wrote: "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."

<https://www.ams.usda.gov/sites/default/files/media/5030.pdf>

OMRI acknowledged that vitamins may be produced using excluded methods in their Generic List, and which contains a Decision Tree For Evaluation of GMO Inputs in Organic Livestock Production on page 85. http://www.omri.org/sites/default/files/app_materials/OMRI-GML-Stan-2013small_0.pdf

Environmental Impact:

No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Accidental release of chemical reagents during the production process, however, may lead to ecological impairment. Specifically, 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.

Aquatic ecosystems are particularly sensitive to the introduction of nutrients from nearby agricultural operations. Releasing excessive amount of agricultural materials—including phosphate and nitrate fertilizers, feed materials and manure—to waterways can encourage the growth of algae (algal bloom) and other aquatic plants and ultimately oxygen depletion in the affected water zone (Wu, 1995; NAS, 1969).

Health Impacts:

In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for human consumption at levels typically ingested through the diet and dietary supplements taken according to label directions. Supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans; hence, the agricultural use pattern for vitamins under review should not adversely impact human health.

International:

The Canadian National Standards Board, the Codex Alimentarius Commission, the EU and the Japanese organic standards all prohibit the use of synthetic vitamins when natural sources are available. If natural sources are not available, synthetic forms of vitamins are allowed. The United Kingdom Soil Association adds an additional stipulation that the producer must demonstrate nutritional deficiency of the animals' feed.

Additional information from Subcommittee:

- 1) What documentation is required by the certifiers and material review organizations to verify that vitamins that have been produced without genetic modification?
- 2) Since production methods, such as rotational grazing or reducing the numbers of grazing animals, has been shown to reduce the demand for vitamin supplements, should there be less need for supplying ruminant livestock feeds with synthetic vitamins?