

Sunset 2021
Meeting 2 - Review
Livestock Substances §205.603
October 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 in 2021. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments

Written public comments will be accepted through October 3, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

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Livestock Substances §205.603
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Note: The materials included in this list are undergoing early sunset review as part of the 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](#)

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

Subcommittee Review:

Background

Atropine sulfate, typically referred to as atropine, is an anti-cholinergic derived from *atropa belladonna* (deadly nightshade) roots; it is isolated via various synthetic extraction processes. Atropine sulfate belongs to a group of medicines called antimuscarinic agents and can be administered by tablet, intravenously, injection, or can be absorbed through the skin. It is a highly controlled substance, administered under orders of a licensed veterinarian. 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

Atropine is administered to block or reverse the adverse effects caused by some medicines and is used to relieve the symptoms of organophosphate poisoning. Atropine is commonly administered as a pretreatment for anesthesia during surgical procedures (EMEA 1998, USDA 2002). The same antimuscarinic properties that provide relief for organophosphate poisoning also works to reduce secretions (e.g., sweat, saliva) and relax smooth muscles prior to the administration of anesthesia, reducing the risk of airway obstruction (Jones et al. 1977, USDA 2002, Brunton et al. 2006, EFSA 2008). Atropine, typically given intravenously or by injection into a muscle, is often administered with many anesthetic agents to prevent the slowing of the heart rate during surgery. After surgery Atropine is effective as a bradycardia treatment to raise heart rates following anesthesia in surgical procedures. Atropine has several ophthalmic (eye-care) applications due to its ability to induce pupil dilation and cycloplegic properties (paralysis of eye muscles) (EMEA 1998, Herring et al. 2000). When applied to the eye, these relaxations act to reduce pain and dilate pupils, making it useful for treatment in equine uveitis and as a presurgical treatment for cataract extractions. Atropine also affects iris permeability for glaucoma treatments....” (Herring et al. 2000, Williams et al. 2000, 106 MedlinePlus 2017)

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 (MgSO₄) 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....”

Public Comment from the Spring 2019 NOSB Meeting

In written comments submitted for the spring 2019 NOSB meeting, five commenters supported relisting atropine as essential for use in organic animal production. Two more commenters stated that atropine was included in the organic system plan of operations they certified. No commenters expressed opposition to relisting.

Subcommittee Vote:

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

Motion by: Dan Seitz

Seconded by: Scott Rice

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

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

Subcommittee Review:

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.

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.

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.

During the Spring 2019 NOSB review the Livestock Subcommittee received comments in favor of relisting hydrogen peroxide and no comments against relisting. One commenter stated hydrogen peroxide is one of the most widely used hard-surface sanitizers and is Generally Recognized as Safe (GRAS) as an antimicrobial agent and for other purposes by the FDA. Unlike many alternatives available to organic producers, it is an excellent choice as it rapidly degrades to oxygen and water, leaving no residue.

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 the lack of new scientific or meritorious information.

Questions

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

Subcommittee Vote:

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

Motion by: Jesse Buie

Seconded by: Ashley Swaffar

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

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

Subcommittee Review:

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?

Public Comments

During the Spring 2019 NOSB the Livestock Subcommittee received several comments in favor of relisting iodine and no comments against relisting iodine. Comments in favor of relisting included the following:

- This product is widely used as a teat dip
- This is a critically important product

Subcommittee Discussion

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

Subcommittee Vote:

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

Motion by: Ashley Swaffar

Seconded by: Jesse Buie

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

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.

(4) 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

Subcommittee Review:

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 anti-microbial 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?

Public Comments

During the Spring 2019 NOSB the Livestock Subcommittee received several comments in favor of relisting iodine and no comments against relisting iodine. Comments in favor of relisting included the following:

- This product is widely used as a teat dip
- This is a critically important product

Subcommittee Discussion

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

Subcommittee Vote:

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

Motion by: Ashley Swaffar

Seconded by: Jesse Buie

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

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

Subcommittee Review:

Specific Uses of the Substance

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, 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.

Additional information requested from subcommittee

1. Is this material still considered to be essential for organic livestock production?

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received several comments in favor of relisting magnesium sulfate and no comments against relisting. Some of the comments in favor of relisting included:

- Magnesium sulfate is essential for organic livestock production. It is used when grass tetany and organophosphate poisoning occur. Both are acute situations and an effective immediate treatment is necessary.
- This product is administered by the intravenous or intramuscular routes as an electrolyte replenisher or anticonvulsant. Magnesium sulfate is used as a laxative and bronchodilator. This product is also added to feed to treat magnesium deficiency. Accordingly, this product is important to the humane treatment of organic animals.

Subcommittee Discussion

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

Subcommittee Vote:

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

Motion by: Ashley Swaffar

Seconded by: Scott Rice

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

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: 3/15/2022

Subcommittee Review:**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 (TR) was completed in 2015 to review fenbendazole, ivermectin, and moxidectin as one group. The TR 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 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, allowing the worms in subsequent generations to avoid drug binding and enables drug resistance. Fenbendazole acts selectively by binding to nematode β -tubulin, disrupting the nematode digestive system and preventing egg formation, while potentiating the GLUCL channel which 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 the feces. Because it is not soluble, there is little mobility of fenbendazole in soils with low risk of groundwater contamination. Laboratory tests show that radiolabeled fenbendazole is degraded with a half-life of 54 days. 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 suggestion a toxic etiology for fenbendazole in birds of the order Columbiformes treatment (Howard et al., 2002).

International Status

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 prohibit parasiticides 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) additionally prohibits the usage of parasiticides to include 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.

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received all favorable comments in favor of relisting fenbendazole, with the exception of one commenter who stated that they believe the

listing of fenbendazole with a shorter withholding period in the absence adopting the NOSB-recommended definition of emergency would be a violation of OFPA §6517(d)(2).

Fenbendazole is recommended for relisting. This determination is based on information in the 2015 TAP review, the [2016 NOSB unanimous recommendation for an annotation change](#), the USDA-NOP publication of the amended annotation effective January 29, 2019, and because there is no new scientific or meritorious information.

Subcommittee Vote:

Motion to remove fenbendazole from §205.603(a)(23)(i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA

Motion by: Sue Baird

Seconded by: Ashley Swaffar

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

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: 3/15/2022

Subcommittee Review:

Background from Subcommittee

In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites. 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.

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. 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 for the first time.

The 2015 Technical Review (TR) reviewed moxidectin and fenbendazole. 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. Moxidectin 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, 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 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 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.

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received all favorable comments for relisting moxidectin, with the exception of one commenter, who stated that they believe the listing of moxidectin with a shorter withholding period in the absence of adopting the NOSB-recommended definition of emergency would be a violation of OFPA §6517(d)(2).

Moxidectin is recommended for relisting. This determination is based on information in the 2015 TAP review, the [2016 NOSB unanimous recommendation for an annotation change](#), the USDA-NOP publication of the amended annotation effective January 29, 2019, and because there is no new scientific or meritorious information.

Subcommittee Vote:

Motion to remove moxidectin from §205.603(a)(23)(ii) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA

Motion by: Sue Baird

Seconded by: Harriet Behar

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

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

Subcommittee Review:**Background**

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.

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."

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 methyl-naphthalene in lake sediments through oxidation of the parent compound.

During the Spring 2019 NOSB the Livestock Committee received comments in favor of relisting Peracetic Acid no comments against relisting. The commenter stated:

- Peracetic acid (PAA) is an important tool in the prevention of illness through its use as a hard surface sanitizer and disinfectant.
- PAA is an effective sanitizer for use against a large number of gram negative and gram positive bacteria, fungi and many human health pathogens.
- PAA is found in an aqueous solution of acetic acid and hydrogen peroxide. PAA rapidly degrades into acetic acid, oxygen and water, none of which are a toxicological concern.

The National Organic Standards Board (NOSB) previously reviewed peracetic acid as a disinfectant, sanitizer, and medical treatment in accordance with Code of Federal Regulation 7(CFR) § 205.603(a)(19). Peracetic acid is a relatively recent development, but 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 the lack of 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.

Question

Is this still necessary for organic livestock production?

Subcommittee Vote:

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

Motion by: Jesse Buie

Seconded by: Ashley Swaffar

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

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: 3/15/22

Subcommittee Review:

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.

According to information posted on the FARAD (Food Animal Residue Avoidance Databank) website (<http://www.farad.org/amduca-law.html>; accessed on Aug. 5, 2019), 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 in as a medical treatment in livestock intended for food production as well as in dairy cows.

International allowance for use

- **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.”

Public Comment from the Spring 2019 NOSB Meeting

In written comments submitted for the spring 2019 NOSB meeting, six commenters supported relisting xylazine as essential for use in veterinary surgical procedures, and two other commenters noted that xylazine was listed on the organic systems plans for operations they certified. No commenters opposed relisting. However, one commenter raised two potential issues with xylazine that the commenter considered worth investigating further: namely, whether there are alternative practices that could replace the need for xylazine, and whether there is an FDA prohibition regarding the use of xylazine in the treatment of food-producing animals; however, this commenter did not recommend removal of xylazine at this time.

Subcommittee Vote:

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

Motion by: Dan Seitz

Seconded by: Ashley Swaffar

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

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: 3/15/2022

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, 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

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 (TAP) 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.

Public Comment

A short update was received from the “methionine task force” a group of stakeholders working on their own to find alternatives to synthetic methionine. A few experiments were done in the past few years, which did not result in a viable non-synthetic alternative. Natural materials that are high in methionine, typically are high in other amino acids as well. When these are added to the poultry ration, the balance of amino acids in the ration is inappropriate and causes health and environmental problems for the poultry. Excess amino acids can lead to higher ammonia levels in the poultry manure, resulting in high ammonia levels in the poultry houses. This organic egg producer group stated they will continue to work on this issue.

Certifiers responded to the change in the DL-methionine annotation and have developed spreadsheets for their certified organic poultry operations to use. These spreadsheets can track the current rations to meet the new annotation, which requires tracking of methionine fed over the full life of the birds, not by each ton of feed.

Some commenters stated that more access to living vegetation would lessen or remove the need for DL-methionine. Organic poultry producers stated they must have DL-methionine for the health and well-being of their animals, and pasture access would not provide sufficient quantities of methionine to promote healthy and productive flocks.

Subcommittee discussion

The Livestock Subcommittee continues to see a need for synthetic DL-methionine in the organic poultry diet. Discussion with the methionine task force on ways to lessen the reliance on this synthetic amino acid included blending numerous plant materials instead of just one as the source of methionine to achieve a better balance of amino acids, as well as researching natural herbal supplements that might enhance the absorption of natural methionine, resulting in less methionine needed in the ration. The methionine task force stated they are looking at these options, and they will continue to provide the NOSB updates over time.

Subcommittee Vote:

Motion to remove 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 from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

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

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](#)

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

Subcommittee Review:

Information below references the 2019 TR, available at the link above.

Background from Subcommittee

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 or

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 this 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 us 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

Canadian General Standards Board (CGSB) Permitted Substance List

CAN/CGSB-32.310, §6.44(c) specifically restricts feeding supplements or additives beyond those required for adequate nutrition and health maintenance for the species at each specific stage of life.

CAN/CGSB-32.311, Table 5.3 includes "Minerals, trace minerals, elements" as substances permitted for use in organic livestock production in Canada and allows for "non-synthetic chelated or sulphated minerals" including oyster shell, calcium chloride, and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. This annotation does not list all the specific minerals allowed; a note in CAN/CGSB-3211*2018, 5.1.2 references Feeds Regulations 1983 as the regulatory document to use when assessing mineral supplements to be used in livestock feed. It is important to note that chromium and molybdenum are not included in this regulation.

Feeds Regulations 1983 also defines a range of nutrient guarantees for complete feeds for use in the exemption of feeds from registration.

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

The CODEX recommends that "feedstuffs of mineral origin, trace elements, 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."

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

Trace minerals, referred to as “trace elements,” are permitted as per article 14 which states that “Livestock should be fed on grass, fodder, and feeding stuffs produced in accordance with the rules of organic farms ...In addition, in order to provide for basic nutritional requirements of livestock, certain minerals, trace elements, and vitamins may need to be used under well-defined conditions.”

Annex VI lists all trace elements approved for inclusion in animal feeds, with the disclaimer that the additives must have been approved under Regulations (EC) No 1831/2003. Chromium is not included in this list.

Japan Agricultural Standard (JAS) for Organic Production

The Japan Agricultural Standards (JAS) for Organic Production defines feed additives as “Those specified by Article 2.3 of the Law Concerning Safety and Quality of Feeds (Law No. 35 1953).” JAS allows for “feed additives” as ingredients in livestock feed “which are natural substances, or those derived from natural substances without chemical treat. In case of a difficulty to obtain those feed additives, the use of similar agents to describe food additives are permitted only for supplementing nutrition and effective compounds in feeds.”

Japanese standards for organic feed also allow the following macro-nutrients – “Limestone, shellfish fossils, shells, dolomite, phosphate rock, and diatomaceous earth (all referred to as ‘limestones’) and those derived from limestones without chemical treatments. This does not include any chemically synthesized substances from calcium carbonate, magnesium carbonate, dicalcium carbonate, tricalcium carbonate, magnesium carbonate, dicalcium phosphate, tricalcium phosphate, and silicic acid.”

IFOAM – Organics International

The IFOAM standards indicate that “organic animal management provides animals with vitamins, trace elements and supplements only from natural sources unless they are not available in sufficient quantity and/ or quality.”

IFOAM standards also state that “Synthetic vitamins, mineral and supplements may be used when natural sources are not available in sufficient quantity and quality.

Human Health and Environment

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. The environmental risks include impairment of plant production, accumulation in edible animal products, and contamination of the water supply. In addition, there is a correlation between increased trace mineral loads and antimicrobial resistance; as a result, trace minerals have upper limits for inclusion. Concerns regarding specific minerals are included in the 2019 TR.

Discussion

The NOSB received comments during the first review cycle from a wide representation of 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.

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. Annotations cannot be amended as part of sunset review; should the Subcommittee choose to consider amending the annotation, this would need to be added to the work plan.

According to the 2109 TR, forages alone do not 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.

Subcommittee Vote:

Motion to remove trace minerals from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA

Motion by: Scott Rice

Seconded by: Ashley Swaffar

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

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

Subcommittee Review:

Background from Subcommittee

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)).

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.

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 genetically engineered 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 commonly be used in production of vitamins A, B2, B5, B6, C, E, and B12. 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.

In response to the TR information, NOP dispersed Guidance 5030 “Guidance Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed” which instructs certifiers to be diligent when 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 published a Decision Tree For Evaluation of GMO Inputs in Organic Livestock Production on page 85 of their Generic List. http://www.omri.org/sites/default/files/app_materials/OMRI-GML-Stan-2013small_0.pdf

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).

Environmental Impact

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. 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 Impact

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.

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 additional stipulation that the producer to must demonstrate nutritional deficiency of the animals' feed.

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received limited comments on retaining vitamins at §205.603. The comments that were received were overwhelmingly favorable comments for relisting Vitamins to §205.603 (d)(3), with many of the commenters stating that the addition of vitamins to the livestock diet was essential for the health and well-being of the animal.

A commenter stated that livestock feed should rarely need supplementation with synthetic vitamins, and then the only synthetic vitamins that may be needed on a limited basis would be vitamins A, C, and D. They detailed that B6 vitamins are naturally produced in the rumens of ruminant livestock and could naturally be added to the diets of pork and poultry by adding meats, rice bran, molasses, potatoes, wheat germ, pistachio nuts, cottonseed, brown rice, amaranth grain, chickpeas, sesame seeds, beans, sunflower seeds, barley malt flour, soy flour, corn, Japanese chestnuts, whey protein powder into the livestock rations.

In regard to this comment, we must comply with §205.237 (b)(5) which states that it is prohibited to *"Feed mammalian or poultry slaughter by-products to mammals or poultry."* which would eliminate the addition of meats or whey protein powders to the rations. Many of the above natural sources cited as good sources for the B Vitamins are not commonly used in livestock rations and may not be readily available for livestock feedstock. During the Spring 2015 sunset review, the NOSB received several written public comments indicating overwhelming support for retaining synthetic vitamins on the NL. The use of green forages and pastures are alternatives; however, concerns were expressed regarding the availability of enough year-round quantity of forages and other. The Subcommittee would like comments from stakeholders to determine the availability of feedstocks to naturally supply the B vitamins.

Vitamins are recommended for relisting to the National List, based on the 2015 Tap Review, the 2015 NOSB unanimous vote to add vitamins to the National List, and the lack of new scientific or meritorious information.

Questions

Are there sufficient year-round supplies of forages and livestock feedstocks available to naturally supply the B vitamins into the livestock rations, or should B vitamins be removed from §205.603?

Subcommittee Vote:

Motion to remove vitamins from §205.603(d)(3) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA

Motion by: Sue Baird

Seconded by: Ashley Swaffar

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