# Formal Recommendation From: National Organic Standards Board (NOSB) To: the National Organic Program (NOP)

Date: October 25, 2019

**Subject:** Sunset Reviews - Livestock 2021

**NOSB Chair:** Harriet Behar

# The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

# The NOSB recommends the following sunset substances be renewed:

**Reference: 7 CFR §205.603** 

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

**NOSB Vote:** See below for votes and rationale supporting each recommendation

# 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:**

## **NOSB Review:**

In written comments submitted for the spring and fall 2019 NOSB meeting, all commenters supported relisting Atropine as essential for us in organic animal production, and several commenters stated that Atropine was included in the organic system plan of operations they certified. No commenters expressed opposition to relisting. This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of Atropine.

## **NOSB 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: 12 Abstain: 0 Absent: 2 Recuse: 0

Outcome: Motion failed

# **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:**

#### **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the Livestock Committee 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 by the NOSB 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.

### **NOSB 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: 13 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion failed

# 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: <u>04/1995 meeting minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>04/2010</u>

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:**

## **NOSB Review:**

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

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

There were numerous public comments asking the NOSB to add an annotation to the iodine listing banning the inclusion of nonylphenol ethoxylates (NPEs) in these iodine-based products. NPEs are proven aquatic toxins and suspected endocrine disruptors. Commenters noted that the dairy industry as a whole offers many iodine-based teat dips and other disinfectants without NPEs to meet both domestic and export market requirements. Commenters requested an annotation that not permit

iodophors containing alkylphenols or alkylphenol ethoxylates in these iodine products. (APs and APEs are the general classes that include NPs and NPEs.). Since annotation changes are not made during our sunset reviews, the livestock subcommittee will discuss this issue and determine the next steps with the National Organic Program.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of lodine.

### **NOSB 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: 13 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion failed

# lodine—§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: <u>1994 TAP</u>; <u>2015 TR</u>

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:**

## **NOSB Review:**

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

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

There were numerous public comments asking the NOSB to add an annotation to the iodine listing banning the inclusion of nonylphenol ethoxylates (NPEs) in these iodine-based products. NPEs are proven aquatic toxins and suspected endocrine disruptors. Commenters noted that the dairy industry as a whole offers many iodine-based teat dips and other disinfectants without NPEs to meet both domestic and export market requirements. Commenters requested an annotation that not permit iodophors containing alkylphenols or alkylphenol ethoxylates in these iodine products. (APs and APEs are the general classes that include NPs and NPEs.). Since annotation changes are not made during our sunset reviews, the livestock subcommittee will discuss this issue and determine the next steps with the National Organic Program.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of lodine.

### **NOSB 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: 13 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion failed

# 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:**

## **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the Livestock Subcommittee received several comments in favor of relisting Magnesium Sulfate and no comments against relisting Magnesium Sulfate. 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.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of magnesium sulfate.

## **NOSB 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: 13 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:**

## **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the Livestock Committee received all favorable comments in favor of relisting Fenbendozole, excepting that one commenter stated that they believe the listing of Fenbendozole with a shorter withholding period in the absence adopting the NOSB-recommended definition of emergency to be a violation of OFPA §6517(d)(2).

Fenbendozole is recommended for relisting to the National List, based on the Tap Review 10/2015, the NOSB <u>04/2016 unanimous recommendation for an annotation change</u>, and the USDA-NOP publication of the Amended Annotation <u>effective January 29, 2019</u>, and no new scientific or meritorious information.

# **NOSB 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: 13 Abstain: 0 Absent: 1 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:**

### **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the NOSB received all favorable comments for relisting Moxidectin, excepting that one commenter stated that they believe the listing of Moxidectin with a shorter withholding period in the absence of adopting the NOSB-recommended definition of emergency to be a violation of OFPA §6517(d)(2).

Moxidectin is recommended for relisting to the National List, based on the Tap Review 10/2015, the NOSB <u>04/2016 unanimous recommendation for an annotation change</u>, and the USDA-NOP publication of the Amended Annotation effective January 29, 2019, and no new scientific or meritorious information.

## **NOSB 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: 13 Abstain: 0 Absent: 1 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:**

## **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the NOSB received comments in favor of relisting Peracetic Acid and 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.

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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)(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.

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

Peracetic acid is recommended by the NOSB 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.

#### **NOSB 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: 13 Abstain: 0 Absent: 1 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:**

#### **NOSB Review:**

In written comments submitted for the Spring and Fall 2019 NOSB meetings, all commenters supported relisting Xylazine as essential for use in veterinary surgical procedures, with several commenters noting 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.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of Xylazine to §205.603(a).

# **NOSB 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: 12 Abstain: 1 Absent: 1 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:**

### **NOSB Review:**

The NOSB received a brief update 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 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.

The use of this synthetic amino acid in poultry rations was modified in January 2019, with a new annotation changing the amounts allowed from a per ton of ration basis per poultry species to an average per ton per poultry species, averaged over the age of the birds. Poultry producers, poultry nutritionists, certifiers and others were happy with this new annotation and believed it better meets the needs of the birds, who need more synthetic methionine in the earlier part of their lives, than at the end of their lives. Producers, certifiers, feed suppliers and nutritionists stated this new annotation was verifiable and that rations are currently being provided to organic producers to meet this new

annotation for DL-methionine. There was also public comment, similar to what has been presented in the past, that if the poultry was given high quality access to pastures with living vegetation, bugs and biologically active soil, there would not be a need for synthetic methionine.

Research illustrating that birds on high quality pasture could be healthy and productive without synthetic methionine has not be provided to the NOSB. In the interest of animal health and welfare, as well as giving farmers this tool to have productive, healthy, and well-feathered birds, the NOSB voted down the motion to remove DL methionine from the list of approved synthetics.

The NOSB 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.

### **NOSB 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: 12 Abstain: 1 Absent: 1 Recuse: 0

Outcome: Motion failed

# **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 (<u>82 FR 14420)</u> Sunset Date: 3/15/2022

**Subcommittee Review:** 

### **NOSB Review:**

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.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of Trace Minerals to §205.603.

#### **NOSB 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: 13 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion failed

### **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:**

## **NOSB Review:**

During the Spring and Fall 2019 NOSB meetings, the NOSB received limited comments on relisting Vitamins on 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.

Comments received during the Fall 2019 comment period included a statement by the Accredited Certifiers which has developed a best practice on the verification of vitamins used in livestock feed. The group agreed that the GMO status of AAFCO-listed vitamins used in certified organic livestock feed does not need to be verified. This position is supported by NOP 5030, which called out only a few specific items as needing to be additionally verified, but not vitamins. Therefore, AAFCO and FDA listed vitamins and minerals, as allowed at 205.603(d), are generally allowed for use in livestock feed and feed additives without additional verification of GMO status, with the exception of proteinated minerals, which require some additional verification, and minerals sourced from bone such as bone charcoal, bone meal, and bone phosphate, which are prohibited.

This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of Trace Minerals to §205.603. Vitamins are recommended for relisting to the National List, based on the Tap Review 2015, the NOSB 2015 unanimous vote to add Vitamins to the National List\_and no new scientific or meritorious information that would prevent the addition of Vitamins.

### **NOSB 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: 13 Abstain: 0 Absent: 1 Recuse: 0