Sunset 2017 NOSB Final Review Livestock Substances §§205.603 - 205.604 October 2015

As part of the National List Sunset Review process, the NOSB has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic livestock production.

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

Alcohols: Ethanol	Parasiticides: Moxidectin
Alcohols: Isopropanol	Peroxyacetic/Peracetic acid
<u>Aspirin</u>	Phosphoric acid
<u>Atropine</u>	<u>Poloxalene</u>
Biologics, Vaccines	<u>Tolazoline</u>
<u>Butorphanol</u>	<u>Xylazine</u>
<u>Chlorhexidine</u>	<u>Copper sulfate</u>
Chlorine Materials: Calcium hypochlorite,	Formic Acid
chlorine dioxide, sodium hypochlorite	<u>lodine</u>
<u>Electrolytes</u>	<u>Lidocaine</u>
<u>Flunixin</u>	Lime, hydrated
<u>Furosemide</u>	Mineral oil
Glucose	Procaine
Glycerin	Sucrose octanoate esters
Hydrogen peroxide	<u>Methionine</u>
lodine	Trace minerals
Magnesium hydroxide	<u>Vitamins</u>
Magnesium sulfate	EPA List 4 - Inerts of Minimal Concern
<u>Oxytocin</u>	<u>Excipients</u>
Parasiticides: Fenbendazole	
Parasiticides: Ivermectin	

Livestock 205.604 Prohibited nonsynthetic substances

Strychnine

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

Alcohols - Ethanol

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive

Technical Report: 1995 TAP; 2014 TR Ethanol Petition(s): N/A Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for ethanol. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove ethanol from §205.603(a) Motion by: Tracy Favre Seconded by: Jean Richardson Yes: 1 No: 12 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Alcohols – Isopropanol

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(1)(ii) Isopropanol - disinfectant only
Technical Report: 1995 TAP; 2014 TR Isopropanol
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010
sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for isopropanol. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove isopropanol from §205.603 Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 1 No: 12 Abstain: 1 Absent: 0 Recuse: 0 **Outcome:** Motion failed. NOSB completed its sunset review.

Outcome: Motion railed. NOSB completed its sunset re

Aspirin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(2) Aspirin-approved for health care use to reduce inflammation
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/15

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for aspirin. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove aspirin from §205.603 Motion by: Jean Richardson Seconded by: Tracy Favre Yes: 0 No: 13 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Atropine

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

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

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

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

Technical Report: 2002 TR Petition(s): 2002 Past NOSB Actions: 05/2003 NOSB recommendation; 04/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/24/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for atropine. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove atropine from §205.603 Motion by: Jean Richardson Seconded by: Ashley Swaffar Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Biologics - Vaccines

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (4) Biologics – Vaccines.

Technical Report: 2014 TR (Aquaculture); 2011 TR (Vaccines from Excluded Methods) **Petition(s)**: 2012 Petition (Aquaculture)

Past NOSB Actions: 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation on Vaccines at § 205.105; 04/2010 NOSB sunset recommendation; 10/2014 recommendation on Vaccines from Excluded Methods

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for biologics—vaccines. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove vaccines from §205.603 Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Butorphanol

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

(5) Butorphanol (CAS #-42408-82-2) - 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 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

Technical Report: 2002 TR

Petition(s): 2002 Petition

Past NOSB Action :s 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation

Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for butorphanol. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove butorphanol from §205.603 Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Chlorhexidine

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Technical Report: 1999 TAP; 01/2010 TR; 2015 TR Petition(s): N/A Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for chlorhexidine. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove chlorhexidine from §205.603(a) Motion by: Francis Thicke Seconded by: Calvin Walker Yes: 1 No: 13 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Chlorine materials

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

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.

Technical Report: 2006 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for chlorine materials. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote Motion to remove chlorine materials from (Calcium hypochlorite, Sodium hypochlorite, Chlorine dioxide) §205.603(a) Motion by: Ashley Swaffar Seconded by: Jean Richardson Yes: 2 No: 12 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Electrolytes

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(8) Electrolytes—without antibiotics
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation, 04/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for electrolytes. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove electrolytes from §205.603(d)(8) Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Flunixin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (9) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA

Technical Report: 2007 TAP Report Petition(s): N/A Past NOSB Actions: 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for flunixin. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove flunixin from §205.603(a) Motion by: Ashley Swaffar Seconded by: Jean Richardson Yes: 1 No: 12 Abstain: 1 Absent: 1 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Furosemide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(10) Furosemide (CAS #-54-31-9)—in accordance with approved labeling; except that for use under 7
CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA
Technical Report: 2003 TR
Petition(s): 2002 Petition
Past NOSB Actions: 05/2003 NOSB recommendation for addition to the National List; 10/2010 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

NOSB Review:

Based on the Subcommittee review and public comment, the NOSB determined that alternatives are available and proposes removal of furosemide from the National List based on the OFPA criteria of essentiality.

Vote Motion to remove furosemide from §205.603(a) Motion by: Ashley Swaffar Seconded by: Jean Richardson Yes: 14 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion passed. NOSB completed its sunset review and recommended removal of furosemide

Glucose

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for glucose. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove glucose from §205.603(a) Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Glycerin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Glycerin - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils
Technical Report: 1995 TAP (Livestock); 2010 TAP (Livestock)
Petition(s): N/A
Past NOSB Actions: 1997 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for glycerin. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove glycerin from §205.605(a) Motion by: Tracy Favre Seconded by: Ashley Swaffar Yes: 0 No: 14 Abstain: Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Hydrogen peroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (13) Hydrogen peroxide
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for hydrogen peroxide. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove hydrogen peroxide from §205.603(a) Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: Absent: 0 Recuse: 0

Iodine

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(14) lodine
Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) lodine
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 10/2010
sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: Public comment indicates that use of iodine as a sanitizer 205.603 (a) is not widespread, but use of iodine as a topical treatment, (per 205.603(b)), is very common, especially in teat dip used pre and post milking. Some public comment suggested that an annotation should be added to restrict iodine products to only those made without nonylphenol ethoxylates (NPEs). The Livestock subcommittee will review this issue, but given the prohibition of antibiotics in organic agriculture, the requirements of animal welfare, sanitary dairy herd management, and the extensive and critical use of iodine in organic dairies, the NOSB determined that iodine should continue to be listed.

Vote

Motion to remove iodine from §205.603(a)(14) and §205.603(b)(2) Motion by: Jean Richardson Seconded by: Harold Austin Yes: 0 No: 14 Abstain: Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Magnesium hydroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (15) Magnesium hydroxide (CAS #-1309-42-8)—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 use by or on the lawful written order of a licensed veterinarian. Technical Report: 2007 TR

Petition(s): 2002 Petition

Past NOSB Actions: 2002 NOSB recommendation; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for magnesium hydroxide. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove magnesium hydroxide from §205.603 Motion by: Ashley Swaffar Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Magnesium sulfate

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (16) Magnesium sulfate Technical Report: 1995 TAP; 2011 TR Petition(s): N/A Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for magnesium sulfate. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove magnesium sulfate from §205.603 Motion by: Ashley Swaffar Seconded by: Calvin Walker Yes: 1 No: 13 Abstain: 0 Absent: 0 Recuse: 0

Oxytocin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (17) Oxytocin -use in post parturition therapeutic applications Technical Report: 1995 TAP; 2005 TR Petition(s): N/A Past NOSB Actions: 10/1995 NOSB minutes and vote;_11/2005 sunset recommendation, 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for oxytocin. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove oxytocin from §205.603(a)17 Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Parasiticides, Fenbendazole

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

(18) 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)—only for use by or on the lawful written order of a licensed veterinarian

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only

Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 TR

Petition(s): 2007 Fenbendazole

Past NOSB Actions: 2008 NOSB recommendation

Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472) Sunset Date: 5/16/2017

Subcommittee Review

NOSB Review: The NOSB sought and received a considerable body of public comment on the three parasiticides as part of the Sunset Review, and also in response to the Parasiticides Discussion Document sent out for public comment. After considerable discussion, both in sub-committee and at the full NOSB Fall 2015 meeting, fenbenzadole was unanimously voted to remain on the National List. In addition, public comment, based on new information and science, indicated strong support for the NOSB to move forward with a proposal to modify the present annotation in regards to both reduction of the withholding period and removing the requirement for veterinarian approval. A proposal will be developed in subcommittee for possible consideration by the NOSB at the Spring 2016 meeting. **Vote**

Motion to remove fenbendazole from §205.603 Motion by: Francis Thicke Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Parasiticides, Ivermectin

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

(18) 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)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 Technical Evaluation Report **Petition(s)**: N/A

Past NOSB Actions: 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 06/27/17

Subcommittee Review

NOSB Review: The NOSB sought and received a considerable body of public comment on the three parasiticides as part of Sunset Review, and also in response to the Parasiticides Discussion Document sent out for public comment. After considerable discussion, both in sub-committee and at the full NOSB

Fall 2015 meeting, Ivermectin was voted to remain on the National List, but with some reluctance because of serious concern raised by a range of stakeholders and Board members about the recent scientific research which indicates that ivermectin has a negative impact on dung beetles in pastures.

It is clear that parasiticides can only be used in an emergency, and, thus, it is reasonable to assume that only small amounts are used in organic livestock production. Because of the probability of ivermectin killing dung beetles in pastures, the subcommittee had recommended removing lvermectin from the List.

However, public comment indicates that in the West and amongst sheep farmers, Ivermectin is still the preferred choice in an emergency, in part because at present fenbenzadole use requires veterinarian orders (per annotation), and in part because of the perception that fenbenzadole does not attack all the helminthes species of concern. Therefore the NOSB reluctantly voted to retain Ivermectin on the List, but suggests that during the next review the NOSB give serious consideration to removing Ivermectin from the National List.

Vote

Motion to remove ivermectin from §205.603 Motion by: Francis Thicke Seconded by: Jean Richardson Yes: 6 No: 4 Abstain: 4 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Parasiticides, Moxidectin

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

(18) 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)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only. **Technical Report**: 2003 TAP (Moxidectin); 2015 Technical Evaluation Report

Petition(s): Moxidectin

Past NOSB Actions: 2004 NOSB recommendation

Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472) Sunset Date: 5/16/2017 **NOSB Review:** The NOSB sought and received a considerable body of public comment on the three parasiticides as part of Sunset Review, and also in response to the Parasiticides Discussion Document sent out for public comment. After considerable discussion, both in sub-committee and at the full NOSB Fall 2015 meeting, moxidectin was voted to remain on the National List.

In addition, public comment, based on new information and science, indicated strong support for the NOSB to move forward with a proposal to modify the present annotation in terms of both withholding periods and internal use as well as external application. Therefore a proposal will be developed in subcommittee for possible consideration by the NOSB at the Spring 2016 meeting.

Vote

Motion to remove moxidectin from §205.603 Motion by: Francis Thicke Seconded by: Jean Richardson Yes: 0 No: 12 Abstain: 2 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Peroxyacetic/peracetic acid

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
Technical Report: 2000 TAP
Petition(s): 2008 Petition
Past NOSB Actions: 11/2000 NOSB recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for peroxyacetic/peracetic acid. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove peroxyacetic/peracetic acid from §205.603 Motion by: Tracy Favre Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Phosphoric acid

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs
Technical Report: 2003 TAP (Handling)
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017
Subcommittee Review

NOSB Review: The NOSB completed the sunset review for phosphoric acid. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove phosphoric acid from §205.603 Motion by: Jean Richardson Seconded by: Francis Thicke Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (21) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat Technical Report: 2001 TAP Petition(s): 2000 Petition Past NOSB Actions: 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for poloxalene. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove poloxalene from §205.603(a) Motion by: Francis Thicke Seconded by: Colehour Bondera Yes: 0 No: 13 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Tolazoline

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

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

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

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for

slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for tolazoline. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove tolazoline from §205.603 Motion by: Francis Thicke Seconded by: Jean Richardson Yes: 1 No: 13 Abstain: 0 Absent: 0 Recuse: 0

Xylazine

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

(23) 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;

(ii) The existence of an emergency; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for

slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for xylazine. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove xylazine from §205.603 Motion by: Jean Richardson Seconded by: Ashley Swaffar Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Copper sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (1) Copper sulfate. Technical Report: 1995 TAP; 2015 TR Petition(s); N/A Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for copper sulfate. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove copper sulfate from §205.603(b) Motion by: Tracy Favre Seconded by: Jean Richardson Yes: 0 No: 13 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (2) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives

Technical Report: 2011 TR Petition(s): 2010 Petition Past NOSB Actions: 2010 NOSB recommendation Recent Regulatory Background: Added to National List, effective August 3, 2012 [77 FR 45903] Sunset Date: 8/3/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for formic acid. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove formic acid from §205.603 Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: Lidocaine use is strongly supported by the public for humane treatment of livestock. There was public comment strongly supporting a possible annotation change to reduce the lengthy withholding period based on new information. The Subcommittee will be completing a proposal for an annotation change in Spring 2016.

Vote

Motion to remove lidocaine from §205.603 Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Lime, hydrated

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for hydrated lime. Based on the Subcommittee

review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove hydrated lime from §205.603(b) Motion by: Tracy Favre Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Mineral oil

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(6) Mineral oil - for topical use and as a lubricant
Technical Report: 2002 TAP; 2015 TR
Petition(s): 2002 Petition
Past NOSB Actions: 10/1995 NOSB minutes and vote; 2003 NOSB recommendation, 11/2005 sunset
recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for mineral oil. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove mineral oil from §205.603(b)(6) Motion by: Tracy Favre Seconded by: Jean Richardson Yes: 2 No: 12 Abstain: 0 Absent: 0 Recuse: 0

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: Procaine's use is supported by the public for humane treatment of livestock. There was public comment strongly supporting a possible annotation change to reduce the lengthy withholding period based on new information. The Subcommittee will be completing a proposal for an annotation change in Spring 2016.

Vote

Motion to remove procaine from §205.603(b) Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 3 No: 9 Abstain: 2 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Sucrose octanoate esters

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling Technical Report: 2005 TR Petition(s): 2004 Petition; 05/2004 petition amendment; 09/2004 petition amendment Past NOSB Actions: 08/2005 NOSB recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for sucrose octanoate esters. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove sucrose octanoate esters from §205.603(b) Motion by: Francis Thicke Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

DL-Methionine

Reference: §205.603(d) As feed additives

(1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 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; 04/2010 NOSB recommendation on Methionine annotation through October 2012; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 10/02/17

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for DL-methionine. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove methionine from §205.603 Motion by: Tracy Favre Seconded by: Colehour Bondera Yes: 3 No: 10 Abstain: 1 Absent: 0 Recuse: 0

Trace minerals

Reference: §205.603(d) As feed additives
(2) Trace minerals, used for enrichment or fortification when FDA approved
Technical Report: 2013 TR Aquatic Trace Minerals_Petition(s): N/A
Past NOSB Actions: 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for trace minerals. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove trace minerals from §205.603(e) Motion by: Tracy Favre Seconded by: Jean Richardson/Calvin Walker Yes: 0 No: 13 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Vitamins

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: 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for vitamins. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove vitamins from §205.603(d)

Motion by: Calvin Walker Seconded by: Jean Richardson Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

EPA List 4—Inerts of Minimal Concern

Reference: §205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 -Inerts of Minimal Concern Technical Report: 2015 TR Nonylphenol Ethoxylates (NPEs) (one group only of List 4 inerts) Petition(s): N/A Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for EPA List 4—Inerts of Minimal Concern. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove EPA List 4 - Inerts of Minimal Concern from §205.603(e)(1) Motion by: Tracy Favre Seconded by: Jean Richardson Yes: 2 No: 12 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Excipients

Reference: §205.603(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application

Technical Report: 2015 TR Petition(s): N/A Past NOSB Actions: 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/2017

Subcommittee Review

NOSB Review: The NOSB completed the sunset review for excipients. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

Vote

Motion to remove excipients from §205.603(f) Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 1 No: 12 Abstain: 1 Absent: 0 Recuse: 0

Outcome: Motion failed. NOSB completed its sunset review.

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.
The following nonsynthetic substances may not be used in organic livestock production:
(a) Strychnine
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (crops only); 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017
Subcommittee Review

NOSB Review: The NOSB completed the sunset review for strychnine. Based on the Subcommittee review and public comment, the NOSB does not recommend removal from the National List.

Vote

Motion to remove strychnine from §205.604 Motion by: Jean Richardson Seconded by: Calvin Walker Yes: 0 No: 14 Abstain: 0 Absent: 0 Recuse: 0