



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Livestock Substances §205.602, §205.603 April 30, 2015

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 2017. 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. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

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

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

Guidance on Submitting Your Comments

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

For Comments That Support Substances Under Review:

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

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic livestock production.

For Comments That Do Not Support Substances Under Review:

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

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

For Comments Addressing the Availability of Alternatives:

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



Sunset 2017 Review Summary
Meeting 1 - Request for Public Comment
Livestock Substances §205.602, §205.603
April 30, 2015

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

[Alcohols: Ethanol, Isopropanol](#)

[Aspirin](#)

[Atropine](#)

[Biologics, Vaccines](#)

[Butorphanol](#)

[Chlorhexidine](#)

[Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Electrolytes](#)

[Flunixin](#)

[Furosemide](#)

[Glucose](#)

[Glycerin](#)

[Hydrogen peroxide](#)

[Iodine](#)

[Magnesium hydroxide](#)

[Magnesium sulfate](#)

[Oxytocin](#)

[Parasiticides: Fenbendazole](#)

[Parasiticides: Ivermectin](#)

[Parasiticides: Moxidectin](#)

[Peroxyacetic/Peracetic acid](#)

[Phosphoric acid](#)

[Poloxalene](#)

[Tolazoline](#)

[Xylazine](#)

[Copper sulfate](#)

[Formic Acid](#)

[Iodine](#)

[Lidocaine](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Procaine](#)

[Sucrose octanoate esters](#)

[Methionine](#)

[Trace minerals](#)

[Vitamins](#)

[EPA List 4 - Inerts of Minimal Concern](#)

[Excipients](#)

Livestock 205.602 Prohibited nonsynthetic substances

[Strychnine](#)

Alcohols

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

(1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive

(1)(ii) Isopropanol-disinfectant only

Technical Report: [1995 TAP](#); [2014 TR Ethanol](#); [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

Additional information requested by NOSB

1. Please provide any information regarding the denaturing material typically used in ethanol used in organic livestock production.
2. What are the most common uses of ethanol?

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

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

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

Additional information requested by NOSB

1. How common is the use of Atropine as a pre-medication before anesthesia?
2. The 2005 Livestock subcommittee mentions the use of Atropine to treat eye infections. Is this still a common practice?

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

Additional information requested by NOSB

1. Since vaccines were last reviewed have alternative materials emerged?
2. Should all vaccines be allowed for preventive livestock healthcare?

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 : [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

Background from Subcommittee

The TAP review was thorough with respect to the use of butorphanol as a drug, but information about impacts of butorphanol and its metabolites when excreted was missing. Since metabolites of the drug can cross the placenta and pass into the mammary gland and into milk, more information about the metabolites would be helpful. When petitioned, it was considered as a safe and necessary option.

Additional information requested by NOSB

1. Do metabolites have an impact on unborn animals if the mother is treated during pregnancy?
2. What are the effects of metabolites that are excreted?
3. Is butorphanol considered the preferred choice at this time, or are there other options?

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

Additional information requested by NOSB

Chlorhexidine is a disinfectant that is used as a topical antiseptic during surgery, for “cold sterilization” of surgical instruments, and as a teat dip. Because chlorhexidine can have residual effects, it is only allowed for use as a teat dip when other teat dips have lost their effectiveness.

1. Have you used chlorhexidine as a teat dip? If so, why did you need to use it?

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

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

Electrolytes

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

(8) Electrolytes—without antibiotics

Technical Report: [1995 TAP](#); 2015 TR in development

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

Additional information requested by NOSB

NONE

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

Additional information requested by NOSB

1. In the event the NOSB votes to remove Flunixin from the National List, would aspirin serve as a replacement? If not, why not?

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

Additional information requested by NOSB

NONE

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

Additional information requested by NOSB

1. What is the ongoing use of glucose?
2. Is this glucose currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) since glucose last sunset review in 2012?



4. Are there any annotation(s) needed for glucose? If so, explain and reference evidence.

Glycerine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Glycerine - 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

Additional information requested by NOSB

NONE

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

Additional information requested by NOSB

1. What is the ongoing use of hydrogen peroxide?
2. Is this hydrogen peroxide currently necessary or essential in organic livestock production?
Please explain.
3. Are there commercially available alternative(s) for hydrogen peroxide last sunset review in 2012?
4. Are there any annotation(s) needed for hydrogen peroxide? If so, explain and reference evidence.

Iodine



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

(14) Iodine

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

(3) Iodine

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

Additional information requested by NOSB

1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPE's? 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 your farm?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

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

Additional information requested by NOSB

NONE

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

Additional information requested by NOSB
NONE

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

Additional information requested by NOSB

1. What is the ongoing use of oxytocin?
2. Is this oxytocin currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) since oxytocin last sunset review in 2012?
4. Are there any annotation(s) needed for oxytocin? If so, explain and reference evidence.

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 in development,

Petition(s): [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

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.

Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

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);

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

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.



Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

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 TR in development,

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

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.

Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

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

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

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

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential for organic livestock production?

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

Background from Subcommittee

Poloxalene is a synthetic substance that can be used in an emergency to reverse the process of bloating in ruminant animals. Bloat can be an acute condition which can occur in ruminant animals when they

eat lush forage legumes. When foaming of the rumen contents becomes persistent foam, gases are produced in the rumen faster than they can be expelled. Rapid expansion of the rumen from the gases can lead to asphyxiation of the animal. There are preventative strategies for bloat, and there are alternative treatments for bloat, but poloxalene is a fast acting treatment for acute bloat and is approved only for emergency treatment of bloat.

Additional information requested by NOSB

NONE

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: [09/002 NOSB recommendation](#); [10/2010 sunset recommendation](#)

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

Sunset Date: 6/27/2017

Background from Subcommittee

Tolazoline is used in conjunction with Xylazine. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of Xylazine.

Additional information requested by NOSB

1. Are there alternative materials that should be petitioned for use?
2. What alternative practices are available?

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: [09/002 NOSB recommendation](#); [10/2010 sunset recommendation](#)

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

Sunset Date: 6/27/2017

Background from Subcommittee

Tolazoline is used in conjunction with Xylazine. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of Xylazine.

Additional information requested by NOSB

- 3. Are there alternative materials that should be petitioned for use?
- 4. What alternative practices are available?

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

Additional information requested by NOSB

Zinc Sulfate has recently been petitioned for use as a footbath treatment. In the event that the NOSB votes to add Zinc Sulfate to the National List, how likely are you to use this material instead of Copper Sulfate?

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

Additional information requested by NOSB

1. Do the alternatives documented in the TR control varroa and tracheal mites?
2. Are the alternatives discussed in the TR available for organic beekeepers?

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

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

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 in development

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

Additional information requested by NOSB

NONE



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 in development

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

Additional information requested by NOSB

NONE

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

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

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

Background from Subcommittee



Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

Additional information requested by NOSB

NONE

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](#); [M2011 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

Additional information requested by NOSB

What would be the impact on your poultry operation should the current annotation remain in effect for an additional 5 years?

Trace minerals

Reference: 205.603(d) As feed additives

(2) Trace minerals, used for enrichment or fortification when FDA approved

Technical Report: none

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

Background from Subcommittee

From the Livestock Committee's October 1995 recommendations: "Producers often may not be able to control the quantity of vitamins and minerals naturally occurring in feedstuffs. Non-synthetic vitamins and minerals should be used if available, but synthetics are allowed...Synthetic vitamins and minerals



should be used in keeping with the recommendations of the National Research Council and the Association of Animal Feed Control Officials,... specific to each species.”

Additional information requested by NOSB

NONE

Vitamins

Reference: 205.603(d) As feed additives

(3) Vitamins, used for enrichment or fortification when FDA approved

Technical Report: 2015 TR in development

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

Additional information requested by NOSB

1. What is the ongoing use of vitamins?
2. Is this listing for vitamins currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) for vitamins since the last sunset review in 2012?
4. Are there any annotation(s) needed for vitamins? If so, explain and reference evidence.

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 nonsynthetic 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

Additional information requested by NOSB

NONE

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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

Additional information requested by NOSB

In reviewing the recent Technical Report, does the present annotation for Excipients continue to provide adequate guidance to MRO's and certifiers doing material 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

Additional information requested by NOSB

NONE