

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

Date: November 2, 2017

Subject: Livestock 2019 Sunset Substances

NOSB Chair: Tom Chapman

The NOSB recommends to the NOP the following:

Rulemaking Action: X

The NOSB recommends the following sunset substances be renewed:

Chlorhexidine

Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)

Glucose

Tolazoline

Copper sulfate

Lidocaine

The NOSB recommends the following sunset substances be removed from the National List:

Oxytocin

Procaine

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

Sunset 2019
Meeting 2 - Review
Livestock Substances §205.603
November 2017

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.

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

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

[Chlorhexidine](#)

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

[Glucose](#)

[Oxytocin](#)

[Tolazoline](#)

[Copper sulfate](#)

[Lidocaine](#)

[Procaine](#)

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: [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](#); [10/2015 sunset recommendation](#)

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

Sunset Date: 03/15/2022

[Subcommittee Review](#)

NOSB review:

There was strong public support for the continued listing of this material. 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.

NOSB vote:

Motion to remove chlorhexidine 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: none

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:

There was strong public support for the continued listing of chlorine materials. The NOSB also recognizes the public's request for a comprehensive review of sanitizers, however, a review of that scope is beyond that of the sunset review process. 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.

NOSB vote:

Motion to remove chlorine materials 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: none

Motion by: Ashley Swaffar

Seconded by: Sue Baird

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:

There was strong public support for the continued listing of this material. 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.

NOSB vote:

Motion to remove glucose 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: none

Motion by: Harriet Behar

Seconded by: Sue Baird

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

[Subcommittee Review](#)

NOSB review:

The NOSB has determined this material is not a necessary tool in organic dairy production. There are numerous alternative methods and materials for addressing the health issues where oxytocin would be used. Its removal addresses consumer expectation that organic dairy animals are not treated with synthetic hormones.

There was public support for the delisting of this material. Based on the Subcommittee review and public comment, the NOSB finds this material to be non-compliant with the OFPA criteria of essentiality, and recommends removal from the National List.

NOSB vote:

Motion to remove oxytocin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (7 U.S.C. 6517) National List (b) (1) (A) (ii) and (iii), Section 2119 (7 U. S. C. 6518 (m) (6) and (7) and/or 7 CFR 205.600(b) (1): essentiality

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion passed

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](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

[Subcommittee Review](#)

NOSB review:

There was strong public support for the continued listing of this material. 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.

The Livestock Subcommittee noted, however, that were xylazine to be removed from the National List in the future, tolazoline, which is used in conjunction with xylazine, would probably no longer be needed for organic production. Thus if xylazine is removed, the NOSB should consider removing tolazoline as well.

NOSB vote:

Motion to remove tolazoline 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: none

Motion by: Daniel Seitz

Seconded by: Jesse Buie

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

[Subcommittee Review](#)

NOSB review:

There was strong public support for the continued listing of this material. 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.

NOSB vote:

Motion to remove copper sulfate from §205.603(b) as topical treatment, external parasiticide or local anesthetic based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Jessie Buie

Seconded by: Harriet Behar

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2015 sunset recommendation](#), [2016 annotation change recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

[Subcommittee Review](#)

NOSB review:

There was strong public support for the continued listing of this material. 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.

NOSB vote:

Motion to remove lidocaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Daniel Seitz

Seconded by: Francis Thicke

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

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](#); [10/2015 sunset recommendation](#), [2016 annotation change recommendation](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:

Six written comments on procaine were submitted prior to the spring 2017 NOSB meeting, which made the following points: (i) procaine is rarely used, (ii) procaine is not as effective as lidocaine, which is used for the same purpose, (iii) procaine is only available in combination with the antibiotic penicillin, which is not allowed for use in organic livestock production, and (iv) since lidocaine is more effective than procaine, keeping procaine on the National List may create confusion. Several of these six comments suggested continued listing despite the points noted above.

Seven written comments on procaine were submitted prior to the fall 2017 NOSB meeting, several of which reiterated the concern that procaine is only available in combination with an antibiotic, and one of which stated that a number of products containing procaine have been voluntarily withdrawn from list of FDA Approved Animal Drug Products and are not considered to be FDA approved. Only one comment recommended continued listing.

A majority of the Subcommittee members recommended that procaine be removed from the list due to the various concerns that had been raised, most notably that procaine is only available in combination with an antibiotic, and because it is widely considered to be less effective than lidocaine, which is used for the same purpose.

There was public support for delisting of this material based on the fact that this material is not available in a form without antibiotics. Based on the Subcommittee review and public comment, the NOSB finds this material to be non-compliant with OFPA criteria, and recommends removal from the National List.

NOSB vote:

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

Motion by: Daniel Seitz

Seconded by: Sue Baird

Yes: 14 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Outcome: Motion passed