

Sunset 2019
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2017

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 crop 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 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at www.regulations.gov by March 30, 2017 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.

Written public comments will be accepted through March 30, 2017 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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Note: The materials included in this list are undergoing early sunset review as part of 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 Date: 06/27/17 (NOP renewal pending)

Background from Subcommittee:

Specific Uses of the Substance: Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre- and post- teat dip to aid in controlling bacteria that causes mastitis. There are numerous synthetic disinfectants currently on the National List of Approved Synthetics for Organic Livestock production including iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide. Not all are useful both in a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation.

Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in

northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months.

Approved Legal Uses of the Substance: Used in agriculture for disinfection during livestock surgery, on teats pre and post milking and on milking equipment. Also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Discussion: In April 2015, the NOSB recommended adding one more teat dip: Acidified Sodium Chlorite—allowed for use on organic livestock as a pre and post teat dip treatment.

Additional information requested by NOSB

1. Does chlorhexidine provide an essential function that other natural materials or synthetics proposed or currently on the national list do not provide?
2. Is chlorhexidine used widely in organic livestock production?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17 (NOP renewal pending)

Background:

Specific Uses of the Substance: Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities.

Approved Legal Uses of the Substance:

Regarding organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. Similarly, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 mg/L).

Discussion: Previous public comments had asked for a comprehensive review of all sanitizers however, the Subcommittee feels that a review of that scope is beyond the sunset review process.

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?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17 (NOP renewal pending)

Background:

Glucose has been on the National List since 1995, and has received minimal public comment, both pro and con at each sunset review. It is used most frequently in organic dairy operations, to manage ketosis or other situations where an infusion of glucose is needed to restore the blood sugar balance in an ill animal. On non-organic dairy operations, propylene glycol, glycerin or corticosteroids might also be used. Careful management of feed rations before and immediately after birthing is typically used to avoid the occurrence of ketosis. There may be some excipient ingredients in glucose used in livestock production.

Additional information requested by NOSB

1. Is this material essential in organic production and why?
2. Are there nonsynthetic materials or methods that can be used to treat the illnesses associated with glucose use?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17 (NOP renewal pending)

Background:

Oxytocin is a hormone, naturally produced in the pituitary glands of humans, cattle and other mammals. In nonorganic production, it can be used regularly to help dairy cows relax and “let down their milk”. There are some concerns with over use of oxytocin in nonorganic production systems, as well as the abuse of this hormone in the human population. In the NOP regulations, it is only allowed post birthing, in a therapeutic way to ease various dam issues that are associated with the birthing of the calf, including displaced abomasum and retained placenta. It has been on the National List of approved synthetics since 1995, with minimal public comment on this material, pro or con. Some organic milk marketers require their organic milk suppliers to not use this material. There was very little public comment on this material over the years, and it appears to be used rarely in organic production. However, it could be considered essential for animal health and welfare in emergency situations.

Additional information requested by NOSB

1. Is oxytocin an essential material for organic production and why?
2. Are there nonsynthetic alternatives, or other methods that can be used to accomplish the same results as oxytocin?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

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

During the 2015 comment period for the 2017 sunset, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list.

Additional information requested by NOSB

1. Is tolazoline still considered useful and/or necessary by the organic community for the purpose allowed?
2. Are there any alternative practices or substances available that might be preferable?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

Copper Sulfate in livestock management is used specifically as a walk-through footbath to help control and prevent hoof-related diseases in dairy cattle and sheep. Some of the specific problems affect skin adjacent to the claw horn of dairy cattle and sheep, i.e., digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions. Depending on the severity of the infection the impact on managed cattle and or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems and in the dairy industry a reduction of milk production ranging from 20 to 50 percent (Brown, et al., 2000, Losinger, 2006). A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes.

According to the Technical Review commissioned by the Livestock Subcommittee, there are no natural (nonsynthetic) products available that can be used as a management strategy to treat hoof-related diseases and lameness in dairy cattle and sheep operations. However, there are various management tools available that could help reduce the cost of treatment and prevent hoof-related diseases. These include the use of additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices (Maas 2009).

Zinc sulfate may be considered a viable alternative, and the NOSB voted at the Spring 2015 meeting to add this substance to the National List for foot and hoof treatment (rulemaking in process by NOP).

Additional information requested by NOSB

1. The livestock subcommittee requests public comment on the use of Copper Sulfate and its essentiality in organic processing.
2. Are there any alternative practices or substances available that might be preferable?

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

Lidocaine is a local anesthetic which has a rapid onset of action and is short term in duration. It numbs only the area to be worked on. For example, Lidocaine is used to humanely de-bud horns on calves, and for minor surgery on mature animals.

During the 2015 sunset review of lidocaine and procaine the Livestock Subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) implies that perhaps the 90 days is a doubling of the FDA or FARAD (Food Animal Drug Residue Avoidance) withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

In FARAD the recommended withdrawal interval for lidocaine in cattle is listed as 1 day for meat and 24 hours for milk after epidural use of lidocaine, and 4 days for meat and 72 hours for milk after subcutaneous use of lidocaine.

The NOSB in its initial request for public comment in April 2015, for Sunset 2107 Review had asked:

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?

In 2015 public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Lidocaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A discussion document on changing the withholding period was presented at the October 2015 meeting, and a proposal to amend section 205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

To amend Section 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~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supports a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production. The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list lidocaine and for the annotation for shorter withholding period.

Additional information requested by NOSB

No additional information requested.

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 published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:

Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on and can be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

During the 2015 Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources

FARAD provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. Procaine on its own is apparently not readily available in the US and public comment from veterinarians only suggests a similarity with lidocaine. Procaine was recommended for continued listing because no public comment was provided to recommend its removal on any criteria. However procaine appears to be rarely used in organic livestock production.

The NOSB in its initial request for public comment in 2015 for Sunset 2017 Review, asked:

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?

In 2015 and 2016 Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Procaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A Discussion Document on changing the Withholding period was presented at the October 2015 meeting, and a Proposal to amend Section 205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC. As follows:

To amend Section 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~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supported a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production. The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list procaine with the annotation for shorter withholding period. Public comment indicates procaine is not readily available in the United States and does not appear to be widely used. Procaine may not be essential and may not need to continue to be listed.

Additional information requested by NOSB

1. Is procaine used in organic livestock production?
2. Is procaine available in the US in its pure form or only in combination with antibiotics?