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

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 renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
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 cause mastitis.

There are numerous synthetic disinfectants currently on the National List 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.

Questions for the public:

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?

Public comment:
Numerous certification agencies noted this to be an important material for organic livestock production. Chlorhexidine is useful as the active disinfectant in a teat dip in cold temperatures, as compared to iodine, which can be problematic in that type of situation. All commenters agreed chlorhexidine's use in

surgical procedures is essential. One public interest group noted that less toxic alternatives, such as vinegar, lavender essential oil, tea tree oil or hydrogen peroxide, might be better alternatives for the teat dip use, while another noted there are alternative teat dips to chlorhexidine.

The Subcommittee did not feel alternatives were present for this material, and were in favor of retaining it as an approved synthetic as annotated. This material fulfills specific functions and is a necessary livestock tool.

Subcommittee 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: 7 Abstain: 0 Absent: 0 Recuse: 0

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:
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).

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?

Discussion:
The Livestock Subcommittee has received several comments both supporting and opposing relisting.

Several commenters opposed to the relisting stated:

- There needs to be a comprehensive review of all sanitizers used.

Several commenters in support of relisting stated:

- Sodium hypochlorite is routinely used to sanitize many surfaces to kill pathogenic microorganisms. Chlorine dioxide is routinely used to kill pathogenic microorganisms in water lines because sodium hypochlorite is corrosive to the pipes. No alternatives currently allowed.
- Chlorine dioxide is very important in controlling the growth of microorganisms in our water lines. Sodium hypochlorite is not a suitable substitute in water lines because it is too corrosive.

Previous public comments asked for a comprehensive review of all sanitizers, but the Subcommittee feels that a review of that scope is beyond the sunset review process. While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of chlorine materials.

Subcommittee 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: 5 Abstain: 0 Absent: 2 Recuse: 0

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:

Background from Subcommittee: Glucose has been on the National List since 1995, with 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 cow. 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?

Public comment:

Numerous certifiers stated this is a commonly used material on their certified organic dairy operations, other said it was not used a lot, but still supported relisting. Its use for managing ketosis was noted as essential by farmers, milk buyers, inspectors and the organic trade. Environmental and public interest groups stated there were no adverse effects and it is an important material to treat animals. No alternative materials or methods, other than feed ration management around birthing, were mentioned.

On an organic dairy farm, glucose is an essential animal health tool. It is used typically to treat ketosis, and there was universal approval for keeping this material on the National List. Since glucose is an ingredient in calcium gluconate used to treat milk fever, retaining glucose on the National List of approved synthetics also maintains this important tool for treatment of this ailment as well.

Subcommittee 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: 7 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; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background from Subcommittee: 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 nonorganic dairy cows relax and "let down their milk". There are some concerns with overuse of oxytocin in nonorganic production systems. In the USDA organic 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 retained placenta. It has been recommended for use with USDA organic livestock since the inception of the USDA organic regulations, 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 for public comment

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?

Public comment:
The two largest milk buyers in the U.S., CROPP Cooperative/Organic Valley and White Wave/Horizon did not support renewal of this material. Numerous comments stated the current annotation "use in post parturition therapeutic applications" is unclear, leading to uses on organic milk animals that do not meet the intention of this annotation. Commenters asked for clarity detailing what time frame is considered "post parturition", and which therapeutic applications are allowed. Some certifiers would not allow its use for "milk let down", others would not allow its use for displaced abomasum, while other certifiers would. Two different certifiers, Pennsylvania Certified Organic (PCO) and California Certified Organic Farmers (CCOF), noted a total of 47 operations had used it, others noted it was not commonly used. Those in favor of relisting stated this is an important material in the dairy health toolkit, to assist animals after giving birth. Those not in favor stated there were preventative measures, as well as other activities that could be performed post birthing, that make oxytocin unnecessary in organic livestock production.

Commenters also noted the annotation was not clear, and the specific health incidents leading to the allowed use of this synthetic hormone were not consistent between certifiers.

Subcommittee Discussion:
Oxytocin has been on the National List of approved synthetics since the USDA organic regulations were implemented. However, over time, methods and materials have been developed that make oxytocin less essential for maintaining animal health and welfare. The expectations and awareness of dairy production tools by consumers has changed over time. They now expect organic milk be produced without the use of synthetic hormones. The Livestock Subcommittee realizes that some producers may need to learn new methods to address post parturition issues, but we believe the knowledge and materials are present, so that there will be no interruption in commerce, economic hardship, or lessening of animal welfare if this material is removed from the National List of approved synthetics. Veterinarians who work with organic dairy farmers, as well as educational organizations that provide information to organic dairy producers can provide this information on the methods and materials used that make oxytocin no longer essential in an organic dairy system.

Subcommittee 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: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

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:

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. Tolazoline was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.

Discussion:
There were three written comments on tolazoline submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used.
- The second comment, also brief, stated that the substance should continue to be allowed, since its use lessens animal suffering; and
- The third comment, which was extensive, focused primarily on whether there is a reasonable basis for keeping xylazine—with which tolazoline works in conjunction—on the National List, since the scientific literature on xylazine indicates that there may be pharmacological side-effects and other problems associated with its use.

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of tolazoline.

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

Subcommittee 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: 5 Abstain: 0 Absent: 2 Recuse: 0

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:
Copper Sulfate is used in livestock management specifically as a walk-through footbath to help control and prevent hoof-related diseases in dairy cattle and sheep. Some of the specific problems that can affect skin adjacent to the claw horn of dairy cattle and sheep include 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 February 2015 technical evaluation report commissioned by the Livestock Subcommittee, there are no natural (non-synthetic) 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). TR lines 575-580.

The Livestock subcommittee feels that copper sulfate, used after appropriate management practices and disposed of properly, provides a valuable tool to livestock producers and recommends this material stay on the National List.

Subcommittee 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: 7 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; 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:
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.

Lidocaine was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.
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**.**

A proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

To amend §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

Discussion:
For the spring 2017 NOSB meeting, there were five comments submitted in support of the continued listing of lidocaine (three from organizations and two from individuals), and there were no comments submitted in opposition. Therefore, it appears that there is still broad stakeholder support for continuing to list lidocaine. Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of lidocaine.

Subcommittee 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: 5 Abstain: 0 Absent: 2 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; 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:
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.

Procaine was last reviewed in 2015, at which time the NOSB voted to renew it, with 3 “yes” votes to remove, 9 “no” votes, and 2 “abstentions.”

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

A Proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC as follows:

> *To amend §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***.**

Additional information requested by NOSB

1. If procaine were removed from the National List and only lidocaine were available for use as a local anesthetic in organic livestock production, would lidocaine fully meet all potential veterinary needs?
2. Is procaine currently only available for use in combination with an antibiotic?

Discussion:
There were six written comments on procaine submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used, but did not express an opinion on renewal.
- 4 brief comments supported renewal, one of which noted that procaine is not very widely used; and
- One comment, which was more extensive, recommended removal for the following reasons:
    - Procaine is used as a local anesthetic, but is not as effective as lidocaine.
    - Procaine is not widely available, except in combination with the antibiotic penicillin, which is not allowed for use in organic livestock production.
    - There is no benefit to using procaine vs. lidocaine, so having it on the National List likely only creates confusion.

Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

Given the comments received so far, the Subcommittee is unclear whether procaine is currently being used in organic livestock production, and whether it is only available in combination with an antibiotic.

Subcommittee 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: 3 No: 2 Abstain: 0 Absent: 2 Recuse: 0