

**Sunset 2024**  
**Meeting 2 - Review**  
**Livestock Substances § 205.603**  
**October 2022**

**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 scheduled 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. This document 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.

**Request for Comments**

Written public comments will be accepted through September 29, 2022 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (see [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: (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 clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant 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 (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

**For Comments that Support the Continued Use of §205.603 Substances in Organic Production:**

If you provide comments supporting the allowance of a substance at §205.603, 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 the Continued Use of §205.603 Substances in Organic Production:**

If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. 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/or
3. inconsistent with organic livestock production.

**For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:**

If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

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

**For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:**

If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic livestock production.

**For Comments Addressing the Availability of Alternatives:**

Comments may include 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 substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- 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 organic operations 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.

**§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:**

- [Chlorhexidine](#)
- [Glucose](#)
- [Tolazoline](#)
- [Copper sulfate](#)
- [Elemental sulfur](#)
- [Lidocaine](#)

**§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:**

- None

## 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:** [2010 TR](#); [2015 TR](#).

**Petition:** N/A

**Past NOSB Actions:** [10/1999 minutes and vote](#); [11/2005 sunset recommendation](#); [11/2009 Annotation change/clarification](#); [04/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#).

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice effective 3/15/2017 ([82 FR 14420](#)); Annotation amendment effective 1/28/2019 ([83 FR 66559](#))

**Sunset Date:** 01/28/2024

### Subcommittee Review

#### Use

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, acidified sodium chlorite, and hydrogen peroxide. Not all alternatives to chlorhexidine are useful in both 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 include disinfection during livestock surgery, on teats pre and post milking, and on milking equipment. Chlorhexidine is also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

#### Manufacture

Limited information is available regarding the manufacture of chlorhexidine for use in commercially available disinfectants, sanitizers, bactericides, and virucides. The general procedure for industrial-scale chlorhexidine production involves initial synthesis of the 1,6-hexamethylenebis(dicyandiamide) intermediate, followed by reaction of the intermediate with 4-chloroaniline hydrochloride. Once purified, chlorhexidine is combined with acetic acid or D-gluconic acid to generate the commercially relevant diacetate or digluconate salts of chlorhexidine.

#### International Acceptance

##### [Canadian General Standards Board Permitted Substances List](#)

The Canadian General Standards Board allows the use of chlorhexidine under Section 5.3 (Health Care Products and Production Aids) of the Permitted Substances Lists for Livestock Production (CAN, 2011). Specifically, the rule states that chlorhexidine may be used in the following ways: (1) for surgical procedures conducted by a veterinarian, and (2) as a post-milking teat dip when alternative germicidal agents and physical barriers have lost their effectiveness.

##### [European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

According to Article 23 (4) of the Commission Regulation concerning organic production and labeling of organic products, *Housing, pens, equipment, and utensils shall be properly cleaned and disinfected to*

*prevent cross-infection and the build-up of disease carrying organisms. Feces, urine and uneaten or split feed shall be removed as often as necessary to minimize smell and to avoid attracting insects or rodents.*

The list of approved substances for cleaning and disinfection of building and installations for animal production includes “cleaning and disinfection products for teats and milking facilities.” However, the rule does not explicitly describe the restrictions of use for available teat dip substances (EC, 2008). It is therefore uncertain whether European regulations allow the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in organic livestock production.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Chlorhexidine is not listed in CODEX.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Appendix 5 of the IFOAM Norms, which provides a list of “substances for pest and disease control and disinfection in livestock housing and equipment,” includes iodine and “cleaning and disinfection products for teats and milking facilities.” However, the standard does not explicitly describe the restrictions of use for available teat dip substances (IFOAM, 2014). It is therefore uncertain whether IFOAM guidelines permit the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in the organic production of dairy animals.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

According to Table 4 of the Japanese Agricultural Standards for Organic Livestock Products, chlorhexidine is an allowed synthetic agent for cleaning and disinfecting livestock housing (JMAFF, 2012). However, chlorhexidine is not explicitly allowed for use in pre- or post-milking teat dips under Japanese organic regulations.

### **Environmental Issues**

The 2015 technical report indicates that, although data is limited, chlorhexidine is readily biodegradable in the atmosphere, with limited biodegradation in the terrestrial and aquatic compartments [TR 275-277]. However, chlorhexidine is not considered to be persistent, bioaccumulative, or toxic to humans. Production and use of chlorhexidine as an antiseptic and disinfectant will result in releases to the environment through waste streams and spills. Chlorhexidine exists primarily in protonated (cationic) form in the environment, and thus is expected to adsorb strongly to organic carbon and clay despite its predicted high mobility in soil. Likewise, chlorhexidine is expected to adsorb to suspended solids and sediments when released to water [TR 433 - 436]. Despite the relatively low risk associated with chlorhexidine, environmental hazards cannot be excluded for improper handling and disposal of chlorhexidine products. Specifically, chlorhexidine salts are highly toxic to aquatic life with long lasting effects [TR 438 - 439]. Registrant-submitted studies indicate that concentrations as low as 60 parts per billion are toxic to half of the freshwater water fleas in an acute toxicity test [TR 439 - 441]. Further, 4-chloroaniline used in the synthesis of chlorhexidine is highly toxic to red blood cells and DNA, and exposure to residues of this substance in contaminated chlorhexidine solutions may lead to toxic effects in terrestrial organisms [441 – 443]. As a general antimicrobial agent chlorhexidine is potentially toxic to beneficial soil organisms, including nitrogen fixing bacteria and mycorrhizal fungi.

### **Discussion**

Chlorhexidine is listed on the National List for two specific uses: as a teat dip; and as a disinfectant during medical procedures. There is unanimous support from the community that chlorhexidine should remain on the National List as a disinfectant used by veterinarians during medical procedures. There were several commenters from the dairy industry who use chlorhexidine in their operations and are supportive of it

remaining on the National List as a teat dip alternative when other products are not effective. They stated that it is used as a critical backup measure when alternative teat dips, such as iodine, prove to be ineffective. It was mentioned that chlorhexidine is not routinely used other than when necessary. A couple commentors urged more evidence should be obtained to weigh the need as a teat dip given the availability of products already approved. The subcommittee acknowledged that inspectors should be trained to validate there is product rotation for teat dips and ensuring chlorhexidine is not used excessively or exclusively in a program.

### **Justification for Vote**

The Subcommittee finds that chlorhexidine continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

### **Subcommittee Vote**

Motion to remove chlorhexidine from the National List

Motion by: Kim Huseman

Seconded by: Amy Bruch

Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

## **Glucose**

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

**Technical Report:** [1995 TAP](#); [2022 TR](#)

**Petition:** N/A

**Past NOSB Actions:** [10/1995 minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#).

**Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#)).

**Sunset Date:** 10/30/2024

### **Subcommittee Review**

#### **Use**

Glucose is a synthetic substance allowed in organic livestock production for medical treatment. For animal health purposes, glucose is used primarily as an aid in the treatment of ketosis in cattle. Additionally, glucose is an important remedy for dehydration, neonatal hypoglycemia, as an ingredient in formulated electrolyte solutions, and as an excipient.

#### **Manufacture**

An updated technical report published in 2022 notes that glucose is made through the hydrolysis of starches, mostly originating from corn, but could be sourced from wheat, rice, potato, barley, sago, or sorghum. In the process of hydrolysis, glucose can be formulated with enzymes or acids as the catalyst.

#### **International Acceptance**

[Canadian General Standards Board Permitted Substances List](#)

Glucose is permitted for use under section 5, Table 5.3 as a Health Care Product and Production Aide with no annotations or restrictions.

[European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

Article 14 addresses Livestock production rules, but glucose is not specifically mentioned

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Annex 1, Principles of Organic Production, Section B, subsections 20 thru 24 address Health Care in Livestock.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Section 5.6 addresses General Principles for use of Veterinary Medicines for Livestock, but glucose is not specifically mentioned.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Glucose is not specifically mentioned

### **Environmental Issues**

According to the 2022 technical report, glucose is abundant in the environment and is easily metabolized. It is not expected to accumulate in the environment, but as excreted in the urine of ruminants after treatment, is expected to be consumed by microbes in soil systems. As an important biomolecule, glucose has very low toxicity. Environmental concerns with glucose are associated with the agricultural production of starch-containing-crops used to produce glucose and the energy and materials consumed during manufacture. The technical report goes on to describe the starch industry as causing very little waste due to the effective use of all side streams as economically valuable products, noting that very little waste is sent to a landfill or incineration. Glucose is not expected to negatively impact environmental or human health from chemical interactions in organic crop, livestock, or handling systems. The use of glucose in organic systems is not expected to threaten water or soil systems.

### **Discussion**

Glucose is an essential animal health remedy in organic systems. It is typically used to treat ketosis and dehydration when preventative measures have failed. While ketosis is a concern in most dairy herds, some producers note that due to an elevated risk of ketosis, it is necessary to maximize pre-parturition confinement in order to prevent ketosis through a low potassium diet. With glucose in the “toolbox”, producers can proceed with grazing pasture closer to parturition with the confidence that they will be able to address ketosis, should it arise. Previous sunset reviews have reflected low levels of glucose usage, but farmers and inspectors have consistently commented that glucose is an essential treatment and there is a high degree of support for keeping glucose on the National List. Since glucose is used as an excipient and in electrolyte formulations (for example), retaining glucose on the National List of allowed synthetics also maintains this important tool in formulations.

### **Justification for Vote**

The Subcommittee finds that glucose continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

### **Subcommittee Vote**

Motion to remove glucose from the National List

Motion by: Liz Graznak

Seconded by: Kim Huseman

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

## Tolazoline

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

(29) 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](#); [2019 TR](#).

**Petition:** [2002](#).

**Past NOSB Actions:** [9/2002 recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#).

**Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#)).

**Sunset Date:** 10/30/2024

### Subcommittee Review

#### Use

Tolazoline is limited to use only by a veterinarian prescription and is further restricted for “use only to reverse the effects of sedation caused by xylazine.” Xylazine is primarily used in veterinary medicine as a sedative, tranquilizer, and analgesic. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent pain and suffering and injury to the veterinarians performing the procedures. Tolazoline is commonly used as a reversal agent for xylazine by competing for the  $\alpha$ 2-adrenergic receptors, blocking binding events for xylazine. Structural similarities with xylazine allow tolazoline to compete with xylazine for biological binding sites, providing the mode of action for its approved use in organic livestock production as a reversal agent for xylazine.

Tolazoline is used only for veterinary applications, with no natural or USDA-approved synthetic alternatives. There are no alternative practices that would make the anesthetic agent unnecessary. Tolazoline may be made unnecessary by allowing the veterinary subject to recover from the effects of xylazine by natural metabolism of the substance, rather than its active reversal. However, the rate of xylazine metabolism is species-dependent; therefore, this may prove problematic in species with slower metabolic rates (e.g., cattle).

#### Manufacture

Tolazoline is a synthetic substance produced by a one-pot process (i.e., no intermediates are isolated) by the reaction of phenylacetaldehyde with ethylene diamine, with the incorporation of an iodine-based oxidation process.

#### International Allowance

[Canadian General Standards Board Permitted Substances List](#)

Although xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances listed in Table 5.3 “health care products and production aids,” as a “sedative,” Tolazoline (the most commonly used substance for a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015.

[European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

Tolazoline is not listed in the EEC EC No. 834/2007 or 889/2008.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Tolazoline is not listed in the CODEX.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Tolazoline is not listed in IFOAM.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Tolazoline is not listed in the JAS for Organic Production.

### **Environmental Issues**

Tolazoline is a synthetic  $\alpha$ 2-adrenergic antagonist that also interacts with histamine and cholinergic receptors temporarily and reversibly. Tolazoline affords several physiological effects, including vasodilation (increasing arterial oxygenation), transient hypotension, and histaminic gastrointestinal effects. There are no published toxicity or carcinogenicity studies on tolazoline's toxicity or lethal dosages.

The EPA lists tolazoline as an inert ingredient of toxicological concern. There are no studies on tolazoline's environmental toxicity, persistence, or concentration.

### **Discussion**

In 2022, Stakeholder comments supported relisting for the rare cases in which tolazoline is needed. Most commenters were unaware of substitutes; however, a few mentioned that Yohimbine is supposedly an antagonist of xylazine, but it is not used with any regularity in farm animal medicine. Additionally, atipamezole is also a potential alternative. Other comments stated that tolazoline and xylazine should sunset together since they are used together.

Although xylazine is not being reviewed for sunset at this time, for documentation purposes, there were concerns about the lack of consistency between the FDA and the American Medical Drug Use Clarification Act regarding the off-label use of xylazine in food-producing animals. The FDA prohibits it, but the American Medical Drug Use Clarification Act permits veterinarians to prescribe extra-label uses of certain approved new animal and human drugs for animals under certain conditions. The TAP and the 2015 NOSB review expressed that the lack of consistency can lead to confusion; therefore, this should be reviewed in further detail during the xylazine sunset.

### **Questions to our Stakeholders**

None.

### **Justification for Vote**

The Subcommittee finds that tolazoline continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

### **Subcommittee Vote**

Motion to remove tolazoline from the National List

Motion by: Amy Bruch

Seconded by: Kim Huseman

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 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: N/A

**Past NOSB Actions:** [10/1995 minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#).

**Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#)).

**Sunset Date:** 10/30/2024

### Subcommittee Review

#### Use

Copper sulfate is listed on the National List of Allowed and Synthetic Substances for use in organic livestock production at § 205.603 as a topical treatment, external parasiticide or local anesthetic. Copper ions have been reported to have antimicrobial activity against a wide range of aerobic and anaerobic bacteria and fungi. The exact mechanisms by which copper sulfate exerts its biocidal effect is a source of numerous ongoing investigations in the scientific literature. Copper sulfate has been used as a footbath antiseptic to help control and prevent infectious hoof disease problems that affect the 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 [2015 TR, 93 – 98].

#### Manufacture

Copper sulfate is a synthetic compound produced by a chemical process. Copper sulfate is produced commercially by reacting various copper minerals and or metal with sulfuric acid [2015 TR 293 - 294].

#### International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Allowed as an essential nutrient (source of copper and sulfur) and for topical use (foot baths).

[European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

Not listed.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Not listed.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Not listed.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not listed.

## **Environmental Issues**

See 2015 TR for references.

Walk-through footbaths are used to help control and prevent hoof related diseases in dairy cattle and sheep. 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. Spent solution is mixed with manure waste and ultimately disposed by land application. Regulators in several states (Ippolito et al., 2013, Rankin, 2012) have expressed concern that soil copper could be increased to an unhealthy level by this practice and have established maximum (lifetime) loading rates of copper. An 8 ft. x 2.5 ft. x 5-inch foot footbath will contain approximately 62 gallons of water and 26 pounds of copper sulfate (charged at the 5% concentration). Since copper sulfate is 25% copper, each time the footbath is dumped, 6.5 pounds of copper is added to the disposal burden. The environmental effect of this copper depends on the volume of footbath solution disposed (a function of the number of animals and intensity of footbath use), concentration of copper sulfate, and the land area of application. Without careful attention, maximum soil copper loading rates may be exceeded in relatively short times (5 to 30 years) (Epperson et al., 2007). Depending on the agricultural crop, the annual removal rate for copper is less than 0.5 pound/acre per year. Federal, state, and local environmental regulations require the development of manure management plans to protect water resources and soil quality. The EPA has specific guidelines for copper loading to agricultural land when sewage sludge or biosolids are applied. The EPA §503.13 standard limits annual loading of copper from biosolids to 66 pounds copper per acre and limits lifetime loading to 1,339 pounds copper per acre (limits are based on biosolids land application) (EPA, 2014). Reaching these limits is almost impossible with dairy waste applications and would devastate most agricultural crops long before the lifetime loading limits were met. Some states have lower limits for copper application. New York and Illinois have set lower lifetime loading limits for copper at 75 and 250 pounds per acre, respectively, in order to avoid the potential of irreversible toxic accumulations of copper in the soil (Socha et al., 2007, Ippolito et al., 2013, Rankin, 2012). While more studies are needed, Ippolito et al. recommended that alkaline soils with greater than 50 ppm extractable copper should not have additional copper load added to soil. This value is advisable for producers' raising alfalfa for dairy cow consumption in order to avoid copper accumulation above the NRC 2005 recommendations for the maximum tolerable Cu level for cattle and sheep. Ippolito et al. suggested that soil samples be tested for extractable copper every two to three years from an accredited soil testing laboratory to determine if a copper accumulation problem exists.

## **Discussion**

The feedback from the community during the Spring 2022 meeting was unanimous that copper sulfate use in livestock is essential as of this review. The subcommittee acknowledges the environmental impact of copper sulfate. The subcommittee received consistent feedback that it remains the goal of the community to find alternatives to copper sulfate and to conduct new research on alternatives to copper sulfate.

## **Questions to our Stakeholders**

1. Can the consistent use of foot trimming allow for the elimination of copper sulfate on dairy farms?
2. Have other foot bath treatments of similar efficacy come on to the market?
3. Could zinc replace copper as a less environmentally toxic foot bath? If so, what are market barriers to facilitating this adoption.
4. The TR recently received by the Crop Subcommittee noted copper used in conventional hog production yields a concentrated amount of copper via hog manure. If using conventional hog manure on organic farms, should certifiers request manure tests to establish copper levels and then require corresponding soil tests to show a deficiency prior to approving the manure as an input?

### Justification for Vote

The Subcommittee finds copper sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

### Subcommittee Vote

Motion to remove copper sulfate from the National List

Motion by: Nate Powell-Palm

Seconded by: Brian Caldwell

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

## Elemental sulfur

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

(2) Elemental sulfur—for treatment of livestock and livestock housing.

**Technical Report:** [2017 TR](#).

**Petition:** [2016](#).

**Past NOSB Actions:** [11/2017 recommendation to add](#).

**Recent Regulatory Background:** Added to National List on 5/30/2019 ([84 FR 18133](#)).

**Sunset Date:** 05/30/2024

### Subcommittee Review

#### Use

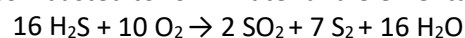
Elemental sulfur is currently allowed for use in organic production as an insecticide, for plant disease control, as a plant or soil amendment, and as a pesticide for domestic livestock.

Elemental sulfur is granulated to a fine powder (325 mesh) for use as a pesticide (control for mites, insects, fungi, and rodents) in livestock production. The particle size for this powder is 44 microns (0.0017 inches) or less. Sulfur is dusted liberally and rubbed into feathers or hair. Sulfur dusting and or spraying is used for both the animals and their respective accommodations. Livestock species include chickens, turkeys, ducks, geese, game birds, pigeons, equine species, cattle, swine, sheep, and goats.

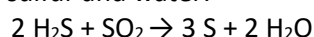
#### Manufacture

Sulfur is an abundant element on the earth. Elemental sulfur is found in volcanic sites and salt domes. Sulfur was classically mined from these using the Frasch process in the U.S. as late as the 1920s, but this is not a major source today.

Sulfur is also found in petroleum, natural gas, and fossil products from which it must be removed as a legal mandate to avoid the production of sulfur dioxide, a contaminant of the air. Hydrogen sulfide from petroleum refining and fossil fuels is converted to pure sulfur by the Claus process. The Claus process is used to produce the majority of sulfur available today. In a heating and cooling cycle, hydrogen sulfide recovered from fossil products is combusted to form water and elemental sulfur:



The addition of an aluminum or titanium catalyst permits the reaction of  $\text{SO}_2$  formed during combustion with additional molecules of  $\text{H}_2\text{S}$  to yield sulfur and water:



In 2015, recovered elemental sulfur and its byproduct sulfuric acid were produced at 103 operations in 27 States. Total shipments were valued at about \$933 million. Elemental sulfur production was 8.7 million tons; Louisiana and Texas accounted for about 52% of domestic production. Elemental sulfur was recovered, in descending order of tonnage, at petroleum refineries, natural-gas-processing plants, and coking plants by 39 companies at 96 plants in 26 States. Domestic elemental sulfur provided 64% of domestic consumption. About 11 million tons of sulfur were used in the US in 2015 (USGS, 2016; for references, please see the 2017 technical report for Elemental Sulfur: Livestock).

### **International Acceptance**

#### [Canadian General Standards Board Permitted Substances List](#)

Sulfur is allowed for control of external parasites.

#### [European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

Commission Regulation (EC) No 889/2008 permits the use of elemental sulfur (98% pure) as a fertilizer or soil amendment and as a fungicide, acaricide and repellent in organic farming. Sulfur is not permitted for use as an insecticide in livestock.

#### [CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Codex Alimentarius guidelines (GL 32-2013) permit the use of sulfur for livestock and livestock products in bee husbandry for pest and disease control. With recognition by the certification body or authority, GL 32-2103 permits the use of sulfur in soil fertilizing and conditioning, and plant pest disease control.

#### [International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

The IFOAM norms allow the use of sulfur as a fertilizer and soil conditioner and as a crop protectant in organic crop production. IFOAM allows the use of sulfur for pest and disease control in beekeeping. Sulfur is not permitted for use as an insecticide in livestock.

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

The Japan Agriculture Standard for Organic Production permits the use of sulfur as a fertilizer or soil improvement. Sulfur is not permitted for use as an insecticide in livestock.

### **Environmental Issues**

Elemental sulfur seems benign unless being handled or administered in very large amounts, for instance in transport in molten form or when stored in open piles. It can also be overfed in unusual cases.

Consumption by ruminants of a high dietary percentage (>0.3%) of sulfur as elemental sulfur or sulfate can cause toxic effects. Sulfur bacteria in the rumen produce the poisonous gases, hydrogen sulfide and sulfur dioxide that eructate from the rumen and are absorbed through the lungs. Diets rich in sulfate can depress feeding. In spite of the liver's capability for detoxifying sulfide in the blood, extreme cases of sulfur toxicity can lead to death [TR 261-221].

In livestock production, hydrogen sulfide can be a hazard to human health. This colorless toxic gas with a rotten egg odor is produced during the degradation of liquid manure stored in anaerobic conditions within agricultural livestock operations. However, the contribution of elemental sulfur to the hydrogen sulfide livestock production hazard for workers is negligible [TR 314-319].

Current available U.S. Environmental Protection Agency (EPA) toxicity studies and literature searches for elemental sulfur do not indicate any systemic human toxicity associated with elemental sulfur exposure and no endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. Only the word caution or no signal word is required on the label for elemental sulfur for acute toxicity, inhalation, and dermal exposure. Sulfur is an eye and skin irritant (category III, moderate irritation (erythema) at 72 hours), but is not a skin sensitizer. The EPA's review of incident data indicates that both the relative number of reported incidents and the severity of reported health effects are low.

### Discussion

In 2022, commenters were again strongly in favor of relisting this material. Commenters mentioned non-synthetic alternatives from the 2017 technical report, that were noted to be ineffective.

### Justification for Vote

Because elemental sulfur is needed to control external parasites in livestock, has no effective alternatives, has low environmental impact, and is compatible with a system of organic agriculture, the Livestock Subcommittee recommends it remain on the National List at: § 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(2) Elemental sulfur—for treatment of livestock and livestock housing.

The Subcommittee finds that elemental sulfur continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

### Subcommittee Vote:

Motion to remove elemental sulfur from the National List

Motion by: Kim Huseman

Seconded by: Liz Graznak

Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

## Lidocaine

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

(5) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

**Technical Report:** N/A

**Petition:** N/A

**Past NOSB Actions:** [10/1995 minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [2016 annotation change recommendation](#); [11/2017 sunset recommendation](#).

**Recent Regulatory Background:** Sunset renewal notice 2017 ([82 FR 14420](#)). Annotation change effective 1/28/2019 [83 FR 66559](#)

**Sunset Date:** 01/28/2024

### Subcommittee Review

#### Use

Lidocaine is a local anesthetic used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment

of animals is critically important, and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all. Section 205.238 establishes a livestock healthcare practice standard permitting physical alterations needed to promote animal welfare in a manner which minimizes stress, and further that a producer must not withhold medical treatment in an effort to preserve its organic status.

### **Manufacture**

Lidocaine, 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide (2.2.2), is synthesized from 2,6-dimethylaniline upon reaction with chloroacetic acid chloride, which gives  $\alpha$ -chloro-2,6-dimethylacetanilide, and its subsequent reaction with diethylamine.

### **International Acceptance**

[Canadian General Standards Board Permitted Substances List](#)

Use of pharmaceutical local anesthetics shall be followed by withdrawal periods of 90 days for livestock intended for slaughter, and seven days for dairy animals.

[European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)

Not listed.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(CXG 32-1999\)](#)

Not listed.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Not listed.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not listed.

### **Environmental Issues**

Lidocaine is extensively and rapidly metabolized in the liver of mammals, followed by excretion via urine. No more than 10% of the dose is excreted as parent lidocaine. There is no excretion via feces.

Lidocaine is not readily biodegradable and is not predicted to bioaccumulate in aquatic organisms. The Predicted Environmental Concentration (PEC) / Predicted No Effect Concentration (PNEC) ratio is  $6.5 \times 10^{-2}$ , which means use of lidocaine is predicted to present an insignificant risk to the environment.

### **Discussion**

The subcommittee noted that animal welfare is an innate aspect of organic livestock production and lidocaine has been a consistent tool to minimize livestock pain. To this end, the subcommittee does encourage the community to think critically about ways the organic industry can further improve animal welfare via pain management.

### **Questions to our Stakeholders**

1. Are there other, more effective anesthetics which should be considered for use in addition to or instead of lidocaine?

**Justification for Vote**

The Subcommittee finds lidocaine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

**Subcommittee Vote**

Motion to remove lidocaine from the National List

Motion by: Nate Powell-Palm

Seconded by: Amy Bruch

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

