

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

Date: January 14, 2026 (Fall 2025 meeting rescheduled)

Subject: 2027 Livestock Sunset Reviews

NOSB Chair: Amy Bruch

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

The NOSB recommends the following sunset substances be renewed:

Butorphanol

Flunixin

Magnesium hydroxide

Oxytocin

Poloxalene

Formic acid

Sucrose octanoate esters

EPA List 4 Inerts

Excipients

Strychnine

Statement of the Recommendation:

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

None

Rationale Supporting Recommendation:

The NOSB recommended removal of substances that no longer meet OFPA criteria. Please see individual substances below for justifications, votes, and outcomes.

Sunset 2027
NOSB Final Review
Livestock Substances § 205.603 & § 205.604
Fall 2025

Introduction

As part of the [Sunset Process](#), the NOSB has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

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

[Butorphanol](#)

[Flunixin](#)

[Magnesium hydroxide](#)

[Oxytocin](#)

[Poloxalene](#)

[Formic acid](#)

[Sucrose octanoate esters](#)

[EPA List 4 Inerts](#)

[Excipients](#)

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

[Strychnine](#)

Butorphanol

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

(5) Butorphanol (CAS #-42408-82-2) – federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian; and
- (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

Technical Report: [2002 TAP](#)

Petition(s): [2002 Petition](#)

Past NOSB Action: 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; [04/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

Subcommittee Review

Use

Butorphanol is used in livestock production as a pre-operative treatment of pain before surgery. Butorphanol belongs to a general class of drugs known as opiate agonists. It is commonly used as an anesthetic used to treat patients prior to surgery. Other related drugs in this class include buprenorphine, fentanyl, meperidine, and morphine. Xylazine, acepromazine, and butorphanol serve similar functions, but each has its own specific advantages that make it the preferred treatment at the time: acepromazine has no analgesic activity, it is only a sedative; xylazine has both analgesic and sedative properties; and butorphanol is a pain killer with no real sedative activity [2002 TAP, page 24]. Although there are non-synthetic opiates (refers to a group of drugs used for treating pain), butorphanol is preferred for several reasons: it is associated with fewer adverse effects for the animal and it has less abuse potential in humans, thereby reducing unwanted consequences if the drug is diverted to illicit use [2002 TAP, page 26].

Manufacture

Butorphanol is an analgesic opioid derived from morphine. Known for the ability to reduce the perception of pain without a loss of consciousness, the original opioids were derived from opium, which is a partially dried latex harvested from the opium poppy, *Papaver somniferum* [2002 TAP, page 3].

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists*, are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada's Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).
- Botanical compounds: Botanical preparations, such as atropine, butorphanol, and other medicines from herbaceous plants shall be used according to label specifications (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- Butorphanol is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Butorphanol is not explicitly mentioned in the regulations.
- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).
- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Butorphanol is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic

chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods. Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer (Animal Production, IFOAM NORMS 2014).

- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthesized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Butorphanol is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary Substances

Butorphanol tartrate includes sodium chloride, sodium citrate, and citric acid.

Human Health and Environmental Issues

Impacts of manufacture of butorphanol are unknown [2002 TAP, page 25]. Butorphanol is administered via injection. Butorphanol and metabolites are not considered toxic if released. Although the fate of butorphanol in the environment is not known, the metabolites that are excreted via urine and bile are water-soluble which will not likely accumulate in the local environment. Butorphanol disposal in city water drainage/sewer systems is an accepted practice [2002 TAP, page 25].

Discussion

During the Spring 2025 meeting we heard from many advocates about keeping butorphanol listed, and also a few stakeholders wanting its removal to be discussed. Specifically, commenters asked the NOSB to consider farmers' need for balancing pain management tools to maintain strong animal welfare practices, while also considering the residues that medications can leave behind in the food produced (meat and milk products). Butorphanol is an important tool for farmers for pain management, which is an important tenet for animal welfare in organic. There are limited pain management medications available to organic

producers, so this needs to be considered in the discussion on butorphanol. The Organic community prides itself on maintaining high standards for animal welfare, and pain control is critical for upholding this tenet for organic certification. Based on what the Board has heard from producers, butorphanol is used only in emergency situations and is critical in those situations. The concerns raised by some stakeholders about residues in meat/milk from medications like butorphanol are mainly quelled due to the low frequency of use and the withdrawal periods, which are double what is listed in the Food Animal Residue Avoidance Databank (FARAD). Commenters at the Fall 2025 NOSB meeting emphasized the importance of this medication to their operations.

Justification for Vote

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

NOSB Vote

Motion to remove butorphanol from the National List

Motion by: Corie Pierce

Seconded by: Nate Lewis

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Flunixin

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

(12) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

Technical Report: [2007 TAP](#)

Petition(s): N/A

Past NOSB Actions: 10/2002 NOSB recommendation; [10/2010 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: National List amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

Flunixin, in its compounded state called flunixin meglumine, is a potent, non-narcotic, nonsteroidal analgesic agent with anti-inflammatory and antipyretic activity. Flunixin, in its drug form, Banamine®, exists for intravenous or intramuscular use in horses and for intravenous use in beef and non-lactating dairy cattle only to treat inflammation and pyrexia [2007 TAP, pages 1-2].

Banamine® has been used to rapidly reduce the fever and lung inflammation that typically accompany Bovine Respiratory Disease (BRD). As a result of usage, cattle feel better faster and have fewer lung lesions in comparison to treatment with other remedies. Additionally, Banamine® has been used to reduce inflammation associated with endotoxemia [2007 TAP, page 3].

If all precautions are followed and the drug is administered appropriately, there will be no harm done to humans who consume the meats from these animals - and the livestock are able to cope with the disorder and actually heal from it, quickly recovering, and granting the farmer economic satisfaction [2007 TAP, page 1].

Manufacture

Flunixin is a synthetic drug more commonly made into flunixin meglumine, which is the primary component of Banamine® (the injectable flunixin meglumine solution). It has been FDA approved and used in horses for intravenous or intramuscular injections for beef and non-lactating dairy cattle for many years to help cope with inflammation, pyrexia, and colic. Administered intravenously and intramuscularly, flunixin is quickly broken down internally and cleared from the bloodstream in urine [2007 TAP, page 1].

Flunixin meglumine is a potent inhibitor of the enzyme cyclooxygenase [2007 TAP, page 19], is often classified as a non-steroidal anti-inflammatory drug (NSAID), and it functions by reducing the production of mediators of the inflammatory process. It acts as an anti-inflammatory by inhibiting the effect of prostaglandins by inhibiting cyclooxygenase (COX), the enzyme responsible for the direct synthesis of prostaglandins [2007 TAP, page 3].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Flunixin is not explicitly mentioned in the regulations.
- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists*, are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada's Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Flunixin is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Flunixin is not explicitly mentioned in the regulations.

- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).
- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
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International Federation of Organic Agriculture Movements (IFOAM)

- Flunixin is not explicitly mentioned in the regulations.
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- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthesized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

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

- Flunixin is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary Substances

Flunixin is an ancillary substance in other pain relief drug formulations.

Human Health and Environmental Issues

Generally, flunixin has been declared safe and the probability of environmental contamination during use or disposal of flunixin is very low. The U.S. Environmental Protection Agency (EPA) stated in a report on PPCP (Pharmaceuticals and Personal Care Products) that are found in the environment, particularly in the water, flunixin was not among the other NSAIDs (i.e., aspirin, ibuprofen, etc.) that had residues left in the waters.

Discussion

The Board has generally heard over the past four meetings that pain management in organic livestock is a top priority. Comments about flunixin indicated it remains necessary in organic livestock production for pain management, and doubling of the withdrawal time following use of flunixin adequately addresses consumer concerns related to residues. The NOSB would also like to acknowledge that there is uncertainty around whether aspirin remains allowed for pain relief in livestock production, and it is critical that livestock producers have access to adequate pain relief measures to support animal welfare goals.

Justification for Vote

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

NOSB Vote

Motion to remove flunixin from the National List

Motion by: Nate Lewis

Seconded by: Brian Caldwell

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Magnesium hydroxide

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

(18) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

Technical Report: [2007 TAP](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: 2002 NOSB recommendation; 03/2005 NOSB sunset recommendation; [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

Magnesium hydroxide, also referred to as milk of magnesia, is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. It is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid [2007 TAP, page 3].

Manufacture

The TAP states magnesium hydroxide (Brucite) is found naturally in serpentine, chlorite or dolomitic schists, or in crystalline limestones as an alteration product of periclase (magnesium oxide). It is prepared by mixing sodium hydroxide with a water-soluble magnesium salt. It is also formed by the hydration of reactive magnesium oxide. Either case produces magnesium hydroxide as a white precipitate [2007 TAP, page 3].

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Magnesium hydroxide is not explicitly mentioned in the regulations.

[European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 and 2021/1165](#)

- Magnesium hydroxide is not explicitly mentioned in the regulations.

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

- Magnesium hydroxide is not explicitly mentioned in the regulations.

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

- Magnesium hydroxide is not explicitly mentioned in the regulations.

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

- Magnesium hydroxide is permitted when obtained by grinding natural ores (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Ancillary Substances

N/A

Human Health and Environmental Issues

According to the TAP, the EPA has deemed magnesium hydroxide environmentally safe. This assessment is based on toxicology reports provided by the Center for Disease Control. Magnesium hydroxide is not listed on the EPA's list of regulated chemicals [2007 TAP, page 8]. In addition, magnesium hydroxide is allowed for extra-label use in livestock under the provisions of AMDUCA [2007 TAP, page 7].

Discussion

The reference material for magnesium hydroxide is from a 2007 TAP. Magnesium hydroxide appears to remain necessary for organic livestock production, and there does not appear to be any new information to suggest it now fails any of the National List criteria. However, there are some questions around the synthetic/nonsynthetic classification of magnesium hydroxide products that are available as livestock drugs, and since the most current information available is from a 2007 TAP, the LS recommends that a full Technical Report be requested for this material at its next sunset evaluation.

Justification for Vote

The NOSB finds magnesium hydroxide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

NOSB Vote

Motion to remove magnesium hydroxide from the National List

Motion by: Nate Lewis

Seconded by: Amy Bruch

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Oxytocin

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

(22) Oxytocin—use in postparturition 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](#); [11/2017 sunset recommendation to remove](#)

Recent Regulatory Background: Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 02/28/2022 ([87 FR 10930](#))

Sunset Date: 03/15/2027

NOSB Review

Use

Oxytocin is a hormone produced primarily in two discrete locations in the brains of all male and female mammals [2005 TR, lines 18-19]. In nonorganic production, it can be used regularly to help dairy cows relax and “let down their milk” [1995 TAP, page 9]. There are some concerns with overuse of oxytocin in nonorganic production systems. In the USDA organic regulations, it is used “in postparturition therapeutic applications,” which is ambiguous.

Manufacture

Oxytocin is chemically manufactured as both a veterinary and medical synthetic hormone. It is identical in structure ($C_{44}H_{68}N_{12}O_{12}S_2$) to the naturally occurring hormone. In brief, oxytocin’s peptide synthesis goes through multiple steps and involves a series of condensation reactions using various solvents (e.g., triethylamine, ether) to form amide bonds. Biologically active oxytocin exists in a cyclic configuration formed by oxidation of two thiol groups to form a disulfide bond between the cysteine and asparagine amino acids. Other molecular configurations (e.g., non-cyclic) also may exist [2005 TR, lines 24-26, 94-101].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Oxytocin is permitted for post-parturition therapeutic use. Meat from treated animals will not lose its organic status. See 6.6.10 d) of CAN/CGSB-32.310, for criteria pertaining to the mandatory withdrawal period (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Oxytocin is not explicitly mentioned in the regulations.
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Oxytocin is not explicitly mentioned in the regulations.
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Oxytocin is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods.
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthesized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

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

- Oxytocin is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations.

Ancillary Substances

One typical product lists 0.9% w/v sodium chloride, 0.5% w/v chlorobutanol (as a preservative), with water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

Human Health and Environmental Issues

In general, the acute toxicity of oxytocin is considered low. The lethal dose (LD₅₀) of oxytocin has been determined by the oral route of administration in rats (>20.5 mg/kg) and mice (>514 mg/kg). Its LD₅₀ in rats via intravenous administration is much lower and has been reported in the literature to range from > 2.275 mg/kg to 5.8 mg/kg. Veterinary oxytocin is not available in oral form because it is destroyed in the stomach and intestines of mammals. More specifically, the nonapeptide is degraded into biologically inactive smaller peptides and amino acids by enzymes of the gastrointestinal tract [2005 TR, lines 164-170].

Because oxytocin is used in small doses on a case-by-case basis and only by or under the direction of a veterinarian in organic livestock production, it is unlikely to reach significant concentrations in the environment (agroecosystem) through normal use [2005 TR, lines 133-135].

Oxytocin consumed by humans in contaminated milk or drinking water would likely be destroyed in their stomach and intestines [2005 TR, lines 248-249].

Discussion

Oxytocin has been on the National List of approved synthetics since the USDA organic regulations were implemented.

In comments received for the 2020 sunset review, the two largest organic 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 of “use in postparturition 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 “postparturition,” and which therapeutic applications are allowed. Some certifiers would not allow its use for “milk let down,” and 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 oxytocin, while 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.

In 2020, the NOSB voted to remove oxytocin from the National List, but this recommendation was not implemented. The NOP stated, “by retaining oxytocin on the National List, organic livestock producers will continue to be permitted to use the drug to treat specific conditions within a limited timeframe following parturition without forfeiting the animal's organic status,” and “the current annotation allows producers to use oxytocin to treat conditions related to labor and to an animal's postpartum survival. Its use is not permitted on a routine basis (i.e., as protocol). Instead, it is available for emergency situations and severe complications in the immediate postpartum (following birth of young) period. It may not be administered

to increase an animal's milk production (volume) or for milk letdown. As previously noted in this document, Federal law restricts this drug to use by or on the order of a licensed veterinarian ([21 CFR 522.1680\(c\)\(3\)](#))."

In the current review, the Livestock Subcommittee discussed the 2020 recommendation for removal, as well as possible reasons for relisting. It was pointed out that some dairy processors do not allow their dairy farms to use oxytocin and, thus, can make the labeling claim of "no synthetic hormones." For other livestock farmers, the use of oxytocin is part of their approach to birthing problems. On the balance of these considerations, the Subcommittee recommended that oxytocin be relisted.

Comments received at the Fall 2025 NOSB meeting were split over relisting oxytocin. However, most of those in favor of removing it added that if the annotation to restrict its use was clarified, they would vote to relist. The NOSB has put forth concurrently with this review a proposal to change the annotation to read: "for use in postparturition therapeutic applications within 3 days after birth. It may not be administered to increase an animal's milk production or for milk letdown." The NOSB voted to relist oxytocin with the understanding that its annotation would be changed.

Justification for Vote

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

NOSB Vote

Motion to remove oxytocin from the National List

Motion by: Brian Caldwell

Seconded by: Logan Petrey

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (26) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat

Technical Report: [2001 TAP](#); [2025 Limited Scope TR](#)

Petition(s): [2000 Petition](#)

Past NOSB Actions: 03/2001 NOSB minutes and vote; [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

Poloxalene (chemical formula: $C_5H_{10}O_2$) is a copolymer of polyethylene and polypropylene ether glycol that is a non-ionic polyol surface-active agent. Poloxalene is a fast-acting synthetic material approved under the

organic regulations only for emergency treatment of bloat in ruminants, such as cattle and sheep. Poloxalene destabilizes foam and allows gas to release from the rumen [2025 TR, line 52].

Manufacture

A limited scope TR was completed in 2025 to evaluate the manufacturing process of poloxalene. As stated in the TR, the process for synthesizing poloxalene always involves the polymerization of ethylene oxide (EO) and propylene oxide (PO) to form a block copolymer. However, the process manufacturers use to produce the monomers can vary. PO and EO manufacturing is further described in the TR, as well as the steps involved in the polymerization reaction used to synthesize poloxalene [2025 TR, lines 65-68]. Once both monomers (PO and EO) are available, they are copolymerized to form poloxalene. Manufacturers typically do this in the presence of a catalyst – such as potassium hydroxide (KOH) – which facilitates the polymerization reaction. The process consists of three steps: initiation, propagation, and termination [2025 TR, lines 133-140]. Poloxalene is not created using excluded methods [2025 TR, line 214].

Prior to the updated TR, manufacturing information was derived from the 2001 NOSB TAP review of poloxalene, which stated, “There are two principal processes used [to manufacture poloxalene], the traditional chlorohydrin process and indirect oxidation by the hydroperoxide process that uses a molybdenum catalyst. Both processes start with propylene (propene) derived from cracking of petroleum. The chlorohydrin process involves reaction of propylene ($\text{CH}_3\text{CH}=\text{CH}_2$) and chlorine in the presence of water to produce two isomers of propylene chlorohydrin. This is followed by dehydrochlorination using caustic soda or lime to produce propylene oxide and salt. The hydroperoxide process involves oxidation of propylene to PO by an organic hydroperoxide, producing an alcohol as a co-product. One of the possible alcohols (tert-butanol, TBE) produced as a by-product from this process is used as feedstock for MTBE, a gasoline additive” [2001 TAP, page 1].

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Poloxalene is not explicitly mentioned in the regulations.
- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists*, are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada’s Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- Poloxalene is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically

produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

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

- Poloxalene is not explicitly mentioned in the regulations.
- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).
- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

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

- Poloxalene is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods. Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer (Animal Production, IFOAM NORMS 2014).
- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthesized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than

double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Poloxalene is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary substances

No clear information on ancillary substances was available.

Environmental/Health Issues

According to the 2001 TAP review, “The production of organic polymers from petroleum sources is a large volume chemical manufacturing process that has significant environmental impact.” The 2001 TAP also states that the “FDA does not list any withdrawal times or residue tolerances for poloxalene (21CFR)” and also added the following in regard to human health: “Poloxalene is listed by USP for use as pharmaceuticals aid. It is reported to have no known toxicity and is not listed in the National Toxicology Program Database” [2001 TAP, page 3].

Discussion

Many preventive measures can be taken to avoid pasture bloat. Organic farmers seeking to establish a pasture-based system for ruminants may occasionally experience unforeseen incidence of pasture bloat that requires an emergency remedy, and the use of poloxalene, a synthetic substance, could be justified to alleviate animal suffering on an emergency basis [2001 TAP, page 4].

The NOSB reviewed stakeholder comments and many either supported continued listing of the substance as necessary in emergencies when natural approaches to treating bloat are not effective, or stated that the substance was used by organic farming operations for emergency situations. The consensus was that while poloxalene is rarely needed, in certain emergency situations, it is essential. However, some commenters stated that allowance of this substance enables lax pasture management and should be removed from the National List.

A question was asked to stakeholders regarding availability of alternatives that are non-synthetic, approved, effective bloat remedies for ruminants, and that are commercially available to ranchers. Many stakeholders consistently emphasized that poloxalene is a last-resort animal welfare tool for acute bloat, not a routine or preventive treatment. Use is rare, but when emergencies occur, producers need immediate access to prevent serious suffering or death. Commenters strongly support retaining the existing emergency-use annotation, with certifier oversight if repeated use is observed. While a minority raised concerns about synthetic compatibility, the dominant view is that limited emergency use remains appropriate.

Justification for Vote

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

NOSB Vote

Motion to remove poloxalene from the National List

Motion by: Logan Petrey

Seconded by: Brian Caldwell

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(3) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives.

Technical Report: [2011 TR](#)

Petition(s): [2010 Petition](#)

Past NOSB Actions: [2010 NOSB recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Added to National List, effective 08/03/2012 ([77 FR 45903](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

Formic acid is a pesticide employed to control Varroa and tracheal mites in honeybee hives. Deployed in the form of a compressed pad inside the hive, the material volatilizes to kill mites throughout the hive, including mites attacking broods, and those located externally on and internally in the adult bees.

The EPA first registered formic acid as a pesticide in 1999 as material control for Varroa and tracheal mites in honeybees [2011 TR, lines 89-95]. Formic acid kills mites by asphyxiation while not causing harm to the bees [2011 TR, lines 121-125]. Typically employed over a 21-day treatment period (per label instructions), the efficacy of formic acid in killing mites has been found to be as high as 95%. Label recommendations instruct producers who treat hives with formic acid to not harvest honey from the hive for two weeks after the introduction of the formic acid pads.

Natural sources of formic acid, which include coffee, nectars, some fruits, as well as the stings of ants and bees, have proven insufficient to extract commercially viable quantities [2011 TR, lines 223-224].

Manufacture

Formic acid is primarily produced through the hydrolysis of methyl formate. Formic acid may be produced as a byproduct of other chemicals (e.g., acetic acid), though these have not proven to be commercially viable [2011 TR, lines 199-203].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Hay or silage preservation products are permitted: Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi and plants and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic and formic (Table 5.2 – Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- Acids: Ascorbic, acetic, propionic, citric, formic and lactic acids and vinegar. Permitted for all uses such as treatment of water and bedding (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formic acid is permitted for apicultural use, to control parasitic mites. This substance may be used after the last honey harvest of the season and shall be discontinued 30 days before the addition of honey supers (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Formic acid, lactic acid, acetic acid and oxalic acid, as well as menthol, thymol, eucalyptol or camphor, may be used in cases of infestation with *Varroa destructor* (Health care, EC No. 2018/848).
- Soft ground rock phosphate is permitted. Product obtained by grinding soft mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients. Minimum content of nutrients (percentage by weight): 25% P₂O₅. Phosphorus expressed as P₂O₅ soluble in mineral acids, at least 55% of the declared content of P₂O₅ being soluble in 2% formic acid (Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- Formic acid is permitted as a preservative (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only: sea salt; coarse rock salt; yeasts; enzymes; whey; sugar or sugar products such as molasses; honey; lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority (Livestock and Livestock Products, CXG 32-1999).
- For pest and disease control the following are allowed: lactic, oxalic, acetic acid; formic acid; sulphur; natural etheric oils (e.g. menthol, eucalyptol, camphor); *Bacillus thuringiensis*; steam and direct flame (Beekeeping and bee products, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Fodder preservatives such as the following may be used: a) bacteria, fungi and enzymes; b) natural products of food industry; c) plant-based products; and d) vitamins and minerals subject to 5.5.6. Synthetic chemical fodder preservatives such as acetic, formic, and propionic acid are permitted in severe weather conditions (Animal Nutrition, IFOAM NORMS 2014).
- For pest and disease control the following are permitted: a) lactic acid, formic acid; b) oxalic acid, acetic acid; c) sulfur; d) natural essential oils (e.g. menthol, eucalyptol, camphor); e) *Bacillus thuringiensis*; f) steam, direct flame and caustic soda for hive disinfection (Bee Keeping, IFOAM NORMS 2014).
- Formic acid is permitted (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).

- Citric, peracetic acid, formic, lactic, oxalic and acetic acid are permitted (Appendix 5 - Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Formic bacteria is permitted (Table A.1 Substances used in the preparation etc., JAS for Organic Feed).
- Natural acids are permitted: limited to those made from lactic bacteria, acetic acid bacteria, formic bacteria or propionic acid bacteria (Table A.1 Substances used in the preparation etc., JAS for Organic Feed).

Environmental Issues

Due to its localized use inside the beehives, no residue is found outside the hive environment. Formic acid is generally recognized as safe (GRAS) by the FDA (21 CFR 186.1316) [2011 TR, lines 99-100]. Human health may be adversely affected if formic acid is inhaled or ingested, so respirators and skin covering personal protective equipment are recommended to protect against applicator contact.

Discussion

Formic acid is found in nature. Synthetic formic acid is a relatively benign substance when used to treat Varroa mites, an important pest of honeybees. Because of its low environmental impact and GRAS status, the Livestock Subcommittee recommends retaining it on the National List. There were multiple written comments supporting the creation of apiculture standards. Because bees are not fully contained and their foraging cannot be fully controlled, creating apiculture standards would be very difficult. At the fall 2025 NOSB full board meeting there was discussion regarding public comments. Two questions were asked to stakeholders regarding alternatives and whether current options are sufficient. Public comments support relisting formic acid for use solely within honeybee hives. Commenters consistently emphasized its effectiveness in controlling varroa and tracheal mites, which are a major driver of honeybee declines and broader crop risk. While acknowledging worker safety concerns and the need for personal protective equipment (PPE), most commenters noted that formic acid is less hazardous than conventional miticides and has no equally effective alternatives under high mite pressure. Several groups also emphasized the need for NOP apiculture standards to provide clearer context. Overall, commenters support continued listing with existing restrictions. A board member also noted that equipping commercial beekeepers with appropriate tools is essential to prevent challenges from spreading into unmanaged or informal beekeeping settings.

Justification for Vote

The NOSB finds formic acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

NOSB Vote

Motion to remove formic acid from the National List

Motion by: Logan Petery

Seconded by: Corie Pierce

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Sucrose octanoate esters

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(10) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.

Technical Report: [2005 TR](#); [2025 Limited Scope TR](#)

Petition(s): [2004 petition](#); [05/2004 petition amendment](#); [09/2004 petition amendment](#)

Past NOSB Actions: [08/2005 NOSB recommendation](#); [10/2010 sunset recommendation](#); [10/2018 sunset recommendation to remove](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 02/28/2022 ([87 FR 10930](#))

Sunset Date: 3/15/2027

NOSB Review

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs) [2005 TR, lines 23-24]. SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals [2005 TR, lines 27-28]. SOEs, marketed as biopesticides, are synthetic analogs of the naturally occurring sugar ester isolates of *Nicotiana* plant species (2025 TR, lines 65-67) that mimic the pest control properties of the natural forms of the compound in wild tobacco and other plants in the *Nicotiana* genus. *glauca* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant [2005 TR, lines 35-38].

Use

Sucrose octanoate esters are listed at §205.603(b)(10) in organic livestock production as a topical treatment, external parasiticide or local anesthetic as applicable, in accordance with approved labeling [2025 TR, lines 32-32]. Producers use SOEs to control soft-bodied pest organisms including mites, aphids, and whiteflies [2024 TR, line 56]. The EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops; for *Sciarid* fly control in mushroom-growing media; and for Varroa mite control on honeybees [2005 TR, lines 70-72].

Manufacture

Commercial synthesis of SOEs involves the use of materials such as alcohols, several catalysts, solvents, and sucrose octanoate acid [2025 TR, lines 68-70]. Steps in the production include (1) Esterification of fatty acids, (2) Neutralization and separation of catalyst, (3) Second esterification with sugar, (4) Vacuum distillation and emulsification, (5) Separation of emulsified product, and (6) Purification and recovery of sugar ester product [2025 TR, lines 75, 162, 176, 203, 208, and 213]. The raw materials are derived from various sources: octanoic acid from both synthetic and nonsynthetic sources, alcohol (methanol or alcohol) from synthetic and nonsynthetic sources, and sucrose that is usually obtained from nonsynthetic sources [2025 TR, lines 222-225]. The petitioned substance is soap derived from coconut oil fatty acids or palm kernel oil fatty acids.

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- **Sucrose octanoate esters** are not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- **Sucrose octanoate esters** are not explicitly mentioned in the regulations.

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

- **Sucrose octanoate esters** are not explicitly mentioned in the regulations.

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

- **Sucrose octanoate esters** are not explicitly mentioned in the regulations.

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

- **Sucrose octanoate esters** are not explicitly mentioned in the regulations.

Ancillary Substances

None

Human Health and Environmental Issues

Effect on the Environment

The chemical structure of SOEs, consisting of sucrose and octanoic acid, renders the material readily biodegradable. Naturally occurring microorganisms in soil and water can break down these compounds. The compound biodegrades within approximately five days at temperatures ranging from 68°F to 80°F in both aerobic and anaerobic conditions. Typical degradation products are carbon dioxide and water, both of which are harmless. In addition to the fact that these degradation products are harmless, some are incorporated as microbial biomass [2025 TR, lines 240-245].

Impact on Non-Target Organisms

The EPA's evaluation report on the potential impact of SOEs on non-target insects and other organisms, such as fish, stated that the use of the compound had minimal potential for exposure and toxicity to these organisms as well as soil and water. According to the EPA, the fact that the mode of action of the compound is via physical effects as opposed to biochemical toxicity gives the compound a minimal toxicity profile [2025 TR, lines 248-251]. The petitioned substance primarily targets soft-bodied insects by physically disrupting the lipid layer of their cuticle, thereby causing dehydration and death. Insects with thicker and/or more robust exoskeletons are not affected by the petitioned substance [2025 TR, lines 256-259].

The physical mode of action enables the compound to target soft-bodied insects without producing general toxic metabolites, thereby decreasing the likelihood of adverse effects on mammals and birds [2025 TR, lines 251-254]. Soft-bodied organisms targeted include mites and insects such as thrips, aphids, and whiteflies [2025 TR, lines 270-275]. The fact that SOEs do not exert their pesticidal effects via a biochemical pathway common to all insects renders it selective, resulting in minimal effects on non-target organisms such as pollinators (e.g., bees and ladybugs), earthworms, and other soil organisms [2025 TR, lines 258-260]. Some non-synthetic pesticides are known to have adverse effects on beneficial organisms such as predators and parasitoids. An assessment of the effect of SOEs on multiple beneficial insects from different insect orders in citrus ecosystems revealed a high survival rate of ladybeetles (*Coccinellidae*), lacewings (*Chrysopidae*), and parasitoids of red scale insects (*Anthocoridae*) even when exposed to 8,000 ppm (i.e., parts per million), which represents twice the recommended field application rate [2025 TR, lines 263-267]. Soil organisms and non-target insects may be exposed to SOEs during and after applications until the compounds biodegrade in approximately five days. Direct and specific detrimental effects from SOEs on soil organisms have not been studied extensively. Available literature does not show detrimental physiological effects of SOEs on soil organisms, soil microbiome, or non-target insects. Current literature states that SOEs have low toxicity and biodegrade rapidly. When SOEs are applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOEs is expected [2025 TR, lines 281-286].

Effect on Human Health

SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified [2005 TR, lines 292-293]. An ocular risk exists but it is unlikely if the product is used according to label [2005 TR, lines 297-300].

Comparison with natural (Nonsynthetic alternatives)

The 2025 TR did not list any natural alternatives to sucrose octanoate esters for use in the management of Varroa mites in honeybee hives [2025 TR, lines 290-295]. In the absence of research studies that compare SOEs to nonsynthetic alternatives, the 2025 TR covered the performance and characteristics of nonsynthetic pesticides used in managing pests in crop production. Alternatives listed include neem extract, Pyrethrins, *Bacillus thuringiensis* (Bt), Spinosad, miscellaneous botanicals such as essential oils derived from thyme and eucalyptus, garlic extracts and biological control agents. Even though neem extracts were reported to be effective against listed insect pests, cases of neem oil poisoning in humans were reported [2025 TR, lines 324-325]. Pyrethrins can harm beneficial insects such as bees and aquatic organisms if used improperly [2025 TR, lines 336-337]. *Bacillus thuringiensis* affects a broader range of organisms than SOEs. There are reports of non-targeted adverse effects on several groups of insects that are closely related or have an affinity to targeted insects [2025 TR, lines 357, 362-363]. At regular field application rates, Bt has been reported to impair the growth and developmental time of non-target true flies such as *Drosophila melanogaster* (common fruit fly) larvae [2025 TR, lines 366-368]. There are also reports of insect pest resistance to Bt products [2025 TR, line 378]. Spinosad breaks down quickly in the environment and is considered safe for humans and most beneficial insects. It can, however, be toxic to bees if applied directly to flowering plants. Spinosad application has also been demonstrated to have adverse effects on genes associated with energy production in honeybees [2025 TR, lines 391-394].

Discussion

Rationale for Previous NOSB Recommendation

During the 2018 sunset review of sucrose octanoate esters (SOEs), information indicated that there were no EPA-registered products formulated using SOEs as an ingredient. There were also no public comments received from beekeepers stating the need for this material.

Since SOEs were first placed on the National List alternatives that are more effective have become available. Additionally, the absence of public comments from organic beekeepers in 2018 was likely due to organic honey being sourced mainly from outside the United States. The views of these international organic honey producers were not captured because they do not typically participate in NOSB meetings.

Public Comments

There were no substantive comments from beekeepers during the Spring 2018 public comment period on the continued listing of SOEs at § 205.603(b); nevertheless, there were comments from other livestock producers who stated that they were aware that SOEs are an important tool for beekeepers in controlling Varroa mites in honeybees.

In 2018, a public health advocacy organization commented that in view of the restrictive use of SOEs and the difficulty that beekeepers are experiencing in maintaining the health of honeybee colonies, they supported keeping SOEs on the National List.

In Spring 2025, an environmental and human health advocacy organization stated the following: SOEs are surfactants –closely related to soaps– that have a mode of action like insecticidal soaps. However, a limited number of experiments have shown SOEs not to affect a range of predators and parasitoids that are killed

by insecticidal soaps. Impacts on soil fauna have not been established. They have low toxicity to humans and are produced in a closed system. The commenting organization stated that the limited available evidence concerning the toxicity of SOE on nontarget organisms, such as predators, parasitoids, soil fauna, and aquatic organisms, shows them to have minimal effect. It requested additional information on the relative efficacy and hazard of SOEs in controlling varroa mites. It stated that one product, with multiple labeled uses, is registered with EPA.

The advocacy organization included the following statements in its written public comments:

1. In the absence of apiculture practice regulations, the NOSB should not be approving materials for use on bees. Materials on the National List are approved within a context that describes generally accepted practices. Those judgments cannot be made without practice rules in place.
2. If SOEs are relisted, the generic annotation “in accordance with approved labeling,” which always applies as a matter of law, should be replaced with one that describes the use, such as “for control of varroa mites in honeybees.”

The organization concluded its comments by stating that in consideration of the difficulty that beekeepers have in maintaining the health of honeybee hives, it would support SOEs within a context of defined organic apiculture practices if they were actually used. It stated that if there was no support from beekeepers for this use, then SOEs should be allowed to sunset. It asked the NOP to adopt apiculture rules, which would provide a framework for making decisions about materials used in organic beekeeping.

A farmers association encouraged the NOSB and NOP to take up the addition of apiculture standards to the USDA organic regulations. It stated that SOE, oxalic acid, and formic acid are used only in apiculture production. It stated that without clear standards and cultural requirements for honeybee management, these substances do not have a clear context in the NOP pest management hierarchy of using cultural, mechanical, and biological approaches before the use of National List synthetic materials. It mentioned the fact that there are USDA-accredited certifiers who certify honey and other bee products as organic, with inconsistent standards between them for forage zones, hive management, and other aspects specific to apiculture. The farmers organization cited an example of one of their staff who is a beekeeper who does not see this material being used in current beekeeping and would like the NOSB to review its essentiality before relisting it again. The commenter indicated that she has used SOEs in the past, it is miserable to apply for both the operator and for the bees, and is not as effective as formic or oxalic acid. The organization recommended that the NOSB conduct a short review to make sure there were no improvements to be made to keep them in harmony with other international apiculture standards.

Another stakeholder organization notes that this is a difficult material to use and is messy and difficult to apply. It is not clear that it is efficacious, and it should be considered for delisting since it is not essential to organic production and other alternatives exist.

Considering the NOSB’s previous recommendation to remove this listing, a trade association expressed interest in hearing from its members about the need for this substance, and whether the EPA-registered products containing this substance are in use by organic producers. A certifier stated that it had an OMRI-listed product in use by one of its clients, and also pointed out the limited use of the material among its clients. A certifier stated that it had received no requests for review of any inputs that use sucrose octanoate esters.

Justification for Vote

The NOSB finds sucrose octanoate esters (SOEs) compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

NOSB Vote

Motion to remove sucrose octanoate esters (SOEs) from the National List

Motion by: Franklin Quarcoo

Seconded by: Nate Lewis

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

EPA List 4 Inerts

Reference: §205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 - Inerts of Minimal Concern.

Technical Report: [2015 Limited Scope TR - Nonylphenol Ethoxylates \(NPEs\)](#) (one group only of List 4 inerts)

Petition(s): N/A

Past NOSB Actions: 02/1999 NOSB minutes and vote; [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

As explained below, the Livestock Subcommittee (LS) expects this listing to be fully replaced before its next sunset review.

Use

Inert ingredients in pesticide formulations are added to enhance functionality and efficacy. Any of the pesticides approved for organic use may contain inert ingredients. For example, surfactants may improve the solubility and half-life of active pesticide ingredients. As described by Shistar, “the relatively few registered pesticides allowed in organic production are contained in product formulations with so-called “inert” ingredients that are not disclosed on the product label. The “inerts” make up the powder, liquid, granule, or spreader/sticking agents in pesticide formulations. The “inerts” are typically included in products with natural or synthetic active pesticide ingredients recommended by the National Organic Standards Board (NOSB) and listed by the National Organic Program (NOP) on the National List of Allowed and Prohibited Substances (Shistar, T. “Inert” Ingredients Used in Organic Production, Beyond Pesticides, Washington, D.C., 2017).”

Manufacture

Since this listing covers many different materials, the manufacture of these substances cannot be specifically stated.

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2

(Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

- Formulants (inerts, excipients) shall be used in conjunction with substances listed in Table 5.3. Formulants are not subject to 1.4 or 1.5 of CAN/CGSB-32.310 or 5.1.2 of this standard (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.2. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 8.2. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.3. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or are non-synthetic may be used with substances in Table 8.3. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.3 – Post-harvest substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation: (a) safeners, synergists, and co-formulants as components of plant protection products; (b) adjuvants that are to be mixed with plant protection products (General production rules, EC No. 2018/848).
- In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists, and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848 (Annex I: Active substances contained in plant protection products authorised for use in organic production, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Inerts are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Organic crop production ensures that co-formulants (e.g. inerts and synergists) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins (Crop Production, IFOAM NORMS 2014).
- Recommendation: In case operators need to use commercial formulated inputs, preference should be given to formulations approved for use in organic agriculture by a specialized organic material review organization/program (Pest, Disease, and Weed Management, IFOAM NORMS 2014).
- Any formulated input shall have only active ingredients listed in Appendix 3. All other ingredients shall not be carcinogens, teratogens, mutagens, or neurotoxins (Pest, Disease, and Weed Management, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Inerts are not explicitly mentioned in the regulations.

Human Health and Environmental Issues

As noted below, some of the materials listed on EPA List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of these substances and their potential environmental issues is not possible without technical reports of each substance.

Discussion

Inerts are not necessarily biologically or chemically inert. They may be relatively benign or may be documented as harmful to the environment or human health. Without a way to individually evaluate each substance listed on EPA List 4 or to evaluate substances as a group, it is difficult to discern the acceptability of each substance for use in organic agriculture.

Presently, § 205.601(m) of the National List references the EPA List 4 – Inerts of Minimal Concern as acceptable in organically-approved pesticide formulations. List 4, however, is outdated and no longer maintained by EPA. The list of inerts that is referenced for review of products for organic certification was last updated in August 2004 (<https://www.epa.gov/pesticide-registration/epas-national-organic-program-guidance>) and may include materials that some stakeholders believe are inappropriate for organic agriculture. For example, nonylphenol ethoxylates (NPEs) are included on List 4. These materials are endocrine disruptors, may adversely impact fauna and flora, and have been identified by the California Department of Toxic Substances Safer Consumer Products program as a likely high priority chemical that should be formally phased out. If evaluated on an individual basis, NPEs would likely not meet OFPA criteria for acceptability.

The NOSB and NOP have struggled with how to evaluate the EPA List 4 – Inerts of Minimal Concern during sunset review. OFPA has specific criteria for inerts which states: “(ii) ... contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern” (§6517 C.1.B.ii). Due to EPA changes in its categorization of inerts and discontinued support for List 4, the NOSB (starting in 2010) adopted a series of recommendations to revise this sunset listing.

Most recently, USDA’s Agricultural Marketing Service (AMS) published an Advance Notice of Proposed Rulemaking (ANPR) incorporating several of these recommendations on September 2, 2022, which received extensive stakeholder feedback on updated references for inert ingredients in organic production. Based on that feedback, the NOP requested that the NOSB evaluate four options for updating the National List. The NOSB recommended two options, plus a hybrid combination of those two options, at the Fall 2024 meeting. At the time of this review, the NOP is moving forward with the rulemaking process based on this recommendation.

The National List motions, approved and recommended by NOSB in Fall 2024, are shown with changes from current language:

Motion to add individual substances identified in Appendix A] at 205.601(m)

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

~~(1) EPA List 4 Inerts of Minimal Concern~~

- ~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) ...

Motion to add individual substances identified in Appendix A at 205.603(e)

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- ~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) ...

OR

Motion to amend 205.601(m)

(m) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:

- ~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances

Motion to amend 205.603(e)

(e) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:

- ~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances
(3) ...

Stakeholder comments from the Fall 2025 meeting were mostly in favor of relisting List 4 Inerts for veterinary use. The NOSB expects the NOP to implement changes to the current listing based on the Board's Fall 2024 recommendation. Therefore, keeping List 4 Inerts on the National List at this time will not hinder a new NOP rule. In the meantime, in order to maintain continuity in formulations used by organic farmers, we recommend that List 4 Inerts be relisted at § 205.603(e).

Justification for Vote

The NOSB finds EPA List 4 Inerts compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

NOSB Vote

Motion to remove EPA List 4 Inerts from the National List

Motion by: Brian Caldwell

Seconded by: Nate Lewis

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Excipients

Reference: §205.603(f) Excipients—only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

- (1) Identified by the FDA as Generally Recognized As Safe;
- (2) Approved by the FDA as a food additive;
- (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or
- (4) Approved by APHIS for use in veterinary biologics.

Technical Report: [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: 10/2002 NOSB minutes and vote; [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 12/27/2018 ([83 FR 66559](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

There are more than 8,000 food, drug, and cosmetic excipients available for conventional production; however, excipients currently appear in the USDA National Organic Program (NOP) regulations at §205.603 for use in the manufacture of drugs used to treat organic livestock when the excipient is identified by the FDA as: 1) Generally Recognized As Safe (GRAS); 2) approved by the FDA as a food additive; 3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or 4) Approved by APHIS (Animal and Plant Health Inspection Service) for use in veterinary biologics. Additionally, excipients are allowed in nutritive supplements, which is listed at §205.603(a)(21).

Excipients are defined in §205.2 as any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Excipients are used in New Animal Drug Applications (NADAs) approved by FDA, and in animal health care products that do not carry NADA registration. They are also used in New Drug Applications (NDAs) in drugs marketed for human consumption that may be administered to animals [2015 TR, lines 38-41].

Excipients are used for a great number of applications in animal drug and health care products but are delineated into broad categories based on the major reasons the excipient is used [2015 TR, lines 75-77]. Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents (§205.2).

Manufacture

Excipients are common in almost all therapeutic products for veterinary use, and, in some cases, the total amount of excipients used is greater than the active substances in the dose. They are derived from natural sources or are synthetically manufactured by chemicals, derived from genetically modified organisms, or manufactured by other means. They range from simple, whole food products to highly characterized organic and inorganic molecules, to complex materials that are difficult to fully characterize chemically [2015 TR, lines 46-50].

Excipients can be added to the active substance individually or together in a formulated excipient package, depending on the drug. Excipients serve many functions but are typically comprised of suspending and viscosity-modifying agents, pH modifiers and buffering agents, preservatives, antioxidants, chelating agents, sequestrants, colorants, flavors, fillers, and diluents. While it is clear the functions that excipients serve, very few of them have been chemically described in any detail [2015 TR, lines 51-55].

Because excipients are manufactured for a wide variety of purposes, the source and origin are highly variable. They range from whole food products, such as wheat middlings and yeast, to synthetic food additives such as sodium benzoate and sodium lauryl sulfate. They may be agricultural, non-synthetic, or synthetic. Some are extracted or produced from plants, animals, minerals or microorganisms, and others are manufactured entirely from chemicals [2015 TR, lines 60-64].

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2 (Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Formulants (inerts, excipients) shall be used in conjunction with substances listed in Table 5.3. Formulants are not subject to 1.4 or 1.5 of CAN/CGSB-32.310 or 5.1.2 of this standard (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.2. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 8.2. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.3. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or are non-synthetic may be used with substances in Table 8.3. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or

1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.3 – Post-harvest substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- Excipients are not explicitly mentioned in the regulations.

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

- Excipients are not explicitly mentioned in the regulations.

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

- Excipients are not explicitly mentioned in the regulations.

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

- Excipients are not explicitly mentioned in the regulations.

Environmental Issues

The primary mechanism through which excipients appear in the environment is via manure application to cropland. There is little known about the actual effects, adverse or not, on the environment from excipients. Only a handful of studies have even identified the presence of specific excipients in the environment, while most studies focus on pharmaceuticals without making a distinction between active and excipient ingredients. Since most excipients used in organic livestock production are GRAS or FDA-approved food additives, the potential for environmental and human health effects has been evaluated by the FDA as part of their legal status. No literature was found to show definitive harmful effects on the environment when excipients are used in animal health care products [2015 TR, lines 542-552].

On the other hand, there are environmental concerns related to the manufacture of excipients. Because of the great variety of substances permitted for use as excipients and the methods of manufacture, some of the excipients could have detrimental environmental effects. Raw material extraction of petroleum products, solvents, and mined minerals pose negative environmental effects; the FDA has gone as far as recommending that the pharmaceutical industry avoid certain solvents (e.g., benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethane, 1,1,1-trichloroethane) that pose exceptional environmental and human health risks. Further processing of certain ingredients, like starches and starch derivatives, can lead to environmental degradation, air pollution, and exploitation of resources. A great number of excipients may be derived from GMOs, i.e., soy, corn, cotton, etc. [2015 TR, lines 554-563].

Health Issues

There is no literature to indicate specific human health effects through the use of excipients in livestock healthcare products, but there is significant literature that shows certain excipients can have detrimental and even lethal consequences when administered directly to human beings, especially infants [2015 TR, lines 571-573]. This is one reason the FDA assesses the safety of excipients as part of each NADA application, rather than individually in a separate program. New excipients undergo a series of preclinical tests recommended by FDA and the International Pharmaceutical Excipients Council that includes acute oral and dermal toxicity, teratology, genotoxicity assays, and skin sensitization studies in rodents. These tests may be conducted on the excipient in combination with the active ingredient, or as a stand-alone ingredient [2015 TR, lines 581-586].

The most likely route of exposure of humans to excipients in animal drugs is through consumption of residues in milk and meat products of treated animals. Most of the research on contamination has focused

on traces of antibiotics, but formulations specifically allowed in §205.603 can also appear in milk and meat [2015 TR, lines 589-592]. Presumably, both the active ingredient and the excipients are cleared from commercial products by the withdrawal times dictated by the NOSB on the active ingredients [2015 TR, lines 594-595]. However, since the majority of excipients used in organic livestock production are GRAS or food additives, the FDA assessment would include human and animal effects of ingestion of such ingredients, including their metabolism and breakdown pathways. Adulterated excipients pose some potential risk to human health; as a result, the FDA identified a partial list of excipients and active ingredients that may also be adulterated and need further testing [2015 TR, lines 608-613, 615-617].

Discussion

Stakeholder comments from the Fall 2025 meeting were mixed about whether excipients should remain on the National List. Most agreed that the approach to evaluating excipients needs to be fully reviewed and that there are some inconsistencies among certifiers. Some questioned whether the OFPA criteria are fully met via the allowances in the annotation. Others cited satisfaction with the current certifier review process; the fact that except for teat dips, excipients are administered infrequently and in small amounts; and that removal would greatly decrease the number of allowed veterinary treatments available to organic producers.

The NOSB recognizes the difficulty of identifying and reviewing all of the excipients currently in use, as well as the disruption to organic livestock farms, distributors, and consumers that would result from delisting. The Board would like to see how the rulemaking for inert pesticide ingredients plays out, and then tackle excipients with an analogous approach. In the meantime, the Board recommends relisting excipients.

Justification for Vote

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

NOSB Vote

Motion to remove excipients from the National List

Motion by: Brian Caldwell

Seconded by: Amy Bruch

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.

(a) Strychnine

Technical Report: None

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#) (crops only); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2020 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/21/2017 ([82 FR 14420](#)); Sunset renewal notice published 08/03/2021 ([86 FR 41699](#))

Sunset Date: 3/15/2027

NOSB Review

Use

Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It is colorless, odorless, and has a bitter taste. It was widely used in poison (toxic) baits to kill rodents and other mammals and is a common adulterant of many illicit (street) drugs. Exposure to strychnine can be fatal.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts quickly to produce muscular hyperactivity, which can rapidly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I by the EPA, indicating the greatest degree of acute toxicity for oral and ocular effects; inhalation toxicity is also presumed to be high ([EPA Prevention, Pesticides, and Toxic Substances](#), 1996).

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control pocket gophers, which can cause structural damage ([USDA-APHIS-Wildlife Services](#), 2023; [EPA Prevention, Pesticides, and Toxic Substances](#), 1996).

Manufacture

The primary natural source of strychnine is extraction from the strychnine tree, *Strychnos nux-vomica*. This plant is found in southern Asia (India, Sri Lanka, and East Indies) and Australia.

International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

- Strychnine is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)

- Strychnine is not explicitly mentioned in the regulations.

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

- Strychnine is not explicitly mentioned in the regulations.

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

- Strychnine is not explicitly mentioned in the regulations.

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

- Strychnine is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

According to the Environmental Protection Agency (EPA), acute toxicity of strychnine to birds is assumed to be very high. Subacute dietary data indicates that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds that are subject to repeated or continuous exposure from spills ([EPA Prevention, Pesticides, and Toxic Substances](#), 1996).

Mammalian studies indicate that strychnine is highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, can occur within one hour. Acute freshwater fish

data reveals that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicates that strychnine is moderately toxic to aquatic invertebrates ([EPA Prevention, Pesticides, and Toxic Substances](#), 1996).

Discussion

Subcommittee discussions on strychnine were very brief. The entire Subcommittee expressed the need to keep this substance on the list of prohibited materials. This view is consistent with public comments received at the 2025 Spring meeting. A commenter noted that strychnine is highly acutely toxic and has been found to be responsible for secondary poisonings. The commenter emphasized the fact that people affected by strychnine poisoning are not likely to survive. It was stated that although all animals are susceptible, birds are particularly sensitive to the toxic effects of strychnine. Public comments also included bird species in Michigan that are poisoned by strychnine. The list includes rock dove, cardinal, Canada goose, dark-eyed junco, mallard duck, common grackle, blue jay, and house sparrow. It was pointed out that strychnine's toxic properties, and the fact that there are numerous alternative materials and practices, make the use of this substance unnecessary.

Justification for Vote

The NOSB finds the prohibition of strychnine at §205.604 compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal of its prohibited status.

NOSB Vote

Motion to remove strychnine from the National List

Motion by: Franklin Quarcoo

Seconded by: Amy Bruch

Yes: 0 No: 12 Abstain: 0 Recuse: 0 Absent: 3

Motion Failed