Sunset 2017 Review
Meeting 2 - Review
Livestock Substances §205.603, §205.604
October 2015

As part of the National List Sunset Review process, the NOSB Livestock Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic livestock production.

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

Alcohols: Ethanol
Alcohols: Isopropanol
Aspirin
Atropine
Biologics, Vaccines
Butorphanol
Chlorhexidine
Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Electrolytes
Flunixin
Furosemide
Glucose
Glycerin
Hydrogen peroxide
Iodine
Magnesium hydroxide
Magnesium sulfate
Oxytocin
Parasiticides: Fenbendazole
Parasiticides: Ivermectin
Parasiticides: Moxidectin
Peroxyacetic/Peracetic acid
Phosphoric acid
Poloxalene
Tolazoline
Xylazine
Copper sulfate
Formic Acid
Iodine
Lidocaine
Lime, hydrated
Mineral oil
Procaine
Sucrose octanoate esters
Methionine
Trace minerals
Vitamins
EPA List 4 - Inerts of Minimal Concern
Excipients

Livestock 205.604 Prohibited nonsynthetic substances

Strychnine

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Alcohols - Ethanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive

Technical Report: 1995 TAP; 2014 TR Ethanol

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

Ethanol is a volatile, flammable, colorless liquid. Its use in organic livestock production is limited to use as a disinfectant and sanitizer and is prohibited as a feed additive. It is an active ingredient in antimicrobial solutions and in wipes, and is commonly used to disinfect surfaces, production implements such as ear tagging equipment, and for wound care. Alcohols, including ethanol and isopropanol, are capable of providing rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores.

For denatured alcohol, one or more denaturing agents are generally added to absolute or diluted ethanol for the purpose of making the resulting products unpalatable and therefore undesirable for human consumption. In addition to methanol, some of the more commonly used alcohol denaturants include 1–5 percent of isopropyl alcohol, acetone, methyl ethyl ketone, methyl isobutyl ketone, and denationium. This attribute allows denatured alcohol to remain exempt from the duty requirements of beverage grade alcohol.

The majority of authorized denaturants are synthetic substances that are not included on the National List. Denaturing agents derived from natural sources could be used to generate denatured alcohol solutions for applications in organic livestock production. Authorized denaturing agents that are naturally derived include essential oils (Bergamot essential oil, cinnamon oil, clove oil, lavender oil, peppermint oil, pine oil, rosemary oil, sassafras oil, spearmint oil, thyme oil, and turpentine oil). Naturally derived substances and pure chemicals, such as camphor, eugenol, menthol, and vinegar, are also listed as authorized denaturants. In addition, the following synthetic substances authorized by FDA as denaturing additives are currently listed on various sections of the USDA National Organic Program's National List:

- **Iodine.** Approved for use in organic livestock production as a disinfectant, sanitizer, and medical treatment. May also be used as a topical treatment, external parasiticide or local anesthetic (7 CFR 205.603(a)(14) and (b)(3)).
- **Isopropanol.** Approved for use in organic crop production as an algicide, disinfectant, and sanitizer, including irrigation system cleaning systems (7 CFR 205.601(a)(1)(ii)). Also approved as a disinfectant only in organic livestock production (7 CFR 205.603(a)(1)(ii)).

- **Potassium Iodide.** Nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic” (7 CFR 205.605(a)).

During the first 2017 Sunset posting for this material, the LS sought feedback on the following questions:

1. Please provide any information regarding the denaturing material typically used in ethanol used in organic livestock production.
2. What are the most common uses of this material?

Public feedback was limited, but was overwhelmingly in favor of continued listing for ethanol. The most common uses listed were for disinfection of the teat end prior to testing for bacteria and for general disinfecting.

While there are several alternatives to this material, ethanol is relatively harmless and provides an additional means of disinfecting, thereby reducing the chances of development of resistant bacteria. The LS is supportive of continued listing of this material.

Motion to Remove

This proposal to remove ethanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ethanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion to remove ethanol from §205.603(a)
Motion by: Tracy Favre
Seconded by: Jean Richardson

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

Alcohols – Isopropanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(1)(ii) Isopropanol-disinfectant only

Technical Report: 1995 TAP; 2014 TR Isopropanol

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

The National Organic Standards Board (NOSB) reviewed isopropanol for livestock production in

accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(1)(ii). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Isopropanol meets all the evaluation criteria.

The framework for the recommendation for relisting is inclusive and consistent with the current information provided in the new isopropanol technical evaluation report (henceforth called TR) of February 3, 2014, the 2015 public written and oral comments, and NOSB 2010 action pertaining to this valuable and essential material. The TR states that the body of evidence indicates that fermentative methods using either natural or genetically modified microorganisms are not currently employed in the commercial production of isopropanol. No agricultural land grant agricultural extension publication repositories contained articles or reports related to the practice of using essential oils as disinfectants or any performance data for these oils relative to isopropanol. Thus, it is therefore uncertain whether essential oil mixtures could serve as viable, naturally derived alternatives to isopropanol-based products for equipment and surface disinfection in livestock production. Isopropanol is allowed by the international organic associations such as the International Federation of Organic Agricultural Movements (IFOAM) and Canadian General Standards Board (CGSB).

It was noted during the spring of 2015 written public comment period, 10 organizations and individuals commented. The dissenting views expressed concern about the environmental effect of isopropanol manufacturing process. The support for and against relisting isopropanol, was 80% and 20%, respectively. Those in support relisting isopropanol included the premier organic trade organization, consumer groups, certifying organizations, a premier food safety group, individuals, environmental, organic businesses, and farmer groups. Isopropanol is used as a disinfectant only. In addition, the recent 2014 TR for isopropanol showed that this material posed minimal risk. No report of the release of this material has been reported according to the 2015 TR on isopropanol as stated on lines 361-365, 475-476, and lines 478-484. No new scientific or sufficient information was presented that warrants removal of this material during the 2017 sunset. NOSB voted unanimously in 2010 to retain this critical and valuable material on the National List (NL). We encouraged new and/or scientific information that warranted consideration for subsequent sunset.

Motion to Remove

This proposal to remove isopropanol from §205.603(a)(1)(ii) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont. The subcommittee proposes removal of isopropanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Impact on the environment.

Vote in Subcommittee

Motion to remove Isopropanol from §205.603
Motion by: Calvin Walker
Seconded by: Jean Richardson
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Aspirin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(2) Aspirin-approved for health care use to reduce inflammation

Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/15

Subcommittee Review

Aspirin has been known and used in medicine for over 100 years. It is widely used as an anti-inflammatory, and to reduce fever and pain. Its half life is short in cattle and it is not as beneficial in reducing pain as flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency.
Aspirin is widely used and supported by stakeholders and should continue to be listed.

This material satisfies the OFPA Evaluation criteria.

Motion to Remove
This proposal to remove Aspirin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee

Motion to remove Aspirin from §205.603
Motion by: Jean Richardson
Seconded by: Tracy Favre
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Atropine

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

(3) Atropine (CAS #-51-55-8) - 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:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for

slaughter; and a milk discard period of at least 12 days after administering to dairy animals

Technical Report: 2002 TR

Petition(s): 2002

Past NOSB Actions: 05/2003 NOSB recommendation; 04/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/24/17

Subcommittee Review

Atropine is an anti-cholinergic derived from the plant atropa belladonna (deadly nightshade). For commercial veterinary uses it is synthetically derived. It is a highly controlled substance, administered under orders of a veterinarian; generally given orally as an antidote for organophosphate poisoning and as an antispasmodic. The TR describes it as a benign treatment without a holistic or natural alternative.

The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI). Atropine is considered an essential treatment of nerve agent poisoning. Public comment indicates its continued listing.

Motion to Remove

This proposal to remove Atropine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Atropine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee

Motion to remove Atropine from 205.603

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

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

Biologics - Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(4) Biologics – Vaccines.

Technical Report: 2014 TR (Aquaculture); 2011 TR (Vaccines from Excluded Methods)

Petition(s): 2012 Petition (Aquaculture)

Past NOSB Actions: 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation on Vaccines at §205.105; 04/2010 NOSB sunset recommendation; 10/2014 recommendation on Vaccines from Excluded Methods

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

Vaccines – Biologics – have been reviewed by the NOSB at Sunset and on several occasions over the

years. Reference is made to the most recent Proposal and Recommendation to the NOP from the NOSB dated August 19, 2014.

The USDA organic regulations at 7 CFR part 205 contain several references that are relevant to the discussion on the use of vaccines in organic livestock production.

The first reference, under the "Livestock healthcare practice standard", requires that "the producer must establish and maintain preventive healthcare practices, including… administration of vaccines and other biologics" (205.238(a)(6)).

The second reference on the National List of Allowed and Prohibited Substances allows the use of synthetic livestock vaccines as follows: "Biologics – Vaccines." (205.603(a)(4)) (without annotation).

The third reference at section 205.672 deals with emergency pest or disease treatment which is defined in section 205.2 as a "mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease." The OFPA Statute (7 U.S.C. 6506(b)(2)) refers to exemptions for organic "farms subject to a Federal or State emergency pest or disease treatment program," suggesting that Congress did not intend to include locally declared programs. In the past, vaccines made with excluded methods have been required as part of disease eradication programs. It is unclear as to the effects of these eradication programs on organic livestock producers.

The fourth reference is found within section 205.105 of the USDA organic regulations, "Allowed and prohibited substances, methods, and ingredients in organic production and handling":

> To be sold or labeled as "100 percent organic", "organic," or "made with organic (specified ingredients or food groups)", the product must be produced or handled without the use of…
>
> (e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with 205.600(a).

Section 205.600(a), "Evaluation criteria for allowed and prohibited substances, methods and ingredients" specifies:

> The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:
>
> 205.600(a) Synthetic and nonsynthetic substances considered for inclusion on, or deletion from, the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

Thus, under this section (205.105(e)), the use of excluded methods is prohibited in organic production. To date, the NOSB has not recommended any vaccines made with excluded methods be added to the National List.

Vaccines are critical for the prevention of disease and to prevent needless suffering of livestock. Organic

livestock cannot be treated with antibiotics and maintain their organic status.

Public Comment strongly supports continuing to re-list Biologics-vaccines.

Motion to Remove
This proposal to remove Biologics-vaccines will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Satisfies OFPA criteria

Vote in Subcommittee

Motion to remove Vaccines from §205.603
Motion by: Jean Richardson
Seconded by: Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 TR
Petition(s): 2002 Petition
Past NOSB Action :s 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
The National Organic Standards Board (NOSB) reviewed butorphanol for use in livestock production as a pre-operative treatment of pain before surgery in accordance with criteria in the Organic Foods Production Act (OFPA), 7 Code of Federal Regulation (CFR) §205.603(a), the 2002 technical advisory panel (TAP), past NOSB actions, and 2015 public comments. No new nor scientific information has been received that warrants removal of this material from the national list (NL) at this time.

Impacts of manufacture of butorphanol are unknown (TAP p25.) Butorphanol is used by 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 accepted practice (TAP pp19, 25). There is a potential for abuse of butorphanol. "Metabolites of the drug can cross the placenta and pass into the mammary gland and into milk" (TAP pp20, 25, 26, 28.)
As it relates to essentiality, the TAP states, "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, merperidine, 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" (TAP p24.) 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; it has less abuse potential in humans thereby reducing unwanted consequences if the drug is "diverted" to illicit use." Butorphanol is used for livestock to ease pain just prior to surgery.

Butorphanol has been FDA approved for use as an anesthetic in non-food animals. Its use in food animals is an extra-label use (ELU) governed by the Animal Medicinal Drug Use Clarification Act, which allows animal drugs to be used for ELUs when, "limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat." The material must be administered by a licensed veterinarian. If all precautions are followed and the drug is administered appropriately, the NOSB judged that there will be no harm done to humans who consume the meats from these animals—and the livestock are able to tolerate surgery, recover quickly, and grant the farmer economic satisfaction, according to the 2002 TAP review of butorphanol.

The withdrawal periods for butorphanol in the organic regulations are twice those in the Food Animal Residue Avoidance Databank (FARAD). FARAD is a university-based national program that serves as the primary source for scientifically-based recommendations regarding safe withdrawal intervals of drugs and chemicals in food-producing animals. From the FARAD website (http://www.farad.org/eldu/eldumain.asp):

> According to AMDUCA, veterinarians who treat food animals with drugs in an extra-label manner must use evidence ***"...derived from food safety data or other scientific information..."*** in order to determine an appropriate withdrawal interval (WDI) that allows for a conservative estimate of drug residue level in edible animal tissues. Based on published scientific reports and population-based pharmacokinetic modeling, FARAD has developed a WDI Lookup Tool that provides recommended WDI values for a limited number of approved food animal drugs used in an extra-label manner.
> **IMPORTANT NOTE:** The withdrawal interval (WDI) is a scientifically-derived recommended withholding time for a drug following its extra-label use in a food animal. The WDI is distinct

from the official withdrawal time (WDT) for a drug. WDTs are established by the FDA for all approved (labeled) uses of food animal drugs and can be located in VetGRAM or at the FDA Center for Veterinary Medicine.

The TAP states, "European Union: Butorphanol tartrate is included as an Annex II type drug (Reg. 1076/98). This means that it is permitted for use in veterinary medicine as of January 1, 2000." (p. 17) However, it is listed for equine species (Commission Regulation (EU) No 37/2010), and EU law permits extra-label use (cascading use) only "provided that the medicinal product , where administered to animals whose flesh or products are intended for human consumption , contains only substances to be found in a veterinary medicinal product authorized for such animals in the Member State concerned and that in the case of food-producing animals the veterinarian responsible specifies an appropriate withdrawal period to ensure that food produced from the treated animals does not contain residues harmful to consumers." (Council Directive 90/676/EEC).

The NOSB judged butorphanol to be consistent with consumer perceptions of organic products. The NOSB's 2002 votes were 11 favored, 1 absent, and 2 abstained and the NOSB's 2010 vote was unanimous to retain this material on the NL.

Comments received generally supported the continued listing of butorphanol. Two dairy organizations, one dairy cooperative, and one former NOSB member commented in favor of continued use. One organization requested that the LS determine the impacts of the metabolites of butorphanol in milk and when excreted; and determine the legality of the use under AMDUCA, since labels prohibit the use in food-use animals. With regard to the legality of the use and the presence of butorphanol and its metabolites in milk, USDA did determine that butorphanol is listed in the Food Animal Residue Avoidance Databank (FARAD), and the listed meat withdrawal and milk discard times are twice those listed in FARAD (2007 FR Notice). With regard to the impacts of the excreted metabolites, the TAP review did not consider them problematic.

However, reliance on AMDUCA's exemption of ELUs can be problematic (Wren, 2008), and the Livestock Subcommittee encourages the Food and Drug Administration to address these uses directly through labeling.

References Cited

NOSB, 2002. Summary of Minutes: National Organic Standards Board, September 17-19, 2002. Washington, D.C.

TAP. 2002. Butorphanol (Livestock).

Geni Wren, 2008. Options for Pain Management. Bovine Veterinarian. https://ahdc.vet.cornell.edu/Sects/NYSCHAP/docs/BovineVetpain01-08.pdf

USDA, 2007. National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Livestock). Federal Register Vol. 72, No. 238, Wednesday, December 12, 2007, pp.70479- 70486.

Council Directive 90/676/EEC Of 13 December 1990 amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31990L0676
Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf

Motion to Remove
This proposal to remove Butorphanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Butorphanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion to remove Butorphanol from §205.603
Motion by: Jean Richardson
Seconded by: Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Technical Report: 1999 TAP; 01/2010 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
In 2009, the NOSB recommended chlorhexidine be added to the National List as a teat dip for use when alternative teat dips have lost their effectiveness. Chlorhexidine kills bacterial cells by damaging cell membranes and precipitation of cytoplasmic proteins and macromolecules.

Chlorhexidine is mildly to moderately toxic to mammals in oral, dermal and inhalation exposure (2015 TR lines 314-315) and is an eye irritant (line 324) and pulmonary toxicant (line 318). However, “chlorhexidine teat dips are typically used in small amounts, at low concentrations (e.g., 0.5%) and under relatively controlled conditions” (TR lines 365-366), which limits exposure concentration.

For the first round of public comments, the subcommittee asked "Have you used chlorhexidine as a teat dip? If so, why did you need to use it?" No comments were received in answer to those questions. Several general comments were received recommending that chlorhexidine should remain on the National List. There were no comments suggesting that chlorhexidine be removed from the List.

Motion to Remove

This proposal to remove chlorhexidine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of chlorhexidine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

Vote in Subcommittee

Motion to remove Chlorhexidine from §205.603(a)
Motion by: Francis Thicke
Seconded by: Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Chlorine materials

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

Technical Report: 2006 TR
Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

Specific Uses of the Substance:

Sodium and Calcium Hypochlorite

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems.

Chlorine Dioxide
Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a).

Bleach materials are currently used for disinfection of livestock facilities.

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

Discussion: The NOSB in its initial request for public comment asked:
1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?

2. Are all three chlorine materials needed for use in livestock production?

The NOSB Livestock committee did not receive specific answers to the above questions. The majority of the comments about chlorine materials were form letters opposing any chlorine use in organic production and non-form letter comments were primarily related to the Crops and Handling Committees.

Several commenters opposed to the relisting stated:

- They are concerned about the NOP clarification on the use of chlorine, which allows for a higher concentration than allowed in the Safe Water Drinking Act to be used in wash tanks. They were especially concerned about organic food products that could absorb the higher concentration of chlorine into the food. They stated that poultry, eggs, leafy vegetables, root crops and more could absorb highly chlorinated water and the final effluent after the wash tank could still only contain the required 4 PPM. To address this concern, they suggested the annotation for chlorine be amended to the following: Chlorine materials, only as present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. They further went on to say that the use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the

wash water.

- There is a growing unease that we (commenters) share about the need to eliminate chlorine from organic disinfection processes because of concerns about its efficacy on the produce and about the environmental and health risks associated with the formation of carcinogenic halogenated disinfection by-products.

Several commenters in support of relisting stated:

- Calcium hypochlorite, chlorine dioxide, sodium hypochlorite: these materials are so basic to hygienic, sanitary livestock keeping that no further comment is needed. To do away with chlorine (as well as iodine, hydrogen peroxide and other germicides) would do permanent damage and harm to the organic livestock industry.
- Chlorine Materials (Calcium hypochlorite, sodium hypochlorite, chlorine dioxide): These chemicals are used in the industry for sanitization and their incorporation is required for food safety per the Pasteurized Milk Ordinance. Our partners in dairy production and in our member farms choose chlorine materials often as the preferred sanitizer for food contact surfaces. Disallowing sodium hypochlorite, calcium hypochlorite and chlorine dioxide would have a profound effect on the dairy industry. We support the continued listing of Chlorine Materials on the National List.
- Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite – The use of these products in disinfecting and sanitizing facilities and equipment is critical to the health of the animals and humans.
- Chlorine products are required by the Federal Government via the Pasteurized Milk Ordinance (PMO) that governs the cleaning of milkhouse equipment on dairy farms shipping milk. To sanitize and sterilize both calf feeding and milking equipment (bottles, nipples, buckets, milking pipeline, receiver jar, bulk tank, etc.)

While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation. There are also specific requirements to use chlorine above the 4ppm SDWA limit in several commodity specific industries. For example, The Pasteurized Milk Ordinance states that the product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of Chlorine Materials.

Motion to Remove

This proposal to remove Chlorine Materials will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of these materials from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee
Motion to remove chlorine materials from (Calcium hypochlorite, Sodium hypochlorite, Chlorine dioxide) 205.603(a)
Motion by: Ashley Swaffar
Seconded by: Jean Richardson
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(8) Electrolytes—without antibiotics
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation, 04/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
The National Organic Standards Board (NOSB) has reviewed electrolytes for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(8) – without antibiotics. The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. It is the NOSB-LS view that electrolytes meet the above evaluation criteria and should not be removed from the National List.

Historically speaking, electrolytes have been recommended for relisting based on the material compatibility as recommended by the technical advisory panel (TAP) of October 1995 and the unanimous NOSB 2010 support of this material. Electrolytes are being used to prevent or treat dehydration with resulting loss of minerals. Also, electrolytes provide minerals and sugars lost in dehydration. The annotation for electrolytes is that it *must not* contain antibiotics. On April 29, 2010, NOSB voted 14 yes, 0 no, 0 abstain, and 1 absent for this material. The most recent Technical Evaluation Report (TR) on March 20, 2015 provided a detail overview of electrolytes use. Also, the 2010 OMRI Generic Material List, states that electrolytes are substances such as potassium, calcium, magnesium, and sodium that are essential to metabolic functioning. Electrolytes are important in the care of animals to prevent dehydration and animals suffering from diarrhea, anorexia or the inability to absorb fluids from the digestive tract (OMRI 2010). In essence, electrolytes are only to be used when preventive practices and veterinary biologics are inadequate these type of conditions or illnesses. They may not be used in the absence of an illness.

The 2015 public comments are overwhelmingly in support the relisting of this material. No new scientific or meritorious information has been brought forth since the last 2010 sunset review to warrant the

removal of this material. During the last sunset review by NOSB in 2010, the material was unanimously supported for relisting on the national list (NL) without any annotation or change, except that any electrolytes must not contain any antibiotics.

During the spring of 2015 public comment period, eight organizations and individuals (67%) supported the relisting, three were neutral (25%), and one individual did not support (8%) the relisting of electrolytes. Those in support included a food safety organization, consumer groups, a cooperative, individuals, etc. The one that was against did not support electrolytes due to the material being a synthetic. The three organizations remain neutral on the material. Thus, in the final analysis, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

References

1. http://www.omri.org/sites/default/files/Newsletter_Summer_2010.pdf

Motion to Remove

This proposal to remove Electrolytes will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Electrolytes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee

Motion to remove Electrolytes from 205.603(d)(8)
Motion by: Calvin Walker
Seconded by: Jean Richardson
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Flunixin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(9) 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 Report
Petition(s): N/A

Past NOSB Actions: 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

Specific Uses of the Substance:
Flunixin is used mostly for veterinary purposes as an analgesic and an anti-inflammatory drug. It persists in inflammatory tissues and is associated with anti-inflammatory properties which extend beyond the period associated with plasma drug concentrations. This has to do primarily with flunixin's counterclockwise spin of light absorption.
Flunixin meglumine, in its drug form, exists for intravenous or intramuscular use in horses and for intravenous use in beef and dairy cattle Flunixin 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, flunixin has been used to reduce inflammation associated with endotoxemia.

Approved Legal Uses of the Substance:
OFPA states in Sec. 6509(d):
(d) **Health Care**.

(1) **Prohibited Practices**. For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not

(A) use subtherapeutic doses of antibiotics;
(B) use synthetic internal paraciticides on a routine basis; or
(C) administer medication, other than vaccinations, in the absence of illness.

Flunixin is often used by veterinarians to treat inflammation and pain.
Discussion: The NOSB in its initial request for public comment asked:

In the event the NOSB votes to remove flunixin from the National List, would aspirin serve and a replacement? If not, why not?

Several commenters in support of relisting stated:

- This is an NSAID (non-steroidal anti-inflammatory drug) related to aspirin, but about 100 times as strong. It is injected and can bring pain relief, fever reduction and keep inflammation in check within a very short time. Often times animals will start to eat again within 30 minutes – this is good for if an animal will start to eat again, it often can "eat its way" out of a problem. It is a critically important material in veterinary medicine. Aspirin would not come close to replacing it. Flunixin is far superior in relieving abdominal pain due to colic and other digestive disturbances.
- Specific comments describing the use of this substance on organic farms: On rare occasions, prescribed by a vet for an acute situation with one of our cows. Specific comments regarding the availability and efficacy of alternatives: Most potent anti-inflammatory available for organic livestock. Don't know of any other available as powerful.
- Flunixin is a nonsteroidal anti-inflammatory (NSAID) drug used for the treatment of pain, inflammation, and pyrexia (fever). This drug contributes significantly to the comfort and welfare of ill or injured animals. It remains an important analgesic with properties different from those of other available drugs. We support the continued listing of Flunixin on the National List.

There were no comments received opposing the relisting of flunixin. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of flunixin.

Motion to Remove
This proposal to remove flunixin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of flunixin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 0 No: 4 Abstain: 1 Absent: 1 Recuse: 0

Furosemide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(10) Furosemide (CAS #-54-31-9)—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 that required by the FDA
Technical Report: 2003 TR
Petition(s): 2002 Petition
Past NOSB Actions: 05/2003 NOSB recommendation for addition to the National List; 10/2010 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

Specific Uses of the Substance:
"Furosemide is a diuretic. It has been used extensively since 1964 in the treatment of edema and hypertension." "This medicine is used to rid the body of excess fluid (salt and water). Patients who frequently have this problem are ones with weakened hearts (congestive heart failure), poor kidney function, or poor liver function. It can be used to reduce blood pressure in these patients." (2003 TR, pg. 4.)

Clinical Uses:

- Major uses: acute pulmonary edema, acute hypercalcemia, management of edema
- Other uses: reduction of intracranial pressure, hyperkalemia: loop diuretics increase potassium

excretion and effect increased by concurrent administration of NaCl and water, acute renal failure: may increase rate of urine flow and increase potassium excretion, may convert oligouric to non-oligouric failure {easier clinical management}and renal failure duration -- not affected, anion overload: bromide, chloride, iodide: all reabsorbed by the thick ascending loop: systemic toxicity may be reduced by decreasing reabsorption, concurrent administration of sodium chloride and fluid is required to prevent volume depletion

International:
IFOAM: not specifically mentioned in approved list
JAPAN: not specifically mentioned in approved list
EUROPEAN UNION: not specifically mentioned in approved list

Discussion: The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on furosemide.

Comments in support of relisting stated:

- Furosemide is used for the treatment of physiological parturient edema of the mammary gland and associated structures. A diuretic-saluretic for prompt relief of edema. This product is important to the humane treatment of organic animals.

Comments opposed to relisting stated:

- This is a compound which could be sunsetted. Its use is very limited and there are other natural compounds that can off-set it, such as coffee, as far as being a diuretic (stimulates urination). I submitted this material in the original "batch" in 2002 but no longer think it is necessary – in contrast to butorphanol, flunixin, xylazine, and tolazoline which are vital to provide humane care and to relieve pain and suffering in the livestock that are part of the organic sector.

The subcommittee is planning to remove furosemide at the fall meeting unless we receive public or written comments from stakeholders why alternatives could not be a suitable alternative for furosemide.

Motion to Remove
This proposal to remove furosemide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of furosemide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee
Motion to remove furosemide from 205.60()
Motion by: Ashley Swaffar
Seconded by: Jean Richardson
Yes: 5 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
The National Organic Standards Board (NOSB) reviewed glucose for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(11). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Glucose meets the above evaluation criteria.

Glucose is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995, the 2015 public written comments, the unanimous NOSB 2010 support of this material, and no new information. Glucose is a synthetic substance allowed in organic livestock production for medical treatment of ketosis. For animal health purpose, glucose is used as an aid in the treatment of primarily ketosis in cattle. In the treatment of hypoglycemia, glucose is used as needed energy source and must bear a veterinarian's prescription. It is critical if used for the aforementioned purposes. The use of glucose provides a more rapid recovery to livestock in a hypoglycemia state. There is no current annotation for glucose. During the last sunset review by NOSB in 2010, the Board unanimously supported the relisting of glucose on the National List (NL) without any annotation or change. During the spring of 2015 public comment period, 11 organizations and individuals (73%) supported the relisting, two were neutral (18%), and one individual did not support (9%) the relisting of glucose. Those that were neutral did not give a reason for their neutrality. Those in support included a premier food safety organization, consumer groups, a cooperative, individuals, etc. Conversely, there was no new scientific or sufficient information presented since the last sunset to warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

Motion to Remove
This proposal to remove glucose from §205.603(a)(11) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of glucose from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

Vote in Subcommittee
Motion to remove Glucose from §205.603(a)
Motion by: Calvin Walker
Seconded by: Jean Richardson
Yes: 0 No: 6 Abstain: Absent: 2 Recuse: 0

Glycerin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Glycerin - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils
Technical Report: 1995 TAP (Livestock); 2010 TAP (Livestock)
Petition(s): N/A
Past NOSB Actions: 1997 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

Glycerin has a wide variety of uses, including use as a food additive, flavor and coloring carrier and humectant.

Glycerin—produced by hydrolysis of fats and oils, is listed at 7 CFR section 205.603, synthetic substances allowed for use in organic livestock production, as a livestock teat dip.
Glycerin has excellent anti-bacterial, anti-fungal, and anti-viral properties. Glycerin is readily biodegradable and will partition into the water phase. Glycerin is readily degraded by microorganism under both aerobic and anaerobic conditions. Glycerin is not expected to bioaccumulate.

Public comment was heavily in favor of the continued listing of this material, as glycerin is the main component in many teat dips and provides unique emollient properties which prevent chapping and damage to udders, especially in winter.

The Livestock subcommittee recommends continued listing of Glycerin.

Motion to Remove
This proposal to remove Glycerin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Glycerin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove Glycerin from §205.605(a)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 5 Abstain: 1 Absent: 2 Recuse: 0

Hydrogen peroxide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(13) Hydrogen peroxide
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

The National Organic Standards Board (NOSB) reviewed hydrogen peroxide for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) § 205.603(a)(13). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Hydrogen peroxide meets the above evaluation criteria.

Hydrogen peroxide is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995 (Crops), the 2015 public written comments, the unanimous NOSB 2010 support of this material, and no new scientific or meritorious information. Hydrogen peroxide is a synthetic substance allowed in organic livestock production for medical treatment. It is used as a readily available disinfectant and broad spectrum germicide. It is an important cleaning agent for use on contact surfaces, such as equipment, calf pails, bottles, and utensils. The material is used to clean wounds. The use of chlorine dioxide and soap and water diluted with iodine are alternatives. There is no annotation needed. During the last sunset review by NOSB in 2010, the material was unanimously supported for relisting on the National List (NL) without any annotation or change.

During the spring of 2015 public comment period, 25 organizations and individuals (93%) supported the relisting, two (2) were against (7%). Those in support included a premier food safety organization, a premier organic trade group, a premier environmentalist group, various consumer groups, a cooperative, a premier farm group, organic food businesses, individuals, etc. Those against did not support hydrogen peroxide due to the material being a synthetic. However, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

Motion to Remove:

This proposal to remove hydrogen peroxide from §205.603(a)(13) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of hydrogen peroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

Vote in Subcommittee

Motion to remove Hydrogen peroxide from §205.603(a)

Motion by: Calvin Walker

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Iodine

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

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) Iodine

Technical Report: 1995 TAP; 2014 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

Iodine has excellent antimicrobial qualities, and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre milking and post milking.

Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus anti-microbial teat dips, used pre and post milking are vital preventive healthcare products.

There are many teat dips available commercially. Iodine based teat dips are the most commonly used. Iodine can be in molecular form or iodophor form.

Typically molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be a number of other ingredients in iodine based teat dips, some

of which may be excipients.
One of the nonionic surfactants used is nonylphenol polyethylene glycol ether (NPE). NPEs are known to have negative environmental impacts, even at low levels, notably in aquatic systems, and a Technical Report for NPEs was requested and received by the NOSB Crops Subcommittee and reviewed as part of this analysis.

The Livestock Subcommittee requested additional information during the first posting for iodine, posing the following questions:
1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comment indicates that iodine is critical to organic livestock production and that it is widely used. Scientific research suggests that the use of NPEs in complexing iodine for use in organic livestock production should be rapidly phased out, and public comment clearly indicates that the dairy industry, starting in Fall 2014, began moving quickly to eliminate NPEs from iodine based livestock teat dips and disinfectants. Iodine based teat dips are now available labeled "NPE-free". Some milk buying companies require dairy producers to stop using teat dips containing NPEs.

It is recommended that dairy producers check with their teat dip suppliers to make sure that from now on their farm's teat dip and other iodine uses will be one of the many formulations with no NPEs.

The Livestock Subcommittee does not recommend removal of iodine from the National List but the Livestock Subcommittee will propose a separate annotation requiring the use of iodine made without NPEs.

Motion to Remove
This proposal to remove iodine will be considered by the NOSB at its public meeting.
The Subcommittee proposes removal of iodine from the National List.

Vote in Subcommittee
Motion to remove iodine from 205.603(a)(14) and 205.603(b)(2)
Motion by: Jean Richardson
Seconded by: Harold Austin
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Magnesium hydroxide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(15) 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 TR
Petition(s): 2002 Petition
Past NOSB Actions: 2002 NOSB recommendation; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
Specific Uses of the Substance:
Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Organic farmers historically use magnesium hydroxide, for cattle, particularly, with digestive problems. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. Magnesium hydroxide is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid. Magnesium hydroxide is also used as a fertilizer (in the form of lime) as a substitute for more expensive chemical fertilizers.

Discussion: The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on magnesium hydroxide.
Comments in support of relisting stated:

- This is a compound which helps correct grass tetany (low magnesium in the blood stream) which occurs in the lush growing times of spring pasture. It is also a good antacid for possible rumen acidosis
- We use for the extremely occasional cow with bowel function problems.

There were no comments received opposing the relisting of magnesium hydroxide. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of magnesium hydroxide.

Motion to Remove
This proposal to remove magnesium hydroxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of magnesium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:
Compatibility

Vote in Subcommittee
Motion to remove Magnesium hydroxide from §205.603
Motion by: AS
Seconded by: CW
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Magnesium sulfate

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(16) Magnesium sulfate
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
Specific Uses of the Substance:
Magnesium sulfate has a number of veterinary uses. It acts as an anticonvulsant, laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically in swine, magnesium sulfate is administered to treat malignant hypothermia (Dodman, 2010).

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure (Organic Livestock Research Group, 2000) (2011 TR Line 87). If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed (Epsom Salt Council, 2009).

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium (Champness, 2007). If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously (Papich, 2007).

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle‘s use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium (Harris, 2005).

Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation (Epsom Salt Council, 2009).

International:
The Canada Food Inspection Agency, Food and Drug Regulations (last modified in 2009) permit the use of magnesium sulfate as a soil amendment and crop nutrient when a soil deficiency has been documented. Acceptable forms of magnesium sulfate include mined kieserite and natural or synthetic Epsom salt. Mined sources of magnesium sulfate are permitted for use in healthcare products and production aids. Nonsynthetic sources of magnesium sulfate are classified as a food additive. Sulfates produced using sulfuric acid are prohibited (Canadian General Standards Board, 2009).
The European Economic Community (EEC) Council Regulation permits the use of non-synthetic magnesium sulfate (kieserite) as a fertilizer and soil conditioner (Annex I, EC No. 889/2008). Non-synthetic magnesium sulfate is also permitted as a feed material of mineral origin (Annex V, EC No. 889/2008). Magnesium sulfate is not listed as an approved organic processing agent.
International Federation of Organic Agriculture Movements (IFOAM) lists magnesium sulfate as a permissible mineral for use as a fertilizer and soil amendment agent (KRAV, 2001). Approved mineral fertilizers can only be applied in their natural form (i.e., without any further processing to increase solubility, with the exception of grinding).

Discussion:
The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on Magnesium Sulfate.
Comments in support of relisting stated:

- This is a good natural laxative.
- We use Epsom salts to occasionally soak sore or infected feet on cows.

There were no comments received opposing the relisting of Magnesium Sulfate. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of Magnesium Sulfate.

Motion to Remove
This proposal to remove Magnesium Sulfate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium Sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:
Compatibility

Vote in Subcommittee
Motion to remove Magnesium sulfate from §205.603
Motion by: Ashley Swaffar
Seconded by: Calvin Walker
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(17) Oxytocin -use in post parturition therapeutic applications
Technical Report: 1995 TAP; 2005 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation, 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review

The National Organic Standards Board (NOSB) conducted a review of oxytocin for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(17). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment.

For 20 years (since 1995), oxytocin has been recommended for relisting to the National List (NL). The technical advisory panel (TAP) of October, 1995 and the unanimous approval by the 2010 NOSB 2010 were to relist of the material. The relisting vote on April 29, 2010 was 14 yes, 0 no, 0 abstain, and 1 absent. Oxytocin is currently included on the NL of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic livestock production 7 CFR §205.603 (a)(17). The use of oxytocin is limited to "use in post parturition therapeutic applications." The uses are not specifically defined, but presumably do not include prolonged use to promote milk production. According to the TAP of 1995, there are no well explored or acceptable alternative practices or materials for the substitution of the injection of synthetic oxytocin in "certain health cases" in livestock production. Homeopathic herbs or acupuncture may alleviate some symptoms and conditions associated with stress at parturition.

During the spring of 2015 public comment period, six (6) organizations and individuals (67%) supported the relisting, two (2) were neutral (22%), and one (1) individual did not support (8%) the relisting of material. Those in support included a premier food safety organization, consumer groups, a cooperative, individuals, etc. The one individual that was against did not support material due to the material being a synthetic. Thus, in the final analysis, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset review of the material.

Oxytocin is used in post parturition therapeutic applications in organic livestock production. Oxytocin is important in some cases when it is necessary to use for relaxing the pelvic bone of the female during birthing to help save the life of the offspring(s) coming through the birth canal and reduce the stress on the female during this critical time of birthing.

Motion to Remove

This proposal to remove Oxytocin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Oxytocin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee

Motion to remove Oxytocin from 205.603(a)17

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

Parasiticides, Fenbendazole

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

(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only

Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 TR

Petition(s): 2007 Fenbendazole

Past NOSB Actions: 2008 NOSB recommendation

Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472)

Sunset Date: 5/16/2017

Subcommittee Review

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of parasiticides, and regulate of the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific

conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided that such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
(ii) Ivermectin (CAS #70288-86-7).
(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only Ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In May 2008, Fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when Fenbendazole was added to the National List, Ivermectin (and possibly Moxidectin) should come off the List.

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): “If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than

two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan."

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.
For conventional livestock production, no milk withdrawal time is required for either Fenbendazole[1,2] or Moxidectin.[3,4] Ivermectin is not labeled for use in dairy animals, and no milk withdrawal time has been established for Ivermectin.[5,6] However it is used under veterinary supervision under provisions of AMDUCA.

Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. (TR 2015)

In its initial request for public comment, the Livestock Subcommittee asked the public "Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?"

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common comment received was that Ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and Ivermectin are both in one class of parasiticides and Fenbendazole is in a

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[1]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf
[2] http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf
[3]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf
[4]http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf
[5]http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=128-409
[6] http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162

separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the National List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas Ivermectin and Moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelminthic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.
There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

1. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian. Ivermectin and Moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticides for convenience.
2. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and Moxidectin have no milk withdrawal time for use in conventional production.

The Livestock Subcommittee will be preparing a proposal to modify Sections 205.603 and 205.238 as they apply to use of fenbenzadole, including reduction in Withholding Period. The Livestock subcommittee may also propose to allow sheep wool to be sold as "organic" after a withholding period.

Motion to Remove
This proposal to remove Fenbendazole will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Fenbendazole from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

Vote in Subcommittee

Motion to remove Fendbendazole from §205.603

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Parasiticides, Ivermectin

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

(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 Technical Evaluation Report

Petition(s): N/A

Past NOSB Actions: 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17

Subcommittee Review

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of parasiticides and regulate the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

(c) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(d) When preventive practices and veterinary biologics are inadequate to prevent sickness, a

producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
(ii) Ivermectin (CAS #70288-86-7).
(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.
In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation "for control of internal parasites only" was included for moxidectin for the given reason that, "There is much less chance of any kind of contamination if it is used for internal parasites versus external." According to the meeting notes, "It was the committee's opinion, that (moxidectin) failed on Criteria 1, and that was the reason for the proposed annotation because of concern about the half–life of the material and impact on soil organisms." However, the board noted then that moxidectin "is also less problematic" than ivermectin. Further, it should be noted that just before the NOSB vote on moxidectin, a board member corrected an error that had been part of the discussion leading to the annotation: it was brought up that the 2003 TAP review indicated the half-life of moxidectin in soil to be two months, not six months as had been reported in the evaluation criteria document (which had led to support for the annotation).

The 2015 TR indicates that "The half-life for degradation of moxidectin in the environment may be up to 130 days," and the half-life of ivermectin to be "127 days in soil." However, other sources indicate that the half-life of these materials can be quit variable, depending on temperature and soil conditions. For example, the half-life of ivermectin in a soil/feces mixture was found to be 91 to 217 days during winter weather conditions and 7 to 14 days during the summer period.[7]

Although the NOSB approved the addition of moxidectin to the National List in 2004, the US Agriculture

[7] Fate of Pharmaceuticals in the Environment and in Water Treatment Systems. 2008. Diana S. Aga ed., p. 128. CRC Press.

Secretary did not initially accept NOSB's recommendation because moxidectin was labeled as a macrolide antibiotic. However, subsequent clarification found that moxidectin belongs to the polyene class of macrolides, "which unlike their erythromycin counterparts do not possess antibiotic properties" (2015 TR lines 100 – 111). Moxidectin was then added to the National List.

In May 2008, fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when fenbendazole was added to the List, ivermectin (and possibly moxidectin) should come off the List (meeting notes, page 207).

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): "If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan."

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

For conventional livestock production no milk withdrawal time is required for either fenbendazole[8,9] or moxidectin.[10,11] Ivermectin is not approved for use in dairy animals, and no milk withdrawal time has been established for ivermectin.[12,13]

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[8]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf

[9] http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf

[10]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf

[11]http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf

Ivermectin is considered to be the most harmful to soil life. From the 2015 TR: "Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. Excreted ivermectin does delay the disappearance of dung pats, but does not affect earthworm populations or health. The delay in ivermectin treated soils may be the result of its toxicity to insects" (2015 TR lines 580 – 583). Ivermectin is more toxic to dung-dwelling insects than moxidectin: "The macrocyclic lactones (the class of parasiticides to which ivermectin and moxidectin belong) can be ranked in decreasing order of toxicity to dung-dwelling insects as abamectin>doramectin ≥ ivermectin > eprinomectin>>moxidectin" (TR Table 7).

The NOP standards prohibit the use of parasiticides in slaughter stock. Although ivermectin is not labeled for use in dairy animals of breeding age, it may be used under veterinary order under provisions of AMDUCA (TR line 321).

In its initial request for public comment, the Livestock Subcommittee asked the public "Are the three parasiticides (ivermectin, moxidectin and fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?"

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common comment received was that ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.
Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and ivermectin are both in one class of parasiticides and fenbendazole is in a separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas ivermectin and moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelminthic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite

[12]http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=128-409
[13] http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162

control systems in the future.
There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

3. Fenbendazole, which is considered the most environmentally benign, is annotated to require the "written order of a licensed veterinarian. Ivermectin and moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticide for convenience.
4. Moxidectin is annotated "for control of internal parasites only." However, moxidectin is widely used as a pour-on, and when used in that form for control of internal parasites it is also a *de facto* control for external parasites. Moreover, as mentioned above, the annotation "for control of internal parasites only: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
5. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and moxidectin have no milk withdrawal time for use in conventional production.

Motion to Remove
This proposal to remove ivermectin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ivermectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Harmful to human health and the environment.

Vote in Subcommittee
Motion by: Francis Thicke
Seconded by: Jean Richardson
Yes: 5 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Parasiticides, Moxidectin

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

(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

Technical Report: 2003 TAP (Moxidectin); 2015 Technical Evaluation Report
Petition(s): Moxidectin
Past NOSB Actions: 2004 NOSB recommendation
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472)
Sunset Date: 5/16/2017

Subcommittee Review

The USDA organic regulations at 7 CFR part 205 provides guidance on livestock production practices to prevent the need for the use of parasiticides, and on regulation of the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

(e) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(f) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
(ii) Ivermectin (CAS #70288-86-7).
(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only

Ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation "for control of internal parasites only" was included for moxidectin for the given reason that "There is much less chance of any kind of contamination if it is used for internal parasites versus external." According to the meeting notes, "It was the committee's opinion, that (moxidectin) failed on Criteria 1, and that was the reason for the proposed annotation because of concern about the half–life of the material and impact on soil organisms." However, the board noted then that moxidectin "is also less problematic" than ivermectin. Further, it should be noted that just before the NOSB vote on moxidectin, a board member corrected an error that had been part of the discussion leading to the annotation: it was brought up that the 2003 TAP review indicated the half-life of moxidectin in soil to be two months, not six months as had been reported in the evaluation criteria document (which had led to support for the annotation).

The 2015 TR indicates that "The half-life for degradation of moxidectin in the environment may be up to 130 days," and the half-life of ivermectin to be "127 days in soil." However, other sources indicate that the half-life of these materials can be quit variable, depending on temperature and soil conditions. For example, the half-life of ivermectin in a soil/feces mixture was found to be 91 to 217 days during winter weather conditions and 7 to 14 days during the summer period.[14]

Although the NOSB approved the addition of moxidectin to the National List in 2004, the US Agriculture Secretary did not initially accept NOSB's recommendation because Moxidectin was labeled as a macrolide antibiotic. However, subsequent clarification found that Moxidectin belongs to the polyene class of macrolides, "which unlike their erythromycin counterparts do not possess antibiotic properties" (2015 TR lines 100 – 111). Moxidectin was then added to the National List.
In May 2008, fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when Fenbendazole was added to the List, ivermectin (and possibly moxidectin) should come off the List (meeting notes, page 207).

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): "If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than

[14] Fate of Pharmaceuticals in the Environment and in Water Treatment Systems. 2008. Diana S. Aga ed., p. 128. CRC Press.

two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan."

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

For conventional livestock production no milk withdrawal time is required for either fenbendazole[15,16] or moxidectin.[17,18] Ivermectin is not approved for use in dairy animals, and no milk withdrawal time has been established for ivermectin.[19,20]

Ivermectin is considered to be the most harmful to soil life. From the 2015 TR: "Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. Excreted ivermectin does delay the disappearance of dung pats, but does not affect earthworm populations or health. The delay in ivermectin treated soils may be the result of its toxicity to insects" (2015 TR lines 580 – 583). Ivermectin is more toxic to dung-dwelling insects than moxidectin: "The macrocyclic lactones (the class of parasiticides to which ivermectin and moxidectin belong) can be ranked in decreasing order of toxicity to dung-dwelling insects as abamectin>doramectin ≥ ivermectin > eprinomectin>>moxidectin" (TR Table 7).

Considering that the NOP standards prohibit the use of parasiticides in slaughter stock and that ivermectin is not labeled for use in dairy animals of breeding age, there seems to be little opportunity for the use of ivermectin in organic production. The only opportunity for use of Ivermectin would be in breeder stock, before the last third of gestation for progeny to be sold as organic.

In its initial request for public comment, the Livestock Subcommittee asked the public "Are the three parasiticides (ivermectin, moxidectin and fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?"

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common

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[15]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf

[16] http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf

[17]http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf

[18]http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf

[19]http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=128-409

[20] http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162

comment received was that ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and ivermectin are both in one class of parasiticides and fenbendazole is in a separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas ivermectin and moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelminthic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

6. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian. Ivermectin and Moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticide for convenience.
7. Moxidectin is annotated “for control of internal parasites only.” However, moxidectin is widely used as a pour-on, and when used in that form for control of internal parasites it is also a *de facto* control for external parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
8. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and Moxidectin have no milk withdrawal time for use in conventional production.
9. Ivermectin is not allowed for use in slaughter stock under the NOP, and it is not allowed for use in dairy animals of breeding age by the FDA, leaving the only legal use of ivermectin to be on breeder stock before the last third of gestation for progeny to be sold as organic.

Motion to Remove

This proposal to remove moxidectin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of moxidectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: This material satisfies the OFPA Criteria.

Vote in Subcommittee
Motion to remove Moxidectin from §205.603
Motion by: Francis Thicke
Seconded by: Jean Richardson
Yes: 4 No: 2 Abstain: 0 Absent: 2 Recuse: 0

Peroxyacetic/peracetic acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
Technical Report: 2000 TAP
Petition(s): 2008 Petition
Past NOSB Actions: 11/2000 NOSB recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

Subcommittee Review
Peracetic acid (PAA) is a relatively recent development, but has been used to clean stalls and to disinfect livestock, particularly dairy cattle. Acetic acid and hydrogen peroxide both have a longer history of use in livestock production than commercial preparations of peracetic acid, but the substance has, in effect, been used by farmers who combine vinegar and peroxide in a cleaning solution. The primary mode of action is oxidation. PAA works synergistically with hydrogen peroxide, decreasing the amount of hydrogen peroxide needed to reduce microorganisms (Lambert et al., 1999). Under normal use and disposal conditions, PAA decomposes into acetic acid, oxygen, and water. Peracetic acid is produced by reacting acetic acid and hydrogen peroxide. (Tap Review, November 3, 2000).

Peracetic acid is an irritant of the skin, eyes, mucous membranes and respiratory tract (NTP, 2000; Budavari, 1996; Lenga, 1985). When heated to decomposition it emits acrid smoke and toxic fumes of carbon monoxide and carbon dioxide. The vapor is heavier than air and can travel a considerable distance to a source of ignition and flash back (NTP, 2000). Misuse at the processing level would cause a bleaching out effect on the color of meat and poultry, resulting in loss of quality that could be visually detected.

Direct consequences of misuse of concentrated solutions could be catastrophic; i.e., burns and explosions. Indirect consequences are minimal, as breakdown into acetic acid and water happens rapidly. Proper use should have minimum consequences, due to the dilute nature of the solutions, although the possibility of irritation of mucous membranes and skin is possible. Therefore, good chemical practices should be followed when using PAA. Alternatives include hydrogen peroxide, chlorine, chlorhexidine solutions. Broad-spectrum synthetic biocides are generally considered incompatible with sustainable agriculture. However, proper farm sanitation and the protection of the public health from food-borne pathogens merits special consideration. Substances are needed to clean milking machines and keep livestock facilities from harboring food- borne pathogens. While sustainable systems should minimize the use of such substances, they should not be eliminated unless and until suitable alternatives are found.
(TAP Review, November 3, 2000).

The 2000 Tap reviewers unanimously agreed that while there were potential issues with PPA, the material is critical to ensure proper sanitation of farm and/or processing facilities.

Public comment was overwhelmingly in support of relisting Peracetic Acid, noting that the material is more effective with longer efficacy than chlorine and is critical to proper sanitation and human and animal health. One commenter did ask that when the NOSB reviews the material to determine whether it is still necessary.

Motion to Remove
This proposal to remove Peracetic Acid will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Peracetic Acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove Peracetic acid from 205.603

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs
Technical Report: 2003 TAP (Handling)
Petition(s): N/A

Past NOSB Actions: 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review
Specific Uses of the Substance:
Phosphoric acid is used in cleaning operations to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining of stainless steel, lime and scale from heat exchangers and in Clean In Place (CIP) cleaning operations, especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

Discussion: The NOSB in its initial request for public comment asked if the material is used in livestock production and if there were alternative materials. Public comment indicates widespread use of phosphoric acid and public did not indicate alternatives.

This material satisfies the OFPA Evaluation Criteria.

Motion to Remove
The Subcommittee proposes removal of Phosphoric Acid from the National List.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Satisfies OFPA criteria

Vote in Subcommittee
Motion to remove Phosphoric acid from §205.603
Motion by: Jean Richardson
Seconded by: Francis Thicke
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Poloxalene

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(21) 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
Petition(s): 2000 Petition
Past NOSB Actions: 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review
Poloxalene is a fast-acting synthetic material approved for emergency treatment of bloat. In the 2001 TAP review, all three reviewers agreed that there are natural alternatives to poloxalene, such as vegetable oils. However, two of the reviewers recommended approval of poloxalene because it is faster-acting than oils in relief of bloat. The third reviewer argued that when rumen bloat becomes acute enough that oils will not stop the bloat and poloxalene is required, a rumenotomy (surgical opening of the rumen) is probably required anyway, so poloxalene is not essential to organic production.

In the first round of public comments for the 2017 sunset, two brief comments were received recommending that poloxalene remain on the National List. Also, one commenter (a veterinarian) suggested that poloxalene is not essential because olive oil and other oils would substitute.

Motion to Remove
This proposal to remove poloxalene will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of poloxalene from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee
Motion to remove Poloxalene from §205.603(a)
Motion by: Francis Thicke
Seconded by: Colehour Bondera
Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Tolazoline

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

(22) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP
Petition(s): 2002 Petition
Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

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

For the first round of public comments, the Livestock Subcommittee asked two questions:

1. Are there alternative materials that should be petitioned for use?
2. What alternative practices are available?

No comments were received specifically answering those questions. However, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list. One commenter questioned the legality of the use of xylazine/tolazoline in food-producing animals. However, off-label use of xylazine/tolazoline was cleared with FDA when they were added to the National List in 2002.

Motion to Remove

This proposal to remove tolazoline will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of tolazoline from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion to remove Tolazoline from §205.603

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 1 Absent: 0 Recuse: 0

Xylazine

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

(23) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) The existence of an emergency; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

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

For the first round of public comments, the Livestock Subcommittee asked two questions:

Are there alternative materials that should be petitioned for use?

What alternative practices are available?

No comments were received specifically answering those questions. However, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list. One commenter questioned the legality of the use of xylazine/tolazoline in food-producing animals. However, off-label use of xylazine/tolazoline was cleared with FDA when they were added to the National List in 2007 (see proposed rule 71 FR 40624).

Motion to Remove

This proposal to remove xylazine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of xylazine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Compatibility**

Vote in Subcommittee

Motion to remove from §205.603
Motion by: Jean Richardson
Seconded by: Ashley Swaffar
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Copper sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR
Petition(s); N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

Specific Use: Walk-through footbaths are used to help control and prevent hoof related diseases in dairy cattle and sheep. A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes. Spent solution is mixed with manure waste and ultimately disposed by land application.

The popularity of copper sulfate footbaths can be attributed to both its relatively low cost per footbath and that it effectively controls the infectious lesions. Research has shown that using copper sulfate footbaths decreases both the incidence and severity of foot lesions over time.

Concerns with using copper sulfate include metal corrosion and disposal of the copper sulfate solution. On the farm, discarding the diluted copper sulfate solution with manure (and placed in wastewater lagoon) is a normal practice. It is fairly common practice for lagoon water and lagoon solids to be applied to farmland. The environmental effect of this copper depends on the volume of footbath solution disposed (a function of the number of animals and intensity of footbath use), concentration of copper sulfate, and the land area of application. Without careful attention, maximum soil copper loading rates may be exceeded in relatively short times (5 to 30 years) (Epperson et al., 2007).

Although the soil rarely produces excessive amounts of copper on its own, copper toxicity can occur from over application of the micronutrient in agricultural production. Neutralizing copper soil toxicity is extremely difficult once the problem occurs. Copper has low solubility, which enables it to persist in the soil for years.

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

The Livestock Subcommittee had put forth the following questions for public comment:

> Zinc sulfate has recently been petitioned for use as a footbath treatment. In the event that the NOSB votes to add zinc sulfate to the National List, how likely are you to use this material instead of copper sulfate?

The NOSB did receive public response to the question posed above, with most respondents stating the addition of zinc sulfate to the National List would likely reduce their reliance solely on copper sulfate. Additional public comments voiced concerns regarding accumulation of copper in soils due to disposal of copper sulfate baths in lagoon water, but generally acknowledged the necessity of this material, and proposed an annotation requiring soil testing to monitor for copper accumulation. Comment was also

received refuting the TR's statement that there are no non-synthetic alternatives to copper sulfate. In particular, hydrated lime was put forth as an alternative to control fungal diseases in cows and sheep.

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

Motion to Remove
This proposal to remove copper sulfate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of copper sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:
Environmental Impacts

Vote in Subcommittee

Motion to remove Copper Sulfate from §205.603(b)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (2) 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
Recent Regulatory Background: Added to National List, effective August 3, 2012 [77 FR 45903]
Sunset Date: 8/3/2017

Subcommittee Review
The National Organic Standards Board (NOSB) reviewed formic acid for use as a pesticide solely within honeybee hives according based on the evaluation criteria in the Organic Foods Production Act (OFPA), 7 Code of Federal Regulation (CFR) §205.603(b), the 2011 technical report (TR), past NOSB actions, and 2015 public comments. Formic acid is used to control varroa and tracheal mites in honeybees. It is less toxic and less hazardous than conventional miticides, but it is a synthetic that poses some hazards to beekeepers. Available alternatives include management practices, nonsynthetic materials, and a synthetic soap on the National List. When the NOSB approved formic acid in 2010, a technical review was not available, and the Livestock Subcommittee evaluated the petition based on information in the petition, but said it, "will reevaluate the recommendation when the TR becomes available." Thus, the technical review and checklist based on it should be considered new information.

Formic acid is found naturally in small amounts in some fruits and nectars and is a natural component of honey, with formic acid being present in a natural state in stinging nettles. It is also present as a defense mechanism in the stings and bites of many insects, including bees and ants. Synthetic formic acid used by beekeepers is produced as a by-product in the manufacture of acetic acid. However, the industrial demand for formic acid is higher than can be made from this route, so dedicated production routes have been developed. One method combines methanol and carbon monoxide in the presence of a strong base, such as sodium methoxide, to produce methyl formate. Other uses of formic acid include use as a preservative and antibacterial agent; in textile dyeing and finishing, leather tanning, nickel plating baths, electroplating, coagulating rubber latex, regenerating old rubber, and de-hairing and plumping hides, and in some commercial paint strippers. It is used: in the manufacture of metal salts, including nickel, cadmium, and potassium formats; as a solvent for perfumes; in the manufacture of lacquers, glass, vinyl resin plasticizers, and formate esters for flavor and fragrance; and in the synthesis of the artificial sweetener aspartame.

Natural formic acid is not available in adequate amount for commercial use. The 2011 TR further states that, "formic acid can serve as an effective treatment for mite infestations because it harms mites but generally not bees. During treatment, formic acid vapors diffuse through the hive and then dissipate to background levels at the end of the treatment."

Formic acid is applied as a fumigant to the interior of the beehive and is unlikely to affect biological or chemical interactions in the agro-ecosystem. If released to water as a result of accident during manufacturing, formic acid is expected to volatilize from the surface of water and is not expected to absorb sediment and suspended solid.

There are management alternatives to formic acid fumigation - use of a screened bottom board and drone-brood trapping. In addition, bees resistant to the mites because of grooming behavior or a trait that prevents mites from reproducing are now available.
The fungus Metarhizium anisopilae is highly pathogenic to varroa mites and does not cause harm to honeybees or affect reproduction.[21] Although beekeepers may use it for this purpose, it is not a registered use.[22] Use of wintergreen-salt grease patties is a natural treatment of varroa and tracheal mites used by many beekeepers. However, the prepared grease patties are not commercially available and are created by beekeepers for personal use, and wintergreen is considered a synthetic and is not on the National List. Neem oil and inert dusts are other nonsynthetic alternatives. Sucrose octanoate ester is listed on §205.601 for this use.

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[21] NPIRS (National Pesticide Information Retrieval System), 2015. *Metarhizium anisopliae* strain F52 spores, http://ppis.ceris.purdue.edu

[22] Kanga, L. H., Jones, W. A., & Gracia, C. (2006). Efficacy of strips coated with Metarhizium anisopliae for control of Varroa destructor (Acari: Varroidae) in honey bee colonies in Texas and Florida. *Experimental & applied acarology*, *40*(3-4), 249-258.

Two questions were put forth seeking public input upon the first stage of sunset listing review. These were:

1. Do the alternatives documented in the TR control varroa and tracheal mites?
2. Are the alternatives discussed in the TR available for organic beekeepers?
3.

During the 2015 public comment period, there were few comments regarding the listing of formic acid and, unfortunately, no beekeepers. Neither OTA nor MOSA reported any responses to their surveys concerning formic acid. One livestock organization supported formic acid, and one environmental organization urged the NOSB Livestock Subcommittee to get input from beekeepers.

Communication directly with a beekeeper who is well established (fourth generation), and significant producer of organic honey, stated that at this time, without formic acid, their 4,000-hive operation would no longer be certified organic.

Specifically, the hives are kept stronger via use of formic acid, and without use of formic acid the hives often or regularly develop hive beetle problems. With use of formic acid, hives also have not been affected by deformed wing virus. Systems management and maintenance of hives means that for at least some organic beekeepers, there is not an effective alternative at this time.

Motion to Remove

The motion to remove Formic Acid from 205.603 as "Synthetic substances allowed for use in organic livestock production" will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove Formic Acid from §205.603
Motion by: Jean Richardson
Seconded by: Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Iodine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(14) Iodine
Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) Iodine
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 10/2010

sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17

Subcommittee Review
Iodine has excellent antimicrobial qualities, and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre milking and post milking.
Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus anti-microbial teat dips, used pre and post milking are vital preventive healthcare products.
There are many teat dips available commercially. Iodine based teat dips are the most commonly used. Iodine can be in molecular form or iodophor form.
Typically molecular iodine is "complexed" into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be a number of other ingredients in iodine based teat dips, some of which may be excipients.
One of the nonionic surfactants used is nonylphenol polyethylene glycol ether (NPE). NPEs are known to have negative environmental impacts, even at low levels, notably in aquatic systems, and a Technical Report for NPEs was requested and received by the NOSB Crops Subcommittee and reviewed as part of this analysis.

The Livestock Subcommittee requested additional information during the first posting for iodine, posing the following questions:
1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comment indicates that iodine is critical to organic livestock production and that it is widely used. Scientific research suggests that the use of NPEs in complexing iodine for use in organic livestock production should be rapidly phased out, and public comment clearly indicates that the dairy industry, starting in Fall 2014, began moving quickly to eliminate NPEs from iodine based livestock teat dips and disinfectants. Iodine based teat dips are now available labeled "NPE-free". Some milk buying companies require dairy producers to stop using teat dips containing NPEs.

It is recommended that dairy producers check with their teat dip suppliers to make sure that from now on their farm's teat dip and other iodine uses will be one of the many formulations with no NPEs.

The Livestock Subcommittee does not recommend removal of iodine from the National List but the

Livestock Subcommittee will propose a separate annotation requiring the use of iodine made without NPEs.

Motion to Remove

This proposal to remove iodine will be considered by the NOSB at its public meeting.
The Subcommittee proposes removal of iodine from the National List.

Vote in Subcommittee

Motion to remove iodine from 205.603(a)(14) and 205.603(b)(2)

Motion by: Jean Richardson

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

Lidocaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on.

Lidocaine is used for example to humanely de-bud horns on calves, and for minor surgery on mature animals.

The NOSB in its initial request for public comment asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rational for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a very short withholding period would be scientifically acceptable.

The Livestock subcommittee cannot make an annotation at Sunset review but will seek further public

comment through a Discussion Document, and depending on public comment and the requested Technical Report, a subsequent proposal to change the withholding period for slaughter stock may be proposed.

There was widespread stakeholder support for continuing to list lidocaine.

Motion to Remove

This proposal to remove lidocaine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lidocaine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion to remove Lidocaine from §205.603

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Lime, hydrated

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes

Technical Report: 1995 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

Hydrated lime is produced by heating calcium carbonate, which results in quicklime. Quicklime is then mixed with water to create hydrated lime. This is a caustic solution which can be used for a variety of reasons, but the material is restricted in organic production to an external parasiticide. The NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle and other livestock. Mange caused by parasitic mites is highly irritating for animals, and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (TR lines 61-64). Hydrated lime scattered in yards and pens is also effective for control of bacteria that causes foot rot. For this purpose, the substance is typically placed in and around areas where sheep congregate such as watering areas, feed bunks or salt and mineral sources. (TR lines 83-86) Hydrated lime and other lime products have a long history of use in agricultural and non-agricultural settings. (TR lines 146-147)

Direct application of large amounts of hydrated lime to soils can cause compaction, a rapid rise in soil pH, and rapid oxidation of soil nutrients. However, per the 1995 TAP review, small amounts reaching the soil from application to livestock may have a beneficial effect on soil calcium.

Hydrated lime can be caustic if inhaled. Respiratory protection should be used during application.

Public comment, while limited in quantity, did support the re-listing of hydrated lime, citing the essentiality of the material for control of external parasites and for control of foot/hoof infections.

Motion to Remove
This proposal to remove Lime, hydrated will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lime, hydrated from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

Vote in Subcommittee

Motion to remove Hydrated Lime from §205.603(b)
Motion by: Tracy Favre
Seconded by: Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Mineral oil

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(6) Mineral oil - for topical use and as a lubricant
Technical Report: 2002 TAP; 2015 TR
Petition(s): 2002 Petition
Past NOSB Actions: 10/1995 NOSB minutes and vote; 2003 NOSB recommendation, 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review
In 1995, mineral oil was approved by the National Organic Standards Board for use in organic livestock production for topical use and as a lubricant.

Mineral oil occurs naturally in the form of pitch, tar, or bitumen and has been used as a sealing and building material or for medicinal purposes for thousands of years. Mineral oil and natural gas are formed by the accumulation of the decomposing remains of large quantities of marine micro-

organisms. To obtain mineral oil, gasoline and kerosene are removed from the crude petroleum by heating, in a method called functional distillation. By using sulphuric acid, applying absorbents, and washing with solvents and alkalis, hydrocarbons and chemicals are removed. (http://www.essentiallyoils.com/Newsletters/April_1997_Newsletter/april_1997_newsletter.html)(TAP Review, August 12, 2002). Mineral oil can interfere with the absorption of some medications and vitamins, including Vitamin K, which can lead to anticoagulant affects. Mineral oil is considered relatively non-toxic (TAP Review, August 12, 2002).

Public comment was limited but generally supportive of relisting, citing mineral oil's importance in fly control. The Livestock Subcommittee supports continued listing of mineral oil.

Motion to Remove
This proposal to remove mineral oil will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of mineral oil from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove Mineral oil from 205.603(b)(6)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 1 No: 3 Abstain: 1 Absent: 1 Recuse: 0

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review
Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on.

Procaine may be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

The NOSB in its initial request for public comment asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rational for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a very short withholding period would be scientifically acceptable.

The Livestock subcommittee cannot make an annotation change at Sunset review but will seek further public comment through a Discussion Document, and depending on public comment and the requested Technical report, a subsequent proposal to change the withholding period for slaughter stock may be proposed.

Public comment indicates procaine is not readily available in the United States and does not appear to be widely used. Procaine may not be essential and may not need to continue to be listed.

Motion to Remove

This proposal to remove procaine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of procaine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

Vote in Subcommittee

Motion to remove Procaine from §205.603(b)

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Sucrose octanoate esters

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling
Technical Report: 2005 TR
Petition(s): 2004 Petition; 05/2004 petition amendment; 09/2004 petition amendment
Past NOSB Actions: 08/2005 NOSB recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Background from Subcommittee

Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

Subcommittee Review

Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

SOEs seem to be fairly benign for health and the environment: “SOEs are rapidly biodegradable, and do not persist or accumulate in the environment” (TR line 298). “EPA has not identified any subchronic, chronic, immune, endocrine, dietary, or non-dietary exposure issues for SOEs in children or the general U.S. population” (TR lines 303-304).

In the first round of public comments, one comment was received on SOEs, recommending that it remain on the National List.

SOEs are used to control mites in honey bee colonies. Given the difficulty bee keepers are experiencing maintaining the health of honey bee colonies in recent times, the subcommittee thought it essential for SOEs to remain on the National List.

Motion to Remove

This proposal to remove sucrose octanoate esters will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sucrose octanoate esters from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

Vote in Subcommittee

Motion to remove Sucrose octanoate esters from §205.603(b)
Motion by: Francis Thicke
Seconded by: Jean Richardson
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

DL-Methionine

Reference: 205.603(d) As feed additives
(1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry - 3 pounds.
Technical Report: 2001 TAP; 2011 TR

Petition(s): 2005 Methionine; 2007 Methionine; 2009 Methionine; 2011 Methionine

Past NOSB Actions: 10/2001 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation through October 2012; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 10/02/17

Subcommittee Review

Methionine is classified as an essential amino acid because it is required in the diet for cell growth, but cannot be biologically produced. Of the 22 amino acids found in body proteins, the National Research Council (NRC) lists 13 as essential in poultry diets, and these must be consumed in feed: arginine, glycine, histidine, isoleucine, leucine, lysine, methionine, cysteine, phenylalanine, proline, threonine, tryptophan, and valine (NRC, 1994). (2011 TR, Lines 104-108). Poultry feed made of corn and soybean does not supply enough methionine to prevent deficiency symptoms that include curled toes, bare spots, and improper feathering (Hungerford, 2007). In addition, amino acids like methionine improve the efficiency of the production of animal protein. (TR Lines 112-144)

The nonsynthetic amino acid methionine is found naturally in foods such as: rice; rapeseed; soybean meal; sunflower, safflower, and sesame seeds; flax; alfalfa; grass; corn; wheat; and peas (Fanatico, 2010). Levels of methionine vary by food. For example, corn has only 0.17% methionine while soybean meal has 0.64% methionine. Methionine is also found naturally in animal protein from insects, fish, and dairy products, which are permitted in organic agriculture. Thus, natural methionine can be obtained from high-methionine foods; however, these foods are also high in protein. High protein diets are not physiologically healthy for birds due to excess excretion of uric acid, which is broken down into water and ammonia in the environment (Fanatico, 2010). (TR, lines 267-274)

Synthetic methionine used as a nutritional supplement in livestock production can enter the environment through waste streams from its production, use, and disposal. Methionine has a relatively low vapor pressure, indicating that methionine present in soil or water is not likely to evaporate into air. Methionine is highly mobile in soil, and research has shown that most of the methionine in soil breaks down in about 16 days. (TR, lines 279-283)

It is unlikely that the use of methionine and its breakdown products will cause harm to the environment. Methionine supplementation can reduce environmental pollution from nitrogen-rich manure, a significant concern in poultry production. (TR, lines 334-336, Lines 386-389). However, feeding systems

that reduce levels of protein fed using amino acid supplementation are not the only means identified to reduce nitrogen pollution from animal manure. Other potential solutions include lower animal densities; more frequent rotations; better manure storage, handling, and application techniques; use of enzymes; improved processing of the feed; and selection of more appropriate land and locations to graze and shelter animals (Archer and Nicholson, 1992; Tamminga, 1992; Tamminga and Verstegen, 1992). (TR, Lines 391-396).

The most likely source of possible environmental contamination associated with synthetic methionine is through waste streams from its production. Methionine is manufactured using a number of toxic intermediates including methyl mercaptan and acrolein. However, it is unlikely that the use of methionine and its breakdown products will cause harm to the environment. (TR, lines 404-407).

There are reports of herbal supplements that mimic methionine activity and which are made up of methionine-rich herbs such as *Cicer arienticum, Triticum sativum, Phaseolus mungo, Mucuna puriens*, and *Allium cepa*; however, the efficacy and commercial availability of these products is unclear. Another way to supplement natural methionine is through consumption of additional plant and animal proteins. Raising chickens with access to pasture is considered a possible alternative to synthetic methionine supplementation. Some sources indicate that they can adequately raise chickens without synthetic methionine as long as the birds have adequate access to pasture (Hungerford, 2007). Forage provides low to moderate levels of methionine and allows birds to obtain high-quality protein from insects and worms (Fanatico, 2010). However, foraging conditions change by season, affecting the pasture's ability to supplement the diet. During certain times of the year, it is difficult for methionine needs to be met from forage alone (Rack et al., 2009). (TR, Lines 439-442 and Lines 460-467).

As of the November 2011 Technical Report, research indicates that the organic poultry industry has not been able to develop a commercially viable, nonsynthetic form of methionine extract for use in organic poultry diets. While methionine can be extracted from intact proteins or proteins partially hydrolyzed to isolate it, there are still no commercially available forms of naturally extracted methionine (Fanatico, 2010). (TR, Lines 474-477).

Public comments regarding the continued listing of synthetic methionine have been extensive, heated and divided. Generally, those in favor of continued listing indicate that synthetic methionine is still critical to production of organic poultry and cite issues around animal welfare, including feather pecking and cannibalism. Those against continued listing of methionine express deep concerns around the continued and routine use of a synthetic ingredient in organic animal feed and predict erosion of public trust if synthetics remain in organic poultry production. To further complicate the issue, the NOSB recommendations for Animal Welfare Standards, and their requirements for outdoor access for poultry (December, 2011), are generally seen by many in the industry as a key component in helping to resolve the continued need for synthetic methionine. Those Standards have not yet been implemented as part of the National Organic Program.

Spring 2015 NOSB Meeting

At the Spring 2015 NOSB meeting in La Jolla, CA, the NOSB voted on and approved the proposal from the Livestock Subcommittee, which addressed a petition from the Methionine Task Force to modify the annotation for methionine. With this vote the annotation for methionine will be changed to read as follows:

> *DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)——for use only in organic poultry production at the following pounds of synthetic 100% Methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.*

Detailed history of the evolution of synthetic methionine in organic poultry production, including arguments both for and against, was included in the proposal for the annotation change.

The Livestock Subcommittee believes that it is important to the long-term public trust in the organic seal that the organic industry strives for continuous improvement. As part of the proposal for annotation change, the NOSB adopted the following resolution:

> *The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.*

It is the intent of the Livestock Subcommittee to bring forth at the Fall 2015 NOSB meeting targeted and specific research priorities to address the urgent need for further development of synthetic methionine alternatives.

Due to the timing of this annotation change recommendation and the fact that methionine sunsets in 2017, the Livestock Subcommittee has moved forward with this sunset review in parallel with the recommendation for annotation change. The Livestock Subcommittee is recommending relisting of methionine, while urging the organic industry to move forward with urgency to develop alternatives.

Motion to Remove

This proposal to remove methionine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of methionine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove Methionine from §205.603

Motion by: Tracy Favre

Seconded by: Colehour Bondera

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Trace minerals

Reference: 205.603(d) As feed additives

(2) Trace minerals, used for enrichment or fortification when FDA approved

Technical Report: 2013 TR Aquatic Trace Minerals **Petition(s):** N/A

Past NOSB Actions: 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

From the Livestock Committee's October 1995 recommendations: "Producers often may not be able to control the quantity of vitamins and minerals naturally occurring in feedstuffs. Non-synthetic vitamins and minerals should be used if available, but synthetics are allowed…Synthetic vitamins and minerals should be used in keeping with the recommendations of the National Research Council and the Association of Animal Feed Control Officials, Inc. specific to each species."

In June 2013, the Livestock Subcommittee received a Technical Report (TR) for Trace Minerals for aquaculture, which also addressed issues around mineral supplementation of terrestrial livestock. Trace mineral elements, whether naturally occurring in the diet or provided in supplements, are important for the maintenance, growth, and reproduction in the healthy production of beef cattle, swine, and poultry. In beef cattle production, minerals needed in larger amounts include calcium, phosphorus, magnesium, potassium, sodium, chlorine, and sulfur, while iron, zinc, manganese, copper, cobalt, and selenium are needed only in trace amounts (2013 TR Line 178). Forages and grains are good sources of calcium and phosphorus, respectively. However, the bioavailability of minerals in forage may vary depending on the mineral content of the soil and the level of pasture fertilization. Mineral premixes are therefore widely used for livestock feed fortification to ensure the adequate intake of minerals (Hale, 2001). Likewise, poultry and swine production uses dietary supplementation of trace mineral compounds (Richards, 2010). (TR lines 173-180). The NOP has issued a guidance document for the use of minerals in livestock feed, which spells out in more detail which minerals are covered under this listing. It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock subcommittee acknowledges this listing also includes macro minerals.

Public comments weighed heavily in favor of continued listing of trace minerals, citing the essentiality of minerals to ensure animal welfare and to offset variables in forage nutrition due to seasonality.

Motion to Remove
This proposal to remove trace minerals will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of trace minerals from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

Vote in Subcommittee

Motion to remove trace minerals from §205.603(e)
Motion by: Tracy Favre
Seconded by: Jean Richardson/Calvin Walker
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Vitamins

Reference: 205.603(d) As feed additives
(3) Vitamins, used for enrichment or fortification when FDA approved
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review
The National Organic Standards Board (NOSB) reviewed vitamins for livestock in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(d)(3). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. The synthetic vitamins reviewed are currently allowed for use in organic livestock production for enrichment and fortification. These vitamins are consistent with those defined as “required nutrients” by the National Research Council (NRC).

The NOSB Livestock Subcommittee received a technical evaluation report (TER) on March 5, 2015. The TER helped to provide the framework and essence for our recommendation of vitamins in synthetic form to be retained on the National List (NL). Vitamins meet all of the above criteria for a material to remain on the NL. Vitamins supplied in the diet are essential for good animal nutrition and health. Vitamins are one of six basic nutrients that must be considered in making rations for livestock such as swine, dairy, beef, and poultry. Without these six basic nutrients (vitamins, minerals, carbohydrate, protein, fat, and water) in the right amount animal welfare and production issues will generally become evident. Synthetic vitamins are allowed by various organic associations such as International Federation of Organic Agricultural Movements (IFOAM), European Union (EU), Canadian General Standards Board (CGSB), United Kingdom Soil Association, Japan Ministry of Agriculture, Forestry, and Fisheries, and

CODEX, when natural sources are not available in adequate amount.

The written public comment showed overwhelming support for retaining synthetic vitamins on the NL. The support for, against and neutral, was 71%, 14%, and 14%, respectively. The use of green forages and pastures are alternatives. However, concerns were expressed regarding the availability of sufficient year-round quantity Also, support was expressed for the approval of use of injectable vitamins, which was passed by a previous NOSB. No new or sufficient information has been submitted to warrant removal of this critical basic feed nutrient from organic livestock ration is warranted at this time. We encouraged new and/or scientific information that warrants otherwise.

Motion to Remove

This proposal to remove vitamins is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of vitamins from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

Vote in Subcommittee

Motion to remove Vitamins from §205.603(d)

Motion by: Calvin Walker

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

EPA List 4—Inerts of Minimal Concern

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 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

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017

Subcommittee Review

Used for a wide range of applications including surfactants and adjuvants in pesticide, herbicide and fungicide formulations.

The Inerts Working Group (IWG) was established in June 2010 and reports to the Crops Subcommittee. The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting. The NOSB and the IWG are

working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the Safer Choice Program (SCP) Program of the EPA.

Earlier this year, a Technical Report (TR) requested by the Crops subcommittee was completed on the class of inerts known as Nonylphenol Ethoxylates (NPEs). The Livestock subcommittee has also reviewed this TR as part of the 2017 Sunset review of the EPA List 4 Inerts of Minimal Concern listed at 205.603. As highlighted in the TR, the US EPA is encouraging industry to eliminate the use of NPE (TR 2015, line 137) because of toxicity concerns and persistence in the environment. It is unlikely that the NPEs would pass favorably through the SCP screening process. The Crops and Livestock Subcommittees are considering removing NPEs through an annotation, while maintaining the general listing for EPA List 4 at sunset while the new SCP review program starts up.

Because of concerns about the adverse health and environmental effects of NPEs, SCP recently completed an alternatives assessment for synthetic surfactants, like NPEs, that are not endocrine disrupting chemicals. SCP's goal is to assist in the voluntary phase-out of NPEs used in industrial detergents. The SCP assessment for NPEs reviewed several alternatives to NPE surfactants that are comparable in cost, readily available, and rapidly biodegrade to non-polluting, lower hazard compounds in aquatic environments.

The Crops Subcommittee has crafted a proposal that outlines the steps for implementation of the Safer Choice Program for inert review. Once it begins, inert manufacturers will have to submit their products to Safer Choice to be reviewed. A long implementation phase will be proposed, so that industry and manufacturers have enough time for submittal of inerts for screening and any required formulation change. Both the Livestock and Crops Subcommittees believe that some inerts currently in use in organic products will likely not fare well in this review, and strongly encourage manufacturers to consider the likelihood of the need for reformulation.

Public comments weighed heavily in favor of robust review of inert ingredients, due in large part to the fact that the original listing of inerts relied upon an EPA screening process which does not take into account the OFPA criteria. Additionally, public comments indicate significant concern that, while inerts are not listed as active ingredients in many pesticide, herbicide and fungicide formulations, they nevertheless exert significant impact on the environment, terrestrial and aquatic ecosystems and human health.

The Livestock subcommittee recognizes the public's deep concerns regarding these materials, while also acknowledging the significant impact that wholesale removal of EPA List 4 Inerts from the National List would have on the Organic industry. Given this dilemma, the Livestock subcommittee proposes re-listing of EPA List 4 – Inerts of Minimal Concern, while working closely with the IWG and Crops Subcommittee to craft a proposed annotation change which would subject inerts to screening through the SCP program.

Motion to Remove

This proposal to remove EPA List 4 Inerts of Minimal Concern will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of EPA List 4 - Inerts of Minimal Concern from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Compatibility**

Vote in Subcommittee

Motion to remove EPA List 4 - Inerts of Minimal Concern
Motion by: Tracy Favre
Seconded by: Jean Richardson
Yes: 1 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Excipients

Reference: 205.603(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

Excipients are ingredients added to livestock medications but which do not exert a therapeutic or diagnostic effect although they may improve drug delivery. They include such substances as dilutants, wetting agents, and absorption enhancers.

There are about 8000 substances that qualify as Excipients. However, most chemicals used as excipients in organic livestock production are recognized by the U.S. Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS), identified in the Everything Added to Food in the United States (EAFUS) database, or found in the FDA's Inactive Ingredient Search for Approved Drug Products database. There is not a comprehensive list of excipients.

Public Comment supports continued Listing.

Motion to Remove

This proposal to remove excipients will be considered by the NOSB at its public meeting.
The Subcommittee proposes removal of Excipients from the National List.

Vote in Subcommittee

Motion to remove Excipients from 205.603(f)

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.
The following nonsynthetic substances may not be used 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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017

Subcommittee Review

Strychnine is a prohibited substance and public comment continues to support that it be on the National List as a prohibited substance.

Motion to Remove

The Subcommittee proposes removal of Strychnine (as a prohibited Substance) from the National List

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Fails OFPA criteria

Vote in Subcommittee

Motion to remove strychnine from §205.604

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0