Sunset 2023
Meeting 2 - Review
Livestock Substances § 205.603 & § 205.604
October 2021

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
Written public comments will be accepted through September 30, 2021 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

- Activated charcoal
- Calcium borogluconate
- Calcium propionate
- Chlorine materials
    - (i) Calcium hypochlorite
    - (ii) Chlorine dioxide
    - (iii) Hypochlorous acid—generated from electrolyzed water
    - (iv) Sodium hypochlorite
- Kaolin pectin
- Mineral oil
- Nutritive supplements (Injectable trace minerals, vitamins, and electrolytes)
- Propylene glycol
- Sodium chlorite, acidified §205.603(a)(28); and Sodium chlorite, acidified §205.603(b)(9)
- Zinc sulfate

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

- None

Activated charcoal

Reference: §205.603 (a)(6) Activated charcoal (CAS # 7440-44-0) - must be from vegetative sources.
Technical Report: 2002; 2021 TR
Petition(s): 2002
Past NOSB Actions: 2002 recommendation/vote
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
The principal veterinary use for activated charcoal is as an antidote to toxic substances—and analogous medical applications include use as a detoxifier. According to the 2002 TAP Review, it is regarded as the poison antidote of choice and the universal antidote to toxic substances. There is no reported overdosage or acute toxicity. Activated charcoal is highly effective against both natural and synthetic toxins. Studies show activated carbon to be effective in removing various mycotoxins, such as aflatoxin, fumonisins, ochratoxin A, trichothenes, and zearalenone. Natural toxins from plants are also removed or attenuated by activated charcoal treatment or supplementation.

Activated carbon can also be used to remove synthetic pesticides from animals that might contaminate milk or meat. Treatment with activated carbon when using certain parasiticides can help reduce the residual levels in flesh and fatty tissue. However, it should be noted that use of such substances and withdrawal from milk or meat production is subject to the applicable USDA organic regulations.

Activated charcoal is used to treat animals for drug overdoses, with efficacy established on pigs, dogs, and rabbits.

Manufacture
Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs, and nut shells. The material undergoes pyrolysis at a very high heat. The resulting charcoal may be chemically activated using a variety of acids, bases, and salts, usually under pressure and elevated temperature. Activation agents include acetic acid, hydrochloric acid, potassium hydroxide, sodium hydroxide, zinc chloride, and several others. According to the 2021 TR, these chemical activation agents are usually collected and reused. The charcoal may also be activated through exposure to oxygenated gas or steam. Activated charcoal can also be produced from animal by products or coal, but these sources are not allowed under this listing.

International Acceptance
Canadian General Standards Board Permitted Substances List
Table 5.3 of the Permitted Substances List includes activated charcoal, stating “shall be of plant origin.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999; Part B, Section 22)
While there is no specific listing for activated charcoal (carbon), the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;

b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
While there is no specific listing for activated charcoal, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

International Federation of Organic Agriculture Movements (IFOAM) Norms
While activated charcoal is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic Production
While activated charcoal is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

Environmental Issues
Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem.

Because of concern regarding the use of certain acids in manufacture, during a sunset review for activated charcoal listed at §205.605(b), some stakeholders commented that they would like to see use limited to sources derived solely from steam activation. The recent TR indicates that this concern is lessened by re-use of the activation agents.

Discussion
This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of activated charcoal at this listing.

Comments on activated charcoal received for the Spring 2021 NOSB meeting were strongly in favor of its continued listing as an approved synthetic substance for use in livestock care. It is used infrequently in relatively small amounts and has little environmental impact. Furthermore, its use can reduce or prevent livestock distress and death.

Justification for Vote
The Subcommittee proposes removal of activated charcoal from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove activated charcoal from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

Calcium borogluconate

Reference: §205.603 (a)(7) Calcium borogluconate (CAS # 5743-34-0) - for treatment of milk fever only.
Technical Report: 2000 TAP
Petition(s): N/A
Past NOSB Actions: 2000 recommendation/vote
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Calcium borogluconate is used for the treatment of hypocalcemia (also called parturient paresis or milk fever) in cattle, sheep, and goats.

Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). The mother mobilizes large amounts of calcium to produce milk to feed newborn, and blood calcium levels can drop below the point necessary for impulse transmission along the nerve tracts. There are three discernable stages of milk fever for cows: in stage one, cows are able to stand but show signs of hypersensitivity and excitability. In stage two, cows are unable to stand. In stage three, cows lose consciousness progressively to the point of coma.

Manufacture
Calcium borogluconate is prepared by the reaction of five parts calcium gluconate to one-part boric acid in an aqueous solution. Boric acid esterifies the alcohol groups on the gluconate. Excess boric acid is removed by distillation with ethanol.

Calcium gluconate is prepared by a number of methods, including the reaction of gluconic acid with calcium hydroxide. Calcium hydroxide was also reviewed by the NOSB for processing and was voted synthetic and allowed. Gluconic acid is most commonly produced in the U.S. by fermentation.

International Acceptance
Canadian General Standards Board Permitted Substances List
Table 5.3 of the Permitted Substances List includes calcium borogluconate "[f]or milk fever. No withdrawal period required."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999) *Part B, Section 22)*
While there is no specific listing for calcium borogluconate, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;

b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;

c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;

d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

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

While there is no specific listing for calcium borogluconate, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

International Federation of Organic Agriculture Movements (IFOAM) Norms

While calcium borogluconate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic Production

Calcium borogluconate is not specifically listed.

Environmental Issues

The TAP review did not discuss environmental issues related to the manufacture of calcium borogluconate. The review noted, "[t]he material is metabolized by the animal, with the calcium entering the blood stream and some being expressed as milk. The animal's urine and feces may contain higher levels of boron as a result, but none of the literature reviewed partitioned the fate. Some claim that introduction of boron and sugar is either unnecessary or causes complications, but these are not specified."

Discussion

This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. This is the first sunset review of calcium borogluconate at this listing.

Calcium borogluconate is also classified on the National List under electrolytes which are currently listed at §205.603 as synthetic substances allowed for organic livestock production when they do not contain antibiotics. Due to the listing of calcium borogluconate as a stand-alone substance and the inclusion of the substance under the listing for electrolytes, the Subcommittee sought feedback on the separate listings and

clarity from the FDA on the status of the substance as a livestock treatment. The NOP conferred with the FDA on the proposed additions and amendments to § 205.603. During this conference, the FDA indicated that their process involves reviewing formulated products for medical treatment approval. FDA indicated they do not review for medical treatment approval of generic materials, as included in this rule. Therefore, individual substances cited in this rule would not be reviewed as medical treatments under the FDA process. Based upon this consultation, NOP believes these substances are not in conflict with FDA regulations.

Stakeholders reflected a general acceptance of calcium borogluconate under separate listings to facilitate consistency amongst certifiers. One comment noted that the majority of certifiers would allow calcium borogluconate as an injectable electrolyte but having the separate listing assures this is the case. One certifier commented the listing is redundant, another certifier adding that having the separate listings does not cause differences in decision making.

Producers support the re-listing of calcium borogluconate, stating that it is a common, inexpensive, and traditional treatment for ketosis in ruminates. A producer group noted that a variety of treatments for ketosis are necessary for organic producers as they perform and are administered in different ways. Two veterinarians commented that the substance is essential for livestock treatment.

Justification for Vote
The Subcommittee discussed stakeholder feedback, the additional listing of the substance on the National List as an electrolyte and the regulatory clarity established by NOP with the FDA. As the substance provides relief from unnecessary animal suffering, it is compatible with a sustainable system of agriculture.

The Subcommittee proposes removal of calcium borogluconate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove calcium borogluconate from the National List
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

Calcium propionate

Reference: §205.603 (a)(8) Calcium propionate (CAS # 4075-81-4) - for treatment of milk fever only.
Technical Report: 2002 TAP; 2015 TR (Electrolytes)
Petition(s): 2002
Past NOSB Actions: 2002 recommendation/vote; 2002 position paper
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Calcium propionate is an electrolyte that is used in organic livestock to treat metabolic conditions such as hypocalcemia, scours, dehydration, milk fever, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, and difficulty in labor and prostration. Lack of treatment often results in death. Although the FDA considers electrolyte formulations to be animal drugs, many of the formulations have not been

formally approved by the FDA; often because they are non-proprietary, general use materials. No company has applied for a New Animal Drug Approval (NADA) for calcium propionate.
Milk production is very closely related to the total glucose supply at the udder. Propionate is used by the liver to make the glucose used by the cow to make lactose, the sugar in milk. Propionate's second function involves the cow's fat metabolism. When the cow's energy demands for milk production exceed the amount of energy she is eating, she begins to break down some of her body fat. The fats are broken down into smaller pieces, called non-esterified fatty acids (NEFA's), and carried to the liver. At the liver, they are broken down to form acetate to generate energy. Acetate is broken down to carbon dioxide and water to yield more energy; however, this process requires propionate. If there is not enough propionate available (which is often the case when cows are making a lot of milk sugar), the excess acetate builds up in the liver, creating acetone, acetoacetate, and beta-hydroxybutyrate. These products are released from the liver into the cow's bloodstream, causing ketosis symptoms.

When lactation starts, milk fever can be treated by intravenous administration of electrolytes containing calcium to the animal. Calcium can be added by oral boluses, pastes, or drenching if the animal is still standing, but when the animal is down, an intravenous injection is needed. Oral doses of calcium chloride can be effective, but it is caustic, causing ulcerations and acidosis. Calcium propionate is less caustic, does not cause acidosis, and the propionate fatty acid is glucogenic. One dose of calcium propionate is given at calving, and another 24 hours later.

Manufacture
Electrolytes are mostly synthetic materials produced by chemical processes. Since many are salts, they are often produced by acid-base reactions. Calcium propionate is produced by reacting propionic acid with an aqueous solution of calcium hydroxide. It is also produced by reacting calcium hydroxide with propionitrile.

International Acceptance
Canadian General Standards Board Permitted Substances List In Canada, the Permitted Substances List for Organic Animal Production allows electrolytes as part of Table 5.3 'Health Care Products and Production Aids.' Electrolytes without antibiotics are permitted, and electrolyte solutions 'with no added active ingredients' are permitted (Canadian Standards 2011). No withdrawal period required.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999) Part B, Section 22)
Electrolytes are not specifically mentioned. However, under Health Care, Section 22 "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Electrolytes are not mentioned specifically in 834/2007. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states "chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007). In 889/2008 many of the electrolyte salts are permitted as feed additives.
While there is no specific listing for calcium propionate, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

International Federation of Organic Agriculture Movements (IFOAM) Norms
In the IFOAM Norms for organic production and processing version 2012, electrolytes are not specifically mentioned for organic animal production. In Section III (5) on Animal Husbandry, only natural sources are

permitted for vitamins, trace elements, and supplements. Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status (IFOAM 2012). But many of the electrolyte substances are mentioned in Appendix 4 as additives and processing aids (IFOAM 2012).
While calcium propionate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005). Later revisions included livestock. A summary in 2007 mentions that organic livestock must be fed organic feed, have exercise and access to pasture, and must not be fed antibiotics or GMOs. Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

Soil Association Standards, United Kingdom
The Soil Association Standards at Section 10.10.22 specifically allow calcium borogluconate, magnesium and phosphorus salts for milk fever. Section 10.10.34 specifically allows glucose/electrolytes as oral rehydration therapy for scours. Antibiotics and other non-allowed substances cannot be used (Soil Association 2005).

Environmental Issues
Electrolytes are used in animal production situations. Since electrolytes are usually added to correct deficiencies, concentrations in the environment due to excretion would be no more than a normal untreated animal with normal electrolyte balances. Most of these materials are produced by acid-base reactions. Environmental contamination from production of calcium propionate is unlikely, as reactions are simple neutralizations, producing the needed salt and water. Any problems would come from excess stocking rates. Excess stocking rates could lead to an excess of metabolic by-products in the immediate environment, plus extra stress on the animals.

Discussion
The 2015 TR on electrolytes, including calcium propionate, discussed whether there were alternative non-synthetic materials or alternative practices that would make the use of calcium propionate unnecessary. The TR concluded that the electrolytes are on the list of allowed synthetics, and non-synthetic sources of electrolyte formulations are typically not commercially available.

Alternative practices that would make the use of calcium propionate less necessary for treatment of hypocalcemia and the prevention of milk fever are low calcium prepartum diets, Dietary Cation Anion Difference (DCAD) diets (prior to parturition), and administration of oral electrolytes. Sometimes combinations of these treatments are used. DCAD diets involve adding electrolytes to food to provide an excess of strong anions or choosing food that will have this effect. Body condition should be managed in late lactation to prevent cows from becoming too fat which adds to the risk of milk fever. Modifying diets of late lactation cows to increase the energy supply from digestible fiber and reduce the energy supply from starch may aid in partitioning dietary energy toward milk and away from body fattening.

Public comments on calcium propionate received for the Spring 2021 NOSB meeting were generally in favor of continuing its listing on the National List as an approved synthetic substance for use in livestock care. A majority of livestock dairy producers, veterinarians, and the organic industry at large stated it was an essential treatment for milk fever. It was noted that calcium propionate products present little opportunity for environmental or human health issues, stating that the calcium propionate is metabolized by the livestock to achieve normal electrolyte balances. One commenter stated that they have not seen new, non-synthetic products available for the treatment of milk fever.

There were a few commenters who noted that the listing for calcium propionate is redundant, as the listings for electrolytes at §205.603(a)(11) and nutritive supplements at§205.603(a)(21) together allow for calcium propionate for the treatment of milk fever, but other commenters stated that having the separate listings does not cause differences in decision making.

Justification for Vote
The Livestock Subcommittee proposes removal of calcium propionate from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(a) if applicable: N/A. Not recommending removal.

Subcommittee Vote:
Motion to remove calcium propionate from the National List
Motion by: Kim Huseman
Seconded by: Sue Baird
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Chlorine materials Calcium hypochlorite, chlorine dioxide, Hypochlorous acid generated from electrolyzed water, sodium hypochlorite

Reference: §205.603 (a)(10) 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) Hypochlorous acid - generated from electrolyzed water
(iv) Sodium hypochlorite

Petition(s): 2016 (Hypochlorous Acid)
Technical Report: 2006 TR (Chlorine materials); 2017 Limited Scope TR (Hypochlorous Acid)

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 Recommendation to add hypochlorous acid; 11/2017 sunset recommendation
Recent Regulatory Background: Added to National List 2/20/2001 (65 FR 80547); Sunset renewal notice 3/15/2017 (82 FR 14420); Hypochlorous acid added to NL effective 1/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 1/28/2024 (hypochlorous acid); 10/30/2024 (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite)

Subcommittee Review

Use
Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is also used in cleaning water systems and disinfecting public drinking water supplies (Agency for Toxic Substances and Disease Registry (*ATSDR*), CDC, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance 5026).

Hypochlorous acid, as formulated via electrolyzed water, is effective as a sanitizer at a much lower chlorine concentration and is safer for health and the environment than the currently listed chlorine sanitizers.

Manufacture
Calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are all synthetic materials that are manufactured by chemical processes. Calcium hypochlorite is produced by passing chlorine gas over hydrated (slaked) lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuum dried. Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na2CO3). Chlorine dioxide is formed by reacting sodium chlorate (NaClO3) and sulfuric acid (H2SO4) with sulfur dioxide (SO2), or chloric acid is reacted with methanol (CH3OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

Hypochlorous acid: Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode but permits ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochlorite acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. (TR lines 48-68).

International Acceptance
Canadian General Standards Board Permitted Substances List
Bleach (not exceeding drinking water standards) is permitted in packaging and sanitation.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Sodium hypochlorite (e.g., as liquid bleach) is authorized for the clearing and disinfecting of livestock buildings and installations.

Environmental Issues
Information available from EPA and FDA on chlorine dioxide, sodium, and calcium hypochlorite, and hypochlorous acid indicates that there is no environmental contamination resulting from proper manufacture, use, or disposal.

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food safety regulations. The Livestock Subcommittee (LS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards. However, at this point in time, chlorine materials are an essential part for maintaining hygiene in livestock facilities.

Public comment was consistently in favor of relisting chlorine materials including (i) Calcium, hypochlorite, (ii) Chlorine dioxide, (iv) Sodium hypochlorite. Due to its efficacy as a sanitizer and the overall lack of

suitable alternatives, livestock producers and other stakeholders in the livestock product supply chain cited chlorine materials as a critical tool to maintain hygiene.

Justification for Vote
The Subcommittee proposes removal of chlorine materials from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove chlorine materials from the National List
Motion by: Kim Huseman
Seconded by: Nate-Powell-Palm
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Kaolin pectin

Reference: §205.603 (a)(17) Kaolin pectin - for use as an adsorbent, antidiarrheal, and gut protectant.
Technical Report: 2002 TAP; 2021 TR Pending
Petition(s): 2002
Past NOSB Actions: 2002 recommendation/vote; 2002 Position Paper
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review
Use
Kaolin pectin is used in livestock for the same reasons that it is administered to humans: as an adsorbent, anti-diarrheal, and gut protectant. It may also be combined with vitamin A to treat bacterial diarrhea in calves.

Status
According to the 2002 Technical Advisory Panel (TAP), the FDA has declared kaolin to be generally recognized as safe (GRAS) as an indirect food additive, and pectin to be GRAS as a direct food additive, both with the limitation that the levels in food are consistent with good manufacturing practices.

In addition to kaolin pectin having been placed on the National List as an allowed synthetic substance, kaolin and pectin are also separately allowed for use in organic systems.
In the 2002 TAP, there was some disagreement about whether kaolin pectin should be categorized as a synthetic or non-synthetic substance.

Manufacture
Kaolin pectin is a formulated mixture of kaolin and pectin. Both kaolin and pectin occur naturally. Kaolin is a mineral dust formed by weathering of aluminum silicates. Pectin may be obtained from appropriate edible plant material, usually citrus fruits or apples, by extraction into an aqueous medium. No organic precipitants are used other than methanol, ethanol, and isopropanol. In some pectin products, a portion of the methyl esters are converted to primary amides by treatment with ammonia under alkaline conditions. The commercial product is normally standardized with sugars and may be buffered with suitable food grade salts.

International Acceptance

Canadian General Standards Board Permitted Substances List. *Kaolin pectin not listed.*

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. *Kaolin pectin not listed.*

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with Article 14, which states that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999). *Kaolin pectin not listed.*

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with the Guidelines, which state the following:

> The use of veterinary medicinal products in organic farming shall comply with the following principles:
>
> a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
>
> b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
>
> c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
>
> d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms. *Kaolin pectin is not listed.*

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with IFOAM's general principles that state that "management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation."

Japan Agricultural Standard (JAS) for Organic Production
Kaolin pectin in not listed.

Environmental Issues
According to the 2002 TAP:

- There is no evidence that kaolin and pectin will contaminate the environment.
- In the manner in which kaolin is to be used, in kaolin pectin, there is an unlikely chance of environmental contamination. However, if workers are to be exposed to kaolin dust during manufacture, they must take appropriate precautions.

Discussion
Under §6509 of OFPA "Animal production practices and materials", Section (d) "Health care" states:

> (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 parasiticides on a routine basis; or
> **(C) administer medication, other than vaccinations, in the absence of illness.**

To the degree to which kaolin pectin is used to address actual livestock illnesses in the context of organic livestock production, its allowance is consistent with OFPA Section 6509.

Public comment during the 2021 spring meeting overwhelmingly supported the relisting of kaolin pectin; it is a vital tool used for gastrointestinal disorders in livestock production. Kaolin pectin does not seem to be overused, but rather being used on an as-needed basis. The TAP on kaolin pectin is from 2002, and the Livestock Subcommittee requested a new TR in 2021. The TR was not available before the Subcommittee voted on this document.

Justification for Vote
The Subcommittee proposes removal of kaolin pectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove kaolin pectin from the National List
Motion by: Sue Baird
Seconded by: Mindee Jeffery
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Mineral oil

Reference: §205.603 (a)(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.
Technical Report: 2002 TAP; 2015 TR; 2021 Limited Scope TR
Petition(s): 2002 Petition
Past NOSB Actions: 11/1995 NOSB minutes and vote; 2002 recommendation/vote; 5/2003 recommendation.
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Mineral oil was petitioned in 2002 to be used for treatment of intestinal compaction and topical

application, and as a dust suppressant. After reviewing the 2003 TAP review, NOSB recommended adding mineral oil for treatment of intestinal compaction only. The scope of this sunset review is for mineral oil, approved in 205.603(a)(20) for administering internally to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. The National Organic Program (NOP) final rule currently permits the use of mineral oil in organic livestock production for treatment of intestinal compaction, prohibited for use as a dust suppressant in 7CFR 205.603(a)(20).

Mineral oil is used as an internal lubricant in livestock production. In the case of "omasal impaction", the ruminant's third stomach (omasum) becomes tightly bound and compacted, resulting in severe pain for the affected animal. Omasal impaction is related to failure of omasal transport, which develops because of a condition that prevents ingested material from passing through the omasal canal into the abomasum, the fourth and final stomach compartment in the ruminants' stomachs. In general, impactions in various segments of the gastrointestinal tract may develop in pregnant beef cows during cold winter months when cattle consume less water and are fed lower-quality roughage. Mineral oil may be applied as an oral drench until the viscous mineral oil treatment lubricates the impaction.

Mineral oil is also commonly used to control bloat. Bloat generally occurs in animals after grazing young, lush pasture, particularly if the pasture contains significant amounts of legume species (clover, medics, or lucerne). Ruminants such as cattle produce large volumes of gas during the digestive process, and natural foaming agents in legumes and some rapidly growing grasses cause stable foam to form in the rumen. The animal is therefore unable to pass the gas trapped as small bubbles in the foam. Severe cases may require insertion of a wide-boar trocar and cannula into the rumen to relieve the pressure followed by direct addition of an anti-bloat preparation (e.g., mineral oil, vegetable oils, or dioctyl sodium sulfosuccinate) into the rumen through the cannula. Sudden death is commonly observed in cattle that are not closely observed. As a preventative measure, veterinary specialists suggest that cattle producers drench each animal twice daily with an anti-bloat preparation when the pasture is considered risky.

Manufacture

The industrial production of highly refined, food-grade mineral oils involve chemical processing and refinement using various chemical reagents and/or catalysts. To produce mineral oil, the chemical composition of natural crude oil is altered through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids, and/or catalysts).

Crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen, and sulfur atoms) as well as polynuclear aromatic hydrocarbons (PAHs) and other aromatic compounds.

Because of the complexity of the mineral oil mixtures, refined mineral oils are identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product. Mineral oils used in organic livestock production are hydrocarbon molecules containing 34 carbon atoms. These untreated mineral oils may also contain small amounts of nitrogen- and sulfur containing compounds. As such, the NOSB classified mineral oil as "synthetic" since initially recommending addition of the substance to the National List.

International Acceptance

Canadian General Standards Board Permitted Substances List

Canadian regulations permit numerous uses for mineral oils of varying purity. Mineral oils are allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999; Part B, Section 22)

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Mineral oils are not specifically mentioned for livestock applications. However, under Health Care, Section 22 "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

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

According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas). Mineral oils are not mentioned specifically in 834/2007 for the use in livestock. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states "chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007). While there is no specific listing for mineral oils in livestock, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phyto-therapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

International Federation of Organic Agriculture Movements (IFOAM) Norms

The IFOAM Norms permit the use of "light mineral oils (paraffin)" under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oils or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005) with later revisions including livestock. Japanese regulations for the organic production of livestock only mentions the use of "petroleum oil aerosol" and "petroleum oil emulsion" for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012).

However, on July 16, 2020 USDA and Japan signed an Organic Livestock Equivalency. Livestock products include beef, eggs, etc., and processed products of animal origin include ham, cheese, chocolate milk, etc. The arrangement is limited to domestic animals (cattle, horses, sheep, goats, and pigs) or domestic poultry (chickens, quails, ostriches, ducks, and wild ducks. Due to this equivalency agreement, livestock treated with Mineral Oil would be allowed for export to Japan.

Human Health and Environmental Issues

Because of their complexity, it is not possible to separate mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components are constituents of crude and refined mineral oil mixtures. Mineral oils may be classified as highly refined or mildly treated/untreated.

Testing in laboratory animals has demonstrated that mineral oils are slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oils are mild irritants, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation. Highly refined "white" mineral oils produced no sensitization reactions in guinea pigs repeatedly exposed to the substance.

The carcinogenicity and genotoxicity potential for mineral oils is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oils, which have undergone the most severe acid, solvent, or hydrocracking treatment, showed no activity in a series of skin-tumor bioassays. Much like the mammalian studies, the results of avian and honeybee studies suggest that refined mineral oils are practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively. Refined mineral oils are generally characterized as minimally toxic to aquatic organisms on an acute exposure basis.

The white mineral oils that are likely to be used for lubrication and external parasite control in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants compared to untreated and mildly treated oils.

Discussion

During the 2015 review of mineral oil some livestock producers indicated that failure to regularly treat for omasal impaction often results in the need for surgery. Mineral oil products are considered unapproved animal drugs according to FDA regulations. Animal drugs containing mineral oils are currently marketed for relief of obstruction or impaction of the intestinal tract in cattle, sheep, goats, swine, and horses. Because these animal drugs are not FDA approved, the labels carry the disclaimer: “this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.”

Accordingly, the NOP was unable to accept the 2015 NOSB recommendation to allow the use of mineral oil as a livestock medication. Mineral oil remains prohibited for use in organic livestock production as an orally administered treatment of constipation in cattle and other ruminants. The NOP currently permits the use of mineral oil in organic livestock production for topical use and as a lubricant at §205.603(b)(6)).

Best management practices may prevent the development of omasal impaction and parasite infestation in cattle, sheep, and other livestock under certain conditions. Omasal impaction generally occurs when the feed provided to cattle is tough and fibrous, particularly alfalfa stalks and cuttings from fodder trees, or under drought feeding conditions in sheep that are fed on the ground. The latter form of impaction in sheep is typically due to the accumulation of soil in the omasum.

In healthy animal stock, providing the necessary nutritional requirement for wintering pregnant beef cattle can prevent abomasal impaction. Producers using low-quality roughage should augment the ration with grain to meet energy and protein requirements, especially if laboratory analyses indicate these key nutrient parameters are low in the roughage alone. Adequate drinking water should be supplied continually for animal welfare, and to encourage proper digestion of feed and pasture materials. Like bloat, omasal impaction may be prevented through provision of rations containing 10–15% cut or chopped roughage mixed into the complete feed to ease the digestion of fibrous materials. The roughage should be a cereal, grain straw, grass hay, or equivalent, and grains should be rolled or cracked as opposed to finely ground.

Public comments received during the Spring 2021 NOSB meeting overwhelmingly supported relisting mineral oil. Commenters stated that mineral oil is used infrequency but when it is needed, there is no alternative that is sufficient because natural oils do not work, as they get digested and do not move or break up the compaction. Other commenters stated that other than invasive surgery, mineral oil was the best option. One livestock producer stated that you can take good care of your animals, but compaction can still happen in rare cases. If the material were prohibited, there would be huge negative effects on cow health. Animal welfare would be impacted, because the animal would either die, or would have to be sold if nonorganic treatments are used. One livestock veterinarian commented that, “Mineral oil has the property of not being absorbed by the gut and thus can coat the gut so there is no absorption and possible reabsorption downstream of toxins. It can be used for frothy bloat. It is indispensable to me as a practitioner to quickly reverse digestive upsets.”

Subcommittee Justification
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): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove mineral oil from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

Nutritive supplements injectable trace minerals, vitamins, and electrolytes

Reference: §205.603 (a)(21) Nutritive supplements - injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.
Technical Report: 1995 TAP ((a)(11) electrolytes); 2015 TR ((d)(3) vitamins); 2015 TR ((a)(11) electrolytes); 2019 TR ((d)(2) trace minerals)
Petition(s): 2009
Past NOSB Actions: 05/2009 recommendation to add to NL
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Nutritive supplements (Injectable trace minerals, vitamins, and electrolytes) are allowed to treat livestock ailments when administered or ordered by a licensed veterinarian.

Manufacture
Trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. Organic compounds are used for some of the trace minerals.

Vitamins can be extracted from foods or synthesized by chemical or fermentation processes. Regarding the former, certain vitamins can be obtained from natural dietary sources in varying quantities. For example, Vitamin C (ascorbic acid) is a major nutritional component of citrus fruits and Vitamin D is a natural constituent nutrient of cold-water fish.

International Acceptance
Canadian General Standards Board Permitted Substances List
From the Permitted Substances List (CAN/CGSB-32.311- 459 2006), vitamins may be used for enrichment or fortification of livestock feed, and synthetic vitamins may be used if non-synthetic sources are not commercially available (CAN, 2011b). Under no circumstances should vitamins be used to stimulate growth or production (CAN, 2011b).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
EC No. 834/2007 and 889/2008, state that “feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production.” Specifically, vitamins are allowed nutritional additives for use in animal production under the following conditions: (1) Vitamins derived from raw

materials occurring naturally in feedstuffs; (2) Synthetic vitamins identical to natural vitamins for monogastric animals and aquatic animals; (3) Synthetic vitamins A, D, and E identical to natural vitamins for ruminants with prior authorization of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations.

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

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced 466 Foods (CAC GL 32-1999) provides criteria for feedstuffs and nutritional elements. Specifically, section 467 of these guidelines pertaining to livestock production states that "feedstuffs of mineral origin, trace minerals, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used" (Codex, 2013).

United Kingdom Soil Association

Nature identical synthetic vitamins may be used in the production of non-herbivores without permission, while producers of herbivores must seek approval to use nature identical synthetic vitamins A, D and E. Regarding the latter group, the operator must demonstrate nutritional deficiency of the animals' feed. Soil Association standards do not permit the use of concentrated vitamins and minerals to encourage early maturity or high levels of production (Soil Association, 2014).

Japan Agricultural Standard (JAS) for Organic Production

The Japan Agricultural Standard (JAS) for Organic Production does not specify the allowed or prohibited status of vitamins in organic livestock feed materials. However, the standard permits 493 natural feed additives: Feed additives (except for those produced by using antibiotic and recombinant DNA technology), which are natural substances or those derived from natural substances without being chemically treated. In case of a difficulty to obtain feed additives listed in 8, the use of similar agents to the described food additives are permitted only for supplementing nutrition and effective components in feeds. This statement suggests that synthetic vitamins may be allowed if naturally derived substitutes are not available (JAS, 2012).

Environmental Issues

The potential exists for environmental contamination resulting from the industrial production of several vitamin compounds. In particular, materials safety data sheets (MSDS) for several feedstock chemicals and other chemical reagents used in the synthesis of calcium pantothenate (vitamin B5) and biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. Isobutyraldehyde and cyanide salts used in the synthesis of calcium pantothenate as well as ethylene oxide used for choline chloride generation have shown toxicity toward fish and aquatic invertebrates. Further, hydrogen sulfide, which is used in the synthesis of biotin, is toxic to fish at low doses, and is therefore listed as very toxic to aquatic life. Strong acids (e.g., nitric acid, hydrochloric acid) used in the syntheses of numerous vitamins may alter the pH of aquatic systems if accidentally released to the environment. Strong acids and bases are also utilized in the extraction of tocopherols from vegetable oils and may lead to environmental impairment if accidentally released or improperly handled. Many of the vitamins synthesized for supplements and feed fortification are derived from petroleum products or genetically modified crop materials.

Discussion

There can be times of stress when certain individual animals need high amounts of vitamins and minerals delivered to target tissues in a rapid manner. If for whatever reason animals are not eating, then they are not taking in the oral forms of vitamins and minerals. They may need nutritive supplementation best delivered by injection. Additionally, with the prohibition of the use of antibiotics in certified organic

livestock, farmers and veterinarians need as many of the remaining tools as possible to prioritize animal health. Injectable forms of vitamins and minerals, allowed strictly on an as-needed basis, provide valuable support to an animal's immune system and work to assist livestock health, well-being, and animal welfare.

Public comments consistently highlighted the need for effective health supplements that can address acute illnesses in livestock. Overall, commenters agreed that the removal of nutritive supplements would hobble organic livestock producers' ability to effectively manage their stock and provide the best care in acute illness scenarios.

Justification for Vote
The Subcommittee proposes removal of nutritive supplements from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove nutritive supplements from the National List
Motion by: Nate Powell-Palm
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Propylene glycol

Reference: §205.603 (a)(27) Propylene glycol (CAS #57-55-6) - only for treatment of ketosis in ruminants.
Technical Report: 2007 TAP; 2021 TR
Petition(s): 2002
Past NOSB Actions: 2002 Position Paper; 9/2002 recommendation to add to NL
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559)
Sunset Date: 1/28/2024

Subcommittee Review

Use
Propylene glycol is allowed for use in organic production only as a treatment for ketosis in ruminants [21 CFR 205.603(a)(27)]. Propylene glycol is typically administered in an oral drench to animals showing signs of clinical ketosis or to animals that a producer suspects of having subclinical ketosis. Propylene glycol is generally recognized as safe (GRAS) by the U.S. FDA (21 CFR 184.1666).

Ketosis is a metabolic disease that can result from energy imbalance in early lactation. According to the most recent technical report, the majority of a dose of propylene glycol is not fermented in the rumen. Instead, it is directly absorbed and metabolized by the liver to form glucose.

Manufacture
Propylene glycol is commercially produced through the hydrolysis of propylene oxide. The original source of the propylene oxide is typically propylene, generated either through the steam cracking of hydrocarbons or through the dehydrogenation of propane, both of which are non-renewable sources.

The 2021 technical report notes that researchers and manufacturers are improving methods to produce propylene glycol on a commercially viable scale via two additional routes:

- Catalytic hydrogenolysis of glycerol, a method that is becoming more economically feasible with the increased production of glycerol through biomass-produced ethanol.
- Microbial fermentation through a number of different microorganisms.

Many of the fermentation methods in development rely on genetically modified microorganisms for the efficient production of propylene glycol.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board includes propylene glycol on CAN/CGSB 32.311-2020 Table 5.3 (Health Care Products and Production Aids) with the annotation, "May only be used as an ingredient in foot baths." Table 5.3 also includes a listing for "Formulants (inerts, excipients)," allowing propylene glycol as an excipient used along with a permitted active ingredient.

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

The CODEX guidelines state in Annex 1, Part B "Health Care" clauses that producers must first prevent disease through species selection and management approaches. If prevention practices are insufficient to keep an animal healthy, a producer may use allopathic veterinary drugs if other homeopathic or phytotherapeutic products are insufficient. Propylene glycol is not explicitly mentioned for livestock health care input materials, but it would fall into the category of "veterinary drug" as defined in Section 2.2 of the 261 Guidelines.

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

Title II, Chapter 2, Section 4 of the EC No. 889/2008 focuses on disease prevention and veterinary treatment in organic livestock production. Article 24, paragraph 3 indicates that if preventive methods and phytotherapeutic and homeopathic products are not effective at combating illness, a producer may use chemically synthesized veterinary medical products. In this case, propylene glycol would be considered a "veterinary medicinal product" under the definition at Article 1(2) of Directive 2001/82/EC of the European Parliament and of the Council concerning the Community code relating to veterinary medicinal products. A 48-hour withdrawal period between the last administration and the production of organically produced milk or meat is noted.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Section 5.6 of the IFOAM Standard for Organic Production and Processing describes the requirements for the use of veterinary medicine in organic livestock production. Section 5.6.1 requires that producers establish preventive practices, including good quality feed and access to the outdoors, to avoid illness in their livestock before using synthetic allopathic veterinary medical products. Propylene glycol, when used to address ketosis symptoms in livestock, would be considered a synthetic allopathic veterinary medical product, and Exception (c) would allow its use under veterinary supervision with a minimum withdrawal period of at least 14 days. Prophylactic use of synthetic allopathic veterinary drugs is prohibited.

Japan Agricultural Standard (JAS) for Organic Production.

Article 4 of the Japanese Agricultural Standard for Organic Livestock, last revised in April 2018, includes the "Health control" section, specifying practices for organic livestock production. The Standard requires that producers implement preventive practices before using veterinary drugs, and veterinary drugs may only be used for therapy purposes. A withdrawal period of 48 hours between last use and milking or slaughter is noted.

Environmental Issues
The technical report on propylene glycol notes that the substance is widely used throughout many U.S. and global economic sectors, with most of the production capacity through propane as part of the petrochemical reduction process. Production of propane can lead to significant environmental impacts, including greenhouse gas emissions, pollution of waterways, water use issues, and petrochemical spills.

In the treatment of ketosis, propylene glycol is used in small volumes and is virtually non-toxic to vertebrates and invertebrates (with the exception of cats). Its use on organic dairy farms presents a very low risk for environmental contamination. Beyond mishandling or leakage from packages, less than 1 percent of the propylene glycol used in a dose is excreted in milk, manure, or urine when used to treat ketosis. Contamination resulting from on-farm use is likely to be minimal.

Based on currently available information, propylene glycol is:

- Not acutely toxic and it has a high lethal concentration in both mammals and aquatic species.
- Readily decomposed into carbon dioxide and water by microorganisms in water and soil, and breaks down in air through reaction with hydroxyl radicals.
- Able to move rapidly through the environment with water and shows little to no bioaccumulation.
- Efficiently retained and consumed as energy for animals so that it will not be applied to soils through manure incorporation.

Discussion
Propylene glycol was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. This is the first sunset review of propylene glycol at this listing.

Public comments were received for the Spring 2021 meeting in written formats. One industry group reported that propylene glycol is a sensible replacement for the administration of bottles of dextrose intravenously, which is a subpar treatment and can be dangerous for the farmer and the cow. According to the written submission, propylene glycol is the easiest route to rehabilitating ruminants suffering from ketosis, as cows can be aggressive when ketotic, making IV administration difficult and dangerous.

Dairy producers noted that there are natural alternatives like oral administration of apple cider vinegar and molasses. In addition to natural and preventative solutions to ketosis, producers provided information that propylene glycol is commonly available in farm stores and veterinary clinics and supported the continued listing of the substance. Additionally, a large animal veterinarian commented that propylene glycol is the gold standard for treatment of ketosis in ruminants.

The USDA organic regulations specify that producers shall not administer any drug in the absence of illness [7 CFR 205.238(c)(2)], limiting the use of propylene glycol to after the onset of ketosis symptoms, both clinical and subclinical, in ruminants.

According to the technical report, many of the available fermentation methods rely on genetically modified microorganisms for the efficient production of propylene glycol. These new methods offer the potential to produce propylene glycol without relying on petrochemical byproducts but are not economically competitive or available at commercial scale at the time of this review.

Subcommittee Recommendation
Despite concerns about the environmental impacts from the manufacturing practices identified in the technical report, and the potential future risk of excluded methods in the manufacture of propylene glycol,

the Subcommittee has determined that the limited use of the substance as a medical treatment for ketosis is necessary and recommends relisting.

Justification for Vote
The Subcommittee proposes removal of propylene glycol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove propylene glycol from the National List
Motion by: Mindee Jeffery
Seconded by: Nate Powell-Palm
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Sodium chlorite, acidified

Reference: §205.603 (a)(28) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only; and
§205.603 (b)(10) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only.
Technical Report: 2013 TR
Petition(s): 2012; 2014 Addendum #1; 2014 Addendum #2
Past NOSB Actions: 4/2015 recommendation
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Acidified sodium chlorite is used as a disinfecting teat dip for organic livestock producers. Acidified sodium chlorite breaks down in the environment to water and salt and is more benign than other teat dip materials currently listed on the National List.

Manufacture
Acidified sodium chlorite solutions are made by mixing an aqueous solution of sodium chlorite with a food-grade acid, such as citric acid. Several industrial synthetic procedures are utilized in the production of sodium chlorite. As examples, the treatment of chlorine dioxide, sodium hydroxide, and a reducing agent (e.g., sodium sulfite) or reaction of chlorine dioxide with sodium peroxide (i.e., Na_2O_2 or an alkaline solution of hydrogen peroxide, H_2O_2) are commercially utilized methods for the synthesis of sodium chlorite. Generally recognized as safe (GRAS) acids, such as citric and lactic acids, are typically produced through fermentative means; however, these naturally occurring compounds may also be extracted from plant-based sources or generated using chemical synthetic methods.

International Acceptance
Canadian General Standards Board Permitted Substances List
Acidified sodium chlorite is not specifically listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
While there is no specific listing for acidified sodium chlorite, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further

notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999) While there is no specific listing for acidified sodium chlorite, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms
While acidified sodium chlorite is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic Production
Acidified sodium chlorite is not specifically listed.

Environmental Issues
While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

Discussion
Acidified sodium chlorite was among 35 NOSB recommendations on amendments to the National List made between November 2000 and November 2016 that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of acidified sodium chlorite at this listing.

Preventive health care is an essential part of organic farming, and mastitis prevention through clean milking parlors and clean animals is always of paramount importance on a dairy farm. Organic farmers cannot use antibiotics and thus the use of pre-milking and post-milking teat dips is a normal practice and may be the most critical factor in preventing mastitis. Acidified sodium chlorite satisfies the criteria related to impact on humans and the environment and is compatible with organic agriculture. Iodine is widely used in teat dips. The technical report (TR) on iodine, received on January 7, 2015, provides recent research information and comparative data on iodine-based teat dips and on teat dips whose primary ingredient is acidified sodium chlorite. The following is excerpted from the iodine TR in its discussion of alternatives to iodine in teat dips: "Information regarding the availability of natural, non-synthetic agricultural commodities or products that could substitute for iodine and iodophor disinfectants is limited." Acidified sodium chlorite thus appears to be a potentially important ingredient in teat dips.

Public comments during the 2021 spring meeting were supportive of relisting sodium chlorite, acidified (ASC) as an approved teat dip for livestock. It was stated a few times that it is not used frequently but key when necessary to prevent mastitis. During the subcommittee review, there was discussion about the two listings at §205.603(a) and §205.603(b), and whether they were redundant. It appears the listings are not redundant. At §205.603(a) Sodium chlorite is allowed as a pre-milking sanitizer while at §205.603(b) it is used for post-milking as a preventative topical treatment.

Justification for Vote
The Subcommittee proposes removal of sodium chlorite, acidified from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove sodium chlorite, acidified from the National List
Motion by: Kim Huseman
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

Zinc sulfate

Reference: §205.603 (b)(12) Zinc sulfate - for use in hoof and foot treatments only.
Technical Report: 2015 TR
Petition(s): 2014
Past NOSB Actions: 4/2015 recommendation
Recent Regulatory Background: Added to NL effective 1/28/2019 (83 FR 66559).
Sunset Date: 1/28/2024

Subcommittee Review

Use
Zinc sulfate is allowed for use in organic livestock as a footbath for control of foot rot in livestock-- primarily dairy cattle, sheep, and goats.

Manufacture
Zinc sulfate is produced synthetically by combining zinc ash with aqueous sulfuric acid (TR line 53). Zinc ash is produced from zinc ore mined from underground or open pit mines (TR line 60).

International Acceptance
Canadian General Standards Board Permitted Substances ListOperators of organic livestock production facilities must establish a provision for prompt treatment for animals with detectable disease, lesions, lameness, injury, and other physical ailments. Where preventive practices and vaccines are inadequate to prevent sickness or injury and where disease and health problems require treatment, the use of biological, cultural, and physical treatments and practices is permitted, in accordance with CAN/CGSB-32.311, Organic Production Systems — Permitted Substances Lists, but may be relaxed under veterinary supervision if listed substances fail to work. TR lines 216 – 221.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Restrictions with respect to courses of treatment and withdrawal periods are defined (EU, 2007); Animal health is based on prevention of disease, but treated livestock may not be sold as organic products if treatment involves an unapproved medication. Treated livestock must be submitted to the defined conversion periods. Zinc sulfate may be used as a trace element in the production of organic livestock. TR lines 231-238.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Where specific disease occurs, and no management practice exists, therapeutic use of veterinary drugs is permitted; zinc can be used as a trace element supplement when the need is recognized by the certification body or authority. The use of zinc sulfate for control of foot rot in cattle sheep and goats has not been specifically addressed (Codex, 2007). TR lines 226-230.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs. Organic animal management never withholds medical treatment considered necessary for the welfare of an animal to maintain the organic status of the animal (IFOAM, 2014). TR lines 245-250.

Japan Agricultural Standard (JAS) for Organic Production
Veterinary Drugs specified by Article 1. 1 of the Ministerial Ordinance for Handling by the Ministry of Health, Labor and Welfare (No.4 of 1961) are permitted. Zinc sulfate use is limited to the case where livestock is unable to grow normally because of its shortage as a trace element (MAFF, 2012). TR lines 241-244.

Environmental Issues
Production of zinc sulfate results in significant local production of tailings in large volumes and lesser amounts of particulates, heavy metals, and gases, which can be filtered out or captured, but may not be depending on where the zinc is mined and processed. The amount of zinc sulfate used for foot rot control is a small proportion of its total use. However, its disposal on farm fields with manure can result in soil zinc buildups beyond desirable levels.

It should also be noted that the use of zinc sulfate should decrease the use of copper sulfate in treating foot diseases. The buildup of persistent copper in agricultural soils is a serious issue. While zinc sulfate can

accumulate in soils, its persistence is less certain due to its mode of attachment to soils. Zinc sulfate is therefore considered a more benign material compared to copper sulfate.

Excess applications of zinc sulfate could disrupt essential nutrient balances in soils and in extremes could become toxic to plants or animals. Zinc sulfate is toxic to fish and aquatic invertebrates. Direct application to water where these exist should be avoided.

Discussion
According to the 2015 TR, "Peracetic acid and hydrogen peroxide foams are also used in the treatment and control of footrot, although the efficacy of these treatments is controversial (Bergstein et al., 2006). It is important to note that antibiotics are increasingly used in treatment of pododermatitis, due to the bacterial nature of its etiology. However, good evidence is available for increased microbial antibiotic resistance in *Dichelobacter nodosus* and other bacteria present during infection (Lorenzo, et al., 2012). Antibiotics are prohibited in organic livestock production (7CFR §205.237, §205.238).These same bacteria have not demonstrated resistance to zinc sulfate treatment…. Some vaccines have been shown to be effective in treating footrot. Because several bacteria are involved in the infection and these are represented by multiple serogroups, the effectiveness of using a monovalent vaccine in treating another serogroup is likely to be limited. Programs are ongoing to address vaccination, but a complete vaccine has not yet been described for footrot in cattle or sheep (Bennett and Hickford, 2010)."

Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Formalin can also be used for this purpose but is not approved for use on organic farms. Zinc sulfate has proven particularly effective at controlling the bacteria associated with foot rot, and is sometimes used in combination with other materials, including copper sulfate. The combination of zinc sulfate with sodium lauryl sulfate (as an excipient) has proven to be more effective than zinc sulfate with copper sulfate.

Copper compounds are toxic to sheep and goats, so the presence of zinc sulfate on the National List allows for its use for these species as an alternative to copper sulfate.

Comments from stakeholders were strongly in favor of retaining zinc sulfate on the national list as an approved synthetic material. Some proposed adding an annotation specifying that its use be curtailed if soil zinc levels become excessive. Zinc sulfate is considered less environmentally damaging than copper sulfate, which is on the National List for the same use. Since zinc sulfate has only been on the National List for a short time, it is not clear whether its presence there will reduce the use of copper sulfate for hoof disease.

Based on this information, including stakeholder comments, the Livestock Subcommittee proposes that zinc sulfate be retained on the National list.

Justification for Vote
The Subcommittee proposes removal of zinc sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove zinc sulfate from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0