National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Chlorine Materials
Spring 2026

Summary of Petition

In September 2024, the National Organic Program received a petition from the Organic Materials Review Institute (OMRI) requesting an amendment to the annotation for Chlorine materials at § 205.603(a)(10) to clarify whether they are allowed for direct treatment of livestock drinking water. The petitioner stated that some entities in the organic industry have established policies that are based on the belief that the National List at § 205.603(a)(10) allows for direct livestock drinking water treatments if the final drinking water meets Safe Drinking Water Act (SDWA) standards. Other entities in the industry interpret the § 205.603(a)(10) annotation as one that limits the use of chlorine materials to disinfection of facilities and equipment.

The historical background of Chlorine materials is that they appeared on the original National List and have been renewed every five years except in 2005 and 2010 when sunset votes were deferred to afford the NOSB additional time to receive additional technical assistance on these materials. The petition noted that four synthetic "chlorine materials" are listed on the National List at § 205.603(a)(10); these are (a) Calcium hypochlorite, (b) Chlorine dioxide, (c) Hypochlorous acid, and (d) Sodium hypochlorite. The petition seeks clarification on whether § 205.603(a)(10) allows for direct livestock drinking water treatments with chlorine materials.

Intended or Current Use of Chlorine Materials

There is no disagreement about the fact that the § 205.603(a)(10) annotation states that chlorine materials are allowed in organic livestock production for disinfecting and sanitizing facilities and equipment. The focus of disagreement is the specification that "residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act." This is the specification in the annotation that is the source of the two divergent interpretations. The petition cited NOP Guidance 5026 which further clarifies that, "Residual chlorine levels in the water in direct food or animal contact (for example, drinking water) should not exceed the maximum residual disinfection level." According to the petitioning organization, it is unclear if this reference to "drinking water" is an attempt to add, clarify or limit the use of chlorine as a livestock drinking water treatment.

The petitioning organization cited the following NOP guidance documents and/or notices to support its request for an annotation to clarify whether chlorine materials can be used in direct treatment of livestock drinking water. It cited *NOP Guidance 5026: The Use of Chlorine Materials in Organic Production and Handling (*2011, updated 2024) and *NOP Notice 11-7: Issuance of Final Guidance and Response to Comments* (2011, updated 2024). Both documents are published in the NOP's Program Handbook.

NOP 5023 defines facility as "A structure or site where production, handling, processing, packaging, or storage of organic products occurs. A facility could include packing lines, wash lines, storage units, coolers, freezing plants, feed mills, milk houses, production structures such as housing for livestock, greenhouses, and mushroom buildings. It, however, remains unclear whether this definition should be used when considering the 205.603(a)(10) use restriction under current discussion. It is important to note that NOP 5023 was published long after the term "facility" was included in annotation language for the 205.603(a)(10) "Chlorine materials" entry.

NOP Notice 11-7 introduces the term "direct use" which is a different from the terms "equipment" and "facility" which are used in the 205.603(a)(10) "Chlorine materials" annotation. In *NOP Notice 11-7,* drinking water treatment is identified as a "direct use" and dairy pipelines would be a "facility use." The notice, however, does not go further to clarify whether drinking water treatment is an "equipment" use or a "facility" use or both.

Regulatory Authority

The regulatory authority over chlorine is not limited to a single government agency. The U.S. Food and Drug Administration (FDA) exercises a substantial amount of regulatory authority over chlorine use in livestock production. The U.S. Environmental Protection Agency (EPA) also exercises regulatory authority over chlorine materials. The Pasteurized Milk Ordinance (PMO) is also an important authority on the use of chlorine materials in livestock production even though it is not a "regulatory authority." Both the FDA and U.S. Department of Health and Human Services endorse the PMO as the minimum standard which many local and state regulators use when establishing standards for dairy producers. The PMO includes requirements for chlorine use in dairies; it gives instructions for direct water sanitization measures such as "well shocking."

Environmental and Health Impacts of Chlorine Materials

According to the petition, when chlorine dioxide is used as a disinfecting agent, it breaks down primarily into chlorite. Chlorite in water may move into groundwater but reactions with soil and sediments may reduce the amount of chlorite reaching groundwater. The toxic action of chlorite is primarily in the form of oxidative damage to red blood cells at doses as low as 10mg/kg of body weight. Toxic reaction products are not known to occur when chlorite is mixed with organic materials. The Environmental Protection Agency (EPA) has set the maximum contaminant level (MCL) of 0.8mg/L for chlorine dioxide in drinking water and 1mg/L for chlorite (EPA, 2002). It is important to note that chlorine dioxide contamination in water is difficult to identify because it is intentionally added to drinking water as a disinfectant in some municipal water treatment systems. In compliance/furtherance of the Information Collection Rule (ICR), levels of chlorite ion were sampled from drinking water distribution systems of publicly owned treatment works (POTW) facilities that utilized chlorine dioxide in the United States. The resulting data revealed that approximately 16 percent of these facilities had levels of chlorite ion over the MCL of 1 mg/L (ATSDR, 2004b)."

According to the petitioning organization, even though it is known that elevated levels of water chlorination may be applicable and even necessary in organic livestock situations, research

acknowledges that excess chlorine may have different impacts depending on the class of animals. While elevated levels of chlorine in water may affect the efficiency of the rumen microbial population and thereby impair rumen function in ruminant livestock, a net positive effect is likely for monogastric livestock. This is partly because of a less susceptible form of digestion in non-ruminants and the fact that they are more affected by pathogens in drinking water. A risk-benefit analysis would suggest that more aggressive water disinfection may be beneficial to non-ruminant livestock in situations where risk of bacterial contamination is high. The petitioning organization stated the need for more research to determine appropriate levels of chlorine for different types of livestock.

The petitioning organization cited a few publications including an extension publication that stated that a 3-ppm concentration of chlorine in water is safe for cattle to drink and helps control algal and bacterial growth in the water. The publication went on to state that use of bleach at a greater concentration could risk creating high chlorine contamination levels and deter cattle from drinking.

Disinfection of water for livestock is highly recommended if microbial contamination is a concern. One of the publications included an unpublished observation that poultry has an elevated level of tolerance for sodium hypochlorite which is described as the most common product used for water sanitation. The observer stated that even considerable overdosing can be well tolerated by poultry over a brief period, with minimal or no effects on production. Even though accidental application of 50 ppm (i.e.,10-fold recommended dose) was reported to result in just a slight transient decline in water consumption, the authors proscribed long term exposure to elevated levels of sodium hypochlorite in water.

One of the publications included in the petition stated that several compounds, known as Disinfection By-Products (DBPs), are formed through the interaction of chlorine molecules with naturally occurring residual organic compounds. These organic compounds include humic and fulvic acids that are commonly found in most water sources. The authors also highlighted the fact that residual organic matter is present in many livestock water sources, especially in surface waters. They also noted that DBPs generated from chlorination of organic compounds may be a source of contaminants that pose risks to both human and animal health. The researchers stated that although direct adverse effects associated with sodium hypochlorite disinfectants are very unlikely, application of these products in water containing organic matter may lead to synthesis of DBPs which can be toxic. The authors called for the treatment of potential adverse effects associated with DBPs as a water quality issue. Filtration and coagulation are two methods used to remove organic materials from water prior to chlorination.

The petition included a publication that cited information from Health Canada (1995) and WHO (1996) who recognized the health hazard associated with DBP in humans and contrasted that with the lack of adequate corrective measures when it comes to water quality for livestock. The researchers listed three main classes of DBPs in drinking water that pose potential risks to livestock: (1) chlorophenols, (2) trihalomethanes (THMs), and (3) haloacetic acids (HAAs). Chlorophenols occur in drinking water because of the chlorination of phenols. Several phenolic DBPs produced during chlorination have been shown to cause lymphomas, leukemia, and hepatic tumors in rats. THMs have been closely linked to an increased

incidence of bladder cancer and possible increases in rectal and colon cancer in humans (Mills et al., 1999).

It is important to note that cancer is infrequent, and carcinogens are usually not an issue for livestock due to their short productive life. According to the authors of one of the publications included in the petition, the carcinogenic characteristics of DBP could potentially present a health hazard in livestock used for breeding and milk production which have longer life spans relative to animals used for meat. It, however, deemed the practical aspect of such problems to be negligible. The authors, however, noted chronic adverse effects of DBPs on reproductive parameters. It cited the findings of Linder et al. (1997) that dichloroacetic acid causes alterations in spermiation, sperm morphology, and sperm motility. It also reported the research of Veeramachaneni (2000) who reported that DBPs can be associated with deteriorating trends observed in male reproduction.

Performance of Alternative Water Disinfectants

Hydrogen peroxide is another common disinfectant used for drinking water treatment. It appears on the National List with no annotation and is an oxidizer like chlorine. According to the petitioning organization, unlike other chemical substances, hydrogen peroxide does not produce residues or gases. High concentrations of this chemical are however required for disinfection. Additionally, hydrogen peroxide reacts with numerous substances and slowly decomposes into water and oxygen.

Iodine also appears on the National List with no annotation. Like chlorine, it kills most disease-causing organisms and requires short to moderate contact times. It is, however, not remarkably effective against biofilms. Harmful effects of excess ingestion and the physiologically active nature of Iodine make them unsuitable for long-term continuous disinfection.

Ultraviolet (UV) radiation effectively destroys bacteria and viruses but lack residual activity against microorganisms. A secondary disinfectant is therefore needed to prevent the regrowth of these organisms. The petitioning organization also stated that UV radiation can be attractive as a primary disinfectant for small systems because (a) it is readily available (b) produces no known toxic residuals (c) requires short contact times and (e) the application equipment is easy to operate and maintain.

Summary of Review

The LS discussed relevant regulations and regulatory agencies, the current and intended use, as well as the health and environmental impacts of the use of chlorine in livestock drinking water. The subcommittee sought additional information on factors affecting the formation of disinfectant by-products in livestock drinking water and any additional input on the correct interpretation of the §205.603(a)(10) annotation in a discussion document published for the Fall 2025 NOSB meeting. This meeting was postponed until January 2026 and had a truncated agenda preventing discussion of this petition. This proposal is, however, informed by comments received in response to the discussion document.

Public Comment and Discussion

Numerous stakeholders provided comments on this discussion document for the Fall 2025 meeting. In general, stakeholders supported the need to have regulations that are fairly administered, safe drinking water for livestock, and clarity on specific allowed used of National List materials. Comments also confirmed that livestock provided municipal sources of drinking water already consume water treated with chlorine, and there is inconsistency among certifiers in the allowance for farmers, themselves, to use chlorine to treat drinking water.

A group of organic dairy producers commented on the wide disparity in the ways producers use chlorine and asked for clarification on the use of chlorine materials for direct treatment of livestock water. This group of producers also mentioned the fact that some certifiers mandate the application of chlorine to well water while others do not. The organization stated that it would be impractical for its members to test every source of livestock water. It expressed concern about the adverse health impact of Trihalomethanes (THMs), which are Disinfection Byproducts (DBPs) produced when chlorine reacts with organic matter in water, particularly surface water that contains high levels of decaying plant and animals. Another area of concern to this group is the absence of clear limits on what is too much either in terms of concentration or frequency of use. Such limits would impact how many times a well can be shocked in a year.

A public and environmental health advocacy group urged the Board to perform a comprehensive review of cleaning, disinfecting, and sanitizing materials that can provide information to support annotations for these materials on the National List. A certifying organization expressed the hope that the Board's discussions and recommendations will clarify issues resulting in improved understanding and thus more consistent material review by certifiers. The organization currently approves several chlorine materials for use as livestock drinking water additives. It allows chlorine materials listed on §205.603(a)(10) to be used as direct livestock drinking water treatments provided the operator verifies residual chlorine levels in the drinking water do not exceed the maximum limit under the Safe Drinking Water Act (SDWA). This certifier bases this policy partly on the guidance in Section 4.2 of NOP Guidance 5026 which states that for livestock operations, "residual chlorine levels in the water in direct food or animal contact (for example, drinking water), should not exceed the maximum residual disinfectant limit under the SDWA." Its policy is also based partly on provisions outlined in §205.239(a)(1) and §205.241(a) which require operators to provide year-round access to clean drinking water for all animals. It encouraged the Board to consider at what point water treatment materials are considered within the scope of material review. Another certifier reported that it currently allows the use of chlorine products to treat livestock drinking water, which is only necessary in situations where treated municipal water is not available. According to the certifier, this type of use should be treated the same way as municipal water that has been treated with chlorine materials, some of which are not on the National List.

An advocacy organization expressed support for the petition to clarify the use of chlorine materials in organic livestock production. It stated that of the three listings of chlorine, only the handling annotation is remotely clear in its application. It therefore asked the Board to thoroughly review all the chlorine listings and their annotations based on up-to-date science on human and environmental effects.

A coalition of various organic stakeholders commented on the wide disparity between producers in the ways in which chlorine is used. It listed uses such as well-shocking, the one-time addition of chlorine to a

tank, and dosing systems that monitor and add chlorine as needed. This group stated that its members were not in favor of a potential requirement for testing of every source of livestock water to document absence of unacceptable levels of chlorine. The group stated that such an impractical requirement will place a significant burden on producers. It advocated for the resolution of observed inconsistencies between certifiers on the use of chlorine in direct treatment of livestock drinking water. Another issue which featured in the coalition's written comments is the need for clarification on whether organic matter in water could react with chlorine materials to form trihalomethanes (THMs). A certifier requested information on whether it is standard operating procedure for livestock producers to employ filtration and/or coagulation methods to remove organic material from (surface) water prior to chlorination. A group of organic farmers stated its interest in reading public comments for information on the best ways to avoid toxic Disinfection Byproducts and the appropriate levels of chlorine in drinking water for dairy and meat animals.

This petition seeks to clarify the specific allowed uses of chlorine in organic livestock production. Based on information reviewed in the petition, evaluation of public comments, and review of the vast amount of information related to chlorine in organic livestock production, the subcommittee is proposing to amend the listing for chlorine as petitioned to allow treatment of livestock drinking water with chlorine, provided residual chlorine levels do not exceed Safe Drinking Water Act levels.

Subcommittee Vote

Motion to classify chlorine as synthetic.
Chlorine is already on the National List and classified as synthetic

Motion to amend chlorine at 7 CFR 205.603(a)(10) as follows:

(10) Chlorine materials—disinfecting and sanitizing facilities, ~~and~~ equipment, and livestock drinking water. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

Motion by: Franklin Quarcoo
Seconded by: Cat McCluskey
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Sunset 2028
Meeting 1 - Request for Public Comment
Livestock Substances § 205.603 & § 205.604
Spring 2026

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 coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances 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, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2025 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

Public comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.603 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at § 205.603, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic livestock production.

For Comments that Do Not Support the Continued Use of § 205.603 Substances in Organic Production:
If you provide comments that do not support a substance at § 205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that

support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments that Support the Continued Prohibition of § 205.604 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the § 205.604 section of the National List, you should provide information demonstrating that the substance is:

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

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

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

For Comments Addressing the Availability of Alternatives:
Comments may include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. 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 TAP; 2021 TR
Petition(s): 2002
Past NOSB Actions: 2002 recommendation/vote; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

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 charcoal 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 can be added to animal feeds to bind to any included toxins and is also reported to increase weight gain [2021 TR, lines 90-94]. It 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 Allowed Substances List (CAN/CGSB 32.311-2020)

- **Activated charcoal** shall be of plant origin (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Activated charcoal** shall be of plant origin. Prohibited for use in the production of maple syrup (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- **Activated charcoal** shall be of plant origin. Prohibited for use in the production of maple syrup (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).

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

- **Activated carbon** is permitted in products of plant and animal origin (Section A2 – Processing Aids and Other Products, EC No. 2021/1165).

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

- **Activated carbon** is permitted for plant products (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Activated carbon** is permitted as a processing and post-harvest handling aid (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Activated carbon** is permitted (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).

Ancillary Substances
The LS is not aware of any used with activated charcoal

Human Health and 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 2021 TR indicates that this concern is lessened by re-use of the activation agents.

Discussion
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.

Questions to our Stakeholders

1. Are any ancillary ingredients used in veterinary activated charcoal products?
2. Is activated charcoal used in organic animal feed mixes?

Calcium borogluconate

Reference: § 205.603 (a)(7) Calcium borogluconate (CAS # 5743-34-0) - for treatment of milk fever only.
Technical Report: 2000 TAP; 2015 TR (electrolytes)
Petition(s): N/A
Past NOSB Actions: 2000 recommendation/vote; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Calcium borogluconate is used for the treatment of hypocalcemia (also called parturient paresis or milk fever) in cattle, sheep, and goats [2000 TAP, page 1].

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 newborns, 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 [2000 TAP, page 1].

Manufacture
Calcium borogluconate is prepared by the reaction of five parts calcium gluconate to one-part boric acid in an aqueous solution [2000 TAP, page 1]. 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 [2000 TAP, page 1].

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

- **Calcium borogluconate** is permitted for milk fever. No withdrawal period required (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- **Calcium borogluconate** is not explicitly mentioned in the regulations.

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

- **Calcium borogluconate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Calcium borogluconate** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Calcium borogluconate** is not explicitly mentioned in the regulations.

Human Health and Environmental Issues
The TAP review did not discuss environmental issues related to the manufacture of calcium borogluconate. The review noted that the 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 [2000 TAP, page 3].

Discussion
This substance was among 35 NOSB recommendations for amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018.

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. As explained in the NOP Final Rule adding calcium borogluconate to the National List:

> "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." (83 FR 66569)

During the last sunset review, 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 that the listing is redundant, another certifier added that having the separate listings does not cause differences in decision making.

During the last sunset review, producers supported the re-listing of calcium borogluconate, stating that it is a common, inexpensive, 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.

Questions to our Stakeholders
Is the listing of calcium borogluconate (and calcium propionate) redundant with electrolytes or is it necessary to keep them listed separately to assure allowance as administered as an IV?

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; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

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 [2015 TR, lines 85-87]. 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 [2015 TR, lines 375-376].

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 [2002 TAP, page 7].

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 [2015 TR, lines 338-342].

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 [2015 TR, lines 708-710].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- **Calcium propionate** is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- **Calcium propionate** is not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
- **Calcium propionate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms
- **Calcium propionate** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- **Calcium propionate** is not explicitly mentioned in the regulations.

Human Health and 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 [2015 TR, lines 806-810].

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 [2015 TR, lines 1006-1007].

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 [2015 TR, lines 1014-1018]. 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 at 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. The LS is seeking comments for the Spring 2026 meeting regarding these previous comments.

Questions to our Stakeholders
1. Is this listing redundant with electrolytes and nutritive supplements?

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); 2025 TR (pending post)
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; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Sunset renewal notice 03/15/2017 (82 FR 14420); Hypochlorous acid added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028
Subcommittee Review

Use

The EPA approved the registration of sodium hypochlorite and calcium hypochlorite pesticides for use on crops, soil, and livestock to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals [Draft 2025 TR, lines 444-446]. These materials are chlorinated inorganic disinfectants which are also 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. The material is used as a disinfectant, sanitizer, and medical treatment [Draft 2025 TR, lines 81-82]. It is also used in cleaning water systems and disinfecting public drinking water supplies. Chlorine dioxide is also 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 [2006 TR, lines 60-71]. Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance 5026).

Hypochlorous acid, 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. A couple of publications stated that hypochlorous acid is the most effective form of chlorine for killing microbial pathogens and parasites that pose food safety risks [Draft 2025 TR, lines 505-506].

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 (Na_2CO_3). Chlorine dioxide is formed by reacting sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) with sulfur dioxide (SO_2), or chloric acid is reacted

with methanol (CH_3OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate [2006 TR, lines 149-171].

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.

International Acceptance

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

- The following chlorine compounds are permitted: **a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite.** Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: **a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite** (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).
- Teat dips and udder wash are permitted. Substances, such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations. Chlorhexidine can be used as a post-milking teat dip if alternative germicidal agents and physical barriers have lost their effectiveness (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.
- **Chlorine dioxide** is not explicitly mentioned in the regulations.
- **Hypochlorous acid** is not explicitly mentioned in the regulations.
- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

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

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.
- **Chlorine dioxide** is not explicitly mentioned in the regulations.
- **Hypochlorous acid** is not explicitly mentioned in the regulations.
- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Calcium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

- **Chlorine dioxide** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).
- **Hypochlorous acid** is not explicitly mentioned in the regulations.
- **Sodium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).
- **Sodium hypochlorite (e.g., as liquid bleach)** is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.
- **Chlorine dioxide** is not explicitly mentioned in the regulations.
- Any substances other than **hypochlorous acid water** and sodium hypochlorite, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of **hypochlorous acid water** produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Hypochlorous acid water** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).
- Any substances other than hypochlorous acid water and **sodium hypochlorite**, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite sodium chloride** is permitted with the following criteria: limited to those obtained by electrolyzing the salt solution (limited to those using salt containing no less than 99% sodium chloride) (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of hypochlorous acid water produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Human Health and Environmental Issues
The last sunset review document on chlorine materials stated that information available from EPA and FDA on chlorine dioxide, sodium, and calcium hypochlorite, and hypochlorous acid indicated that there was no environmental contamination resulting from proper manufacture, use, or disposal. A Technical Report in 2025, however, provided information on adverse environmental impacts of two of the three methods used in producing chlorine needed for manufacturing chlorine materials.

Chlorine and its disinfection byproducts (DBPs) can contaminate milk in equipment and bulk milk tanks that have been sanitized with chlorinated water [Draft 2025 TR, lines 666-676]. Halogenated teat dips, such as ASC and iodophors, are another potential source of Trihalomethanes (THMs) and other DBP contaminants in the milk supply chain. Various researchers reported that DBPs found in the milk supply include THMs, chlorites, chlorates, and perchlorates [Draft 2025 TR, lines 669-671]. Free chlorine residues cause taste and odor sensory defects in milk. Residual chlorine will inhibit organisms responsible for making fermented and cultured dairy products, such as cheese [Draft 2025 TR, lines 671-672]. Most importantly, chlorine DBPs pose a public health risk by exposing people to probable carcinogens and other oncogenic substances [Draft 2025 TR, lines 673-674]. Some DBPs in milk and dairy products are endocrine disruptors [Draft 2025 TR, lines 674-675].

Chlorate enters the food supply almost exclusively as a DBP through the use of chlorine-based sanitizers in food production. DBPs found in the milk supply have been linked to the use of hypochlorous acid, hypochlorites, and chlorine dioxide (2025 TR, lines 678-680). The use of chlorine-based sanitizers throughout the cleaning process in Clean In Place (CIP) systems, that is not followed by a sufficient clean water or acid rinse, is one of the leading causes of milk contaminated with DBPs [Draft 2025 TR, lines 969-698]. Because of quality and food safety concerns, the Republic of Ireland prohibited the use of chlorine disinfectants in CIP systems starting in 2021 [Draft 2025 TR, lines 680-684].

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) in its most recent sunset review generally supported continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS declared its support for research priorities that investigate alternatives to chlorine compounds and encouraged the use of alternative, less toxic materials, when their use can meet strict food safety standards. The LS at the time concluded that chlorine materials were an essential part for maintaining hygiene in livestock facilities.

Public comments during the last sunset review were 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 at the time, livestock producers and other stakeholders in the livestock product supply chain cited chlorine materials as a critical tool to maintain hygiene.
Various subsequent studies have revealed that alternatives to chlorine are also of interest to livestock producers and handlers of animal products [Draft 2025 TR, lines 1330-1331]. Generation of chlorine gas poses a worker safety hazard. Chlorination reduces the biodiversity of raw milk and lowers counts of beneficial bacteria—like *Lactobacillus* spp.—that are used to make cheese and other fermented dairy products [Draft 2025 TR, lines 1331-1333].

Alternatives to chlorine materials in livestock production include Hydrogen peroxide as a livestock management tool and production aid [Draft 2025 TR, lines 1348-1349]. Alternative products for livestock

health care include botanicals, essential oils, herbal preparations, and cleaning agents. Alternative processing sanitizers and cleaners include bacteriophages, post-harvest fruit and vegetable wash, citric acid, peracetic acid/peroxyacetic acid, and post-harvest use of peracetic acid/peroxyacetic acid [Draft 2025 TR, lines 1348-1360]. It is important to note that this is not an exhaustive list of alternatives and some of the listed materials require additional research or regulatory action prior to substitution for chlorine [Draft 2025 TR, lines 1336-1341].

Questions to our Stakeholders

1. Additional information and perspectives are needed from various stakeholders on the stated health and environmental impact of chlorine materials.
2. Are there specific procedural or processing steps that reduce the health and environmental risks associated with the use of chlorine materials in livestock production?

Kaolin pectin

Reference: § 205.603 (a)(17) Kaolin pectin - for use as an adsorbent, antidiarrheal, and gut protectant.
Technical Report: 2002 TAP; 2021 TR
Petition(s): 2002
Past NOSB Actions: 2002 recommendation/vote; 2002 Position Paper; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

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 [2021 TR, lines 164-166, 207-208].

Kaolin pectin, as a combination, is not listed by the FDA as generally recognized as safe (GRAS). However, kaolin and pectin are individually considered as GRAS [2021 TR, lines 168-169].

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.

Manufacture
Kaolin pectin is a formulated mixture of kaolin and pectin, produced through standardization and buffering steps to create a consistent oral livestock medication. Kaolin is a naturally occurring aluminum silicate clay, and pectin is derived from citrus peel or apple pomace through extraction and purification. Because the commercial product undergoes processing such as buffering, standardization, and blending with carriers, kaolin pectin meets the definition of a synthetic substance under 7 CFR 205.2.

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

- **Kaolin pectin** is not explicitly mentioned in the regulations.

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

- **Kaolin pectin** is not explicitly mentioned in the regulations.

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

- **Kaolin pectin** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Kaolin pectin** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Kaolin pectin** is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

According to the 2002 TAP and the 2021 TR:

- 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.
- Extensive safety and toxicological data exist on the impact of kaolin and pectin on human health and the environment. Reviews by JEFCA (the Joint FAO/WHO Expert Committee on Food Additives) and the U.S. FDA suggest that the petitioned substance is not harmful to human health or the environment [2021 TR, lines 442-443].
- There is no evidence that kaolin pectin for use as medicine in livestock would cause harmful interactions in organic crop, livestock production, or livestock handling. Because kaolin is made up of natural components, the fecal excretion of kaolin will not cause harm. Most of the pectin consumed in the intestine is degraded [2021 TR, lines 481-484].

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 review 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.

Questions to our Stakeholders

None

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; 05/2003 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL at § 205.603(b) effective 04/21/2001 (65 FR 80548, 66 FR 15619); Added to NL § 205.603(a) effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 5/29/2028

Subcommittee Review

Use
The scope of this sunset review is for mineral oil, listed at § 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) regulations at § 205.603(a)(20) currently permit the use of mineral oil in organic livestock production for treatment of intestinal compaction, prohibited for use as a dust suppressant.

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 [2021 TR, lines 111-120].

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 [2021 TR, lines 136-147].

Manufacture
The industrial production of highly refined, food-grade mineral oils involves 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 [2021 TR, lines 136-147].

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 Allowed Substances List (CAN/CGSB 32.311-2020)

- **Mineral oil** is permitted for external use (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- **Mineral oil** is not explicitly mentioned in the regulations.

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

- **Mineral oils** are permitted in traps with the following condition for use: need recognized by the certification body or authority (Table 2 - Substances for plant pest and disease control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Light mineral oils (paraffin)** of mineral origin are permitted (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Mineral oil** is not explicitly mentioned in the regulations.

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 [2021 TR, lines 43-46].

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 [2021 TR, lines 486-490].

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 [2021 TR, lines 518-520]. 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 [2021 TR, lines 534-535, 548-549].

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 [2021 TR, lines 481-484].

Discussion
During the 2015 sunset review of mineral oil listed at § 205.603(b)(6), producers noted that untreated omasal impaction can lead to invasive surgery. Because mineral oil products are considered unapproved animal drugs by FDA, they must carry the disclaimer that they are not proven safe or effective.

Good management—adequate water, balanced nutrition, and proper roughage—can reduce the risk of impaction, though it may still occur even under strong management, especially in wintering pregnant cattle or when low-quality forage is fed.

In 2021, public commenters and NOSB members were uniformly supportive of relisting. Mineral oil is used infrequently but is considered essential. Commenters emphasized that no natural oil works as an effective substitute. Without access to mineral oil, serious animal welfare impacts could occur. A veterinarian testified that mineral oil is "indispensable". Commenters also noted confusion among certifiers about how mineral oil may be administered, though all agreed on its therapeutic necessity. Mineral oil is permitted under several international organic standards.

Questions to our Stakeholders
None

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 (electrolytes); 2015 TR (vitamins); 2015 TR (electrolytes); 2019 TR (trace minerals); 2026 Limited Scope TR
Petition(s): 2009
Past NOSB Actions: 05/2009 recommendation to add to NL; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

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 [2019 TR, lines 71-73].

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 [2015 TR, lines 46-49].

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

- **Minerals**, **trace minerals**, and elements are permitted with the following origin/usage conditions: unprocessed rock dusts; ground animal or plant material (other than blood or bone meal); and seawater are preferred sources. Chelated and sulphated forms are permitted. If none of the aforementioned sources are commercially available, other versions are permitted except for forms containing or produced with EDTA or EDDHA (Table 5.2 - Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- **Electrolytes** are permitted including, but not limited to: CMPK (calcium, magnesium, phosphorus, potassium). Orally or **by injection** (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Minerals**, **trace minerals**, and elements are permitted with the following origin/usage conditions: non-synthetic chelated or sulphated minerals. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are permitted for medical use (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Vitamin** formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of this standard are permitted. Orally, topically or **by injection** (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- Feed of **mineral origin**, **trace elements**, **vitamins** or provitamins are of natural origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available (Authorisation of products and substances for use in organic production, EC No. 2018/848).
- When despite preventive measures to ensure animal health referred to in point 3.1.4.1 a health problem arises, veterinary treatments may be used in the following order of preference: (i) substances from plants, animals or **minerals** in a homoeopathic dilution; (ii) plants and their extracts not having anaesthetic effects; and (iii) substances such as **trace elements**, metals, natural immunostimulants or authorised probiotics (Veterinary treatments, EC No. 2018/848).
- Compounds of **trace elements** permitted include: iron (II) carbonate (siderite); iron (II) sulphate monohydrate; iron (II) sulphate heptahydrate; potassium iodide; calcium iodate, anhydrous; coated granulated calcium iodate anhydrous; cobalt (II) acetate tetrahydrate; cobalt (II) carbonate; cobalt (II) carbonate hydroxide (2:3) monohydrate; coated granulated cobalt (II) carbonate; cobalt (II) sulphate heptahydrate; copper (II) carbonate dihydroxy monohydrate; copper (II) oxide; copper (II) sulphate pentahydrate; dicopper chloride trihydroxide; manganese (II) oxide; manganous sulfate, monohydrate; zinc oxide; zinc sulphate heptahydrate; zinc sulphate monohydrate; zinc chloride hydroxide monohydrate; sodium molybdate dihydrate; sodium selenite; coated granulated sodium selenite; sodium selenate; selenised yeast, *Saccharomyces cerevisiae*, inactivated (Nutritional Additives, EC No. 2021/1165).

- Non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or of **mineral origin**, feed additives and processing aids may be used only if they have been authorised pursuant to Article 24 for use in organic production (General nutrition requirements, EC No. 2018/848).
- Feed materials of **mineral origin** authorised pursuant to Article 24 for use in organic production, nutritional additives authorised pursuant to Article 24 for use in organic production, and phytotherapeutic and homeopathic products shall be used in preference to treatment with chemically synthesised allopathic veterinary medicinal products, including antibiotics, provided that their therapeutic effect is effective for the species of animal and for the condition for which the treatment is intended (Disease prevention, EC No. 2018/848).
- For the purposes of point (c) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex III to this Regulation may be used in organic production as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or **mineral origin**, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 767/2009 of the European Parliament and of the Council and, where applicable, in accordance with national provisions based on Union law (Non-organic feed material of plant, algal, animal or yeast origin or feed material of microbial or mineral origin, EC No. 2021/1165).
- Feed materials of mineral origin are permitted and include: calcium carbonate; calcareous marine shells; maerl; lithothamn; calcium gluconate; magnesium oxide; magnesium sulphate anhydrous; magnesium chloride; magnesium carbonate; dicalcium phosphate; monocalcium phosphate; calcium-magnesium phosphate; magnesium phosphate; monosodium phosphate; calcium sodium phosphate; monoammonium phosphate (ammonium dihydrogen orthophosphate); sodium chloride; sodium bicarbonate; sodium carbonate; sodium sulphate; potassium chloride (Annex III: Authorised products and substances for use as feed or in feed production, EC No. 2021/1165).
- **Vitamins**, pro-vitamins and chemically well-defined substances having similar effects are permitted if they are derived from agricultural products. If not available from agricultural products: derived synthetically, only those identical to **vitamins** derived from agricultural products may be used for monogastric animals and aquaculture animals; derived synthetically, only **vitamins A, D and E** identical to vitamins derived from agricultural products may be used for ruminants; the use is subject to prior authorisation 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 (Nutritional Additives, EC No. 2021/1165).

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

- Specific criteria for feedstuffs and nutritional elements: b) feedstuffs of **mineral origin**, **trace elements**, **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 (Livestock and livestock products: Nutrition, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and **trace elements** shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used

under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Livestock and livestock products: Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Organic animal management provides animals with **vitamins**, **trace elements** and **supplements** only from natural sources unless they are not available in sufficient quantity and/or quality (Main objectives and detailed requirements of the COROS, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Feed additives (excluding antibiotics and those produced by using recombinant DNA technology), which are natural substances or substances derived from natural sources that have not undergone any chemical treatment. In the cases where it is difficult to obtain such feed additives, similar feed additives (similar to the relevant feed additives) may be used only for the purpose of **supplementing the nutrients** and other active ingredients of feed (Production Methods, JAS 1607 Organic Feed).
- Such natural substances or feeds derived from natural substances (that have not undergone chemical treatment), which are intended for **vitamin or mineral supplementation**. In case it's difficult to obtain such feed, feed additives intended for **mineral supplementation** may be fed (Feeding, JAS 1608 Organic Livestock Products).
- **Vitamins**, **minerals**, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS 1608 Organic Livestock Products).

Human Health and 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 [2015 TR, lines 897-909]. Despite the potential for some vitamin compounds to pose some environmental harm during manufacture, their use in livestock agriculture is targeted and minimal. In the case of injectable nutritive supplements, the potential for these products to cause environmental harm is negligible.

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.

The Livestock Subcommittee commissioned a limited scope TR in 2026 to support the 2028 sunset review of this substance. In this TR the LS requested information about formulations unique to the injectable supplements, acknowledging that many of the same compounds are allowed to be consumed orally by livestock as either “electrolytes” or “nutritive vitamins and minerals.” The biggest distinction drawn between injectable forms of these substances versus the orally consumed ones is oversight. When formulated into an injectable, FDA provides oversight, and these substances must be used in accordance with laws governing livestock drugs. Similarly, as these injectables are considered livestock drugs, excipients allowed at 7 CFR 205.603(f) may be used as part of the formulations. Despite these differences with electrolytes and nutritive vitamins and minerals, the TR revealed no new information warranting removal from the national list or further restriction on use.

Questions to our Stakeholders
Do the current restrictions on injectable nutritive supplements pose any challenges to producers in accessing the therapies they need to treat their livestock?

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; 09/2002 recommendation to add to NL; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

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) [2021 TR, lines 71-73, 92].

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 [2021 TR, lines 82-84].

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 [2021 TR, lines 41-44].

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 [2021 TR, lines 46-52, 358-359].

International Acceptance

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

- Botanical preparations, such as atropine, butorphanol and other medicines from herbaceous plants shall be used according to label specifications. Substances containing petroleum-derived formulants, such as **propylene glycol**, shall not be fed to livestock (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Propylene glycol** may only be used as an ingredient in foot baths (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- **Propylene glycol** is not explicitly mentioned in the regulations.

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

- **Propylene glycol** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Propylene glycol** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Propylene glycol** is not explicitly mentioned in the regulations.

Human Health and 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 [2021 TR, lines 507-511].

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 [2021 TR, lines 519-524].

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 [2021 TR, lines 612-618].

Discussion
Propylene glycol was added to the National List following NOSB recommendations made between 2000–2016, with final rulemaking completed in 2018.

The 2021 NOSB review included comments from stakeholders who were largely supportive of continued listing. Commenters noted that propylene glycol is a practical and safer alternative to intravenous dextrose for treating ketosis, especially since ketotic cows can be difficult to handle. Dairy producers acknowledged natural options such as apple cider vinegar and molasses but emphasized that propylene glycol remains the most effective and widely available treatment. A large-animal veterinarian described it as the "gold standard" for ketosis therapy. Additionally, one stakeholder noted that prior to the allowance of propylene glycol, farmers commonly used intravenous dextrose to treat ketosis—an approach that is both less effective and dangerous for cows and farmers. IV dextrose can cause extreme blood sugar spikes, lead to abscesses if not administered correctly, and is difficult to give because ketotic cows may become aggressive. In contrast, propylene glycol provides a far safer and easier method for rehabilitating ruminants suffering from ketosis.

Use of propylene glycol is restricted by 7 CFR 205.238(c)(2), which prohibits administering drugs in the absence of illness, thereby limiting use to animals showing ketosis symptoms.

The 2021 TR noted that while emerging fermentation methods could reduce reliance on petrochemical sources, many rely on genetically modified microorganisms and are not yet commercially viable. Despite concerns about manufacturing impacts and potential future use of excluded methods, the Subcommittee determined that propylene glycol provides necessary, limited-use medical treatment for ketosis and recommends relisting.

Questions to our Stakeholders

1. Do stakeholders have concerns about excluded methods in the manufacture of propylene glycol, or should additional clarification or annotation be considered to ensure continued compliance with organic standards?

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)(9) Sodium chlorite, acidified – allowed for use on organic livestock as a teat dip treatment only.
Technical Report: 2013 TR; 2025 TR (Chlorine Materials - pending post)
Petition(s): 2012; 2014 Addendum #1; 2014 Addendum #2
Past NOSB Actions: 04/2015 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Acidified sodium chlorite is used as a disinfecting teat dip for organic livestock producers both as a pre- and post-milking application/treatment [2025 TR, lines 347-348]. 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 [2013 TR, lines 47-54].

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

- **Acidified sodium chlorite** is not explicitly mentioned in the regulations.

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

- **Acidified sodium chlorite** is not explicitly mentioned in the regulations.

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

- **Acidified sodium chlorite** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Acidified sodium chlorite** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Acidified sodium chlorite** is not explicitly mentioned in the regulations.

Human Health and 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. 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 [2013 TR, lines 359-369].

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.

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 previous sunset review of acidified sodium chlorite relied on a technical report (TR) on iodine, received on January 7, 2015. This technical report provided the most up to date 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. Iodine's efficacy as a post-milking teat disinfectant is comparable to acidified sodium chlorite [2025 TR, lines 1666-1667].

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 NOSB Review, there was discussion about the two listings at § 205.603(a) and § 205.603(b), and whether they were redundant. 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.

A 2012 study compared treatments of beef infected with fecal slurry pathogen cocktail containing *E. coli* O157:H7, *Salmonella typhimurium, Campylobacter coli,* and *Campylobacter jejuni* with a number of productions including: acidified sodium chlorite, sodium hypochlorite, chlorine dioxide, peroxyacetic acid, ozone gas, acetic acid, citric acid, lactic acid and a control experiment consisting of plain water rinse [2025 TR, lines 1580-1593]. The organic acid rinses effectively reduced bacterial loads in beef comparable to treatment with chlorine compounds. Lactic acid applied with hand-held equipment at a 2% solution was the most effective treatment as a carcass rinse for beef. The 2025 technical report on chlorine materials cites other studies that cover the relative performance of chlorine materials and alternative materials as disinfectants.

Questions to our Stakeholders
Is lactic acid in use as a teat dip by livestock producers.

Zinc sulfate

Reference: § 205.603 (b)(11) Zinc sulfate - for use in hoof and foot treatments only.
Technical Report: 2015 TR
Petition(s): 2014
Past NOSB Actions: 04/2015 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)

Sunset Date: 05/29/2028

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 [2015 TR, line 53]. Zinc ash is produced from zinc ore mined from underground or open pit mines [2015 TR, line 60].

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

- **Zinc sulfate** is not explicitly mentioned in the regulations.

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

- **Zinc sulphate** is not explicitly mentioned in the regulations; zinc sulphate heptahydrate and zinc sulphate monohydrate are permitted (Nutritional Additives, EC No. 2021/1165).

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

- **Zinc sulfate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Trace elements (e.g., boric acid; sodium borate; calcium borate; borethanolamin; cobalt-acetate; cobalt-sulphate; copper oxide; copper sulfate; copper hydroxide; copper silicate; copper carbonate; copper citrate; ferric oxide; ferric sulfate; ferrous sulfate; iron citrate; iron sulfate; iron tartrate; manganous oxide; manganese sulfate; manganese carbonate; selenic acid; selenous acid; sodium molybdate; molybdic oxide; zinc carbonate; zinc oxide; zinc silicate; and **zinc sulfate**) are permitted as calcareous and magnesium amendments of mineral origin with the following conditions for use: use restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert. Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant (Appendix 2: Fertilizers and soil conditioners, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Zinc sulfate** is not explicitly mentioned in the regulations.

Human Health and 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 weaker mode of attachment to soil particles. 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

Copper sulfate and zinc sulfate are two of the most accepted treatments for foot rot and are comparable in efficacy. 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."[2015 TR lines 699-705]

> "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)." [2015 TR lines 709-713]

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 during the last sunset review 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 has reduced the use of copper sulfate for hoof disease.

Questions for stakeholders

1. Are livestock producers using less copper sulfate by substituting zinc sulfate for foot rot management?

National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee (CACS)
Residue Testing for a Global Supply Chain: Regulation Review (§205.670 &UREC)
Proposal
Spring 2026

Executive Summary

This proposal recommends updates to various aspects of § 205.670: Inspection and testing of agricultural products to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)). These include:

1. **Mandated testing of a minimum of 5% of operations annually by certifiers**
    a. Recommendation to update the regulatory text to require certifiers to include risk-based and random selection when determining which operations will be tested as part of the 5% of operations tested annually.

2. **Certifiers conducting all testing at their own expense**
    a. Recommendation to update the regulatory text to allow certifiers to charge operations tested only when the:
        - test is being conducted as part of a credible complaint or investigation; and
        - contamination is determined to be caused by an intentional application or failure of an operation to adhere to their OSP (i.e., results in a noncompliance or adverse action).

3. **Public access to results**
    a. Recommendation to link § 205.504(b)(5)(iii) and § 205.670(f) together.
    b. Encourage industry partners to continue to develop a centralized database (e.g., ORG-Tracker) and incentivize certifiers to participate.

4. **Downstream notification of noncompliant organic product to buyers**
    a. Recommendation to update the regulatory text to require notification of downstream buyers only when the:
        - Residues exceed action thresholds (e.g., >5% of EPA tolerances)
        - Willful violations have occurred
    b. Recommendation that the NOP utilizes the ANPR process, as recommended by commenters, if the NOP deems this to be appropriate.

5. **Unavoidable residual environmental contamination (UREC)**
    a. Encourage NOP to implement NOSB's Spring 2025 Final Recommendation to update NOP 2613 guidance to provide certifiers with clearer direction for evaluating residue findings when:
        - residues are detected without an established EPA tolerance or FDA action level; and
        - contamination is the result of indirect, unintentional applications of unknown origin (e.g., volatile drift events), rather than intentional application or failure of an operation's Organic System Plan.

Discussion

Mandated testing of a minimum of 5% of operations annually by certifiers

The current testing requirements in the rule related to operation selection are minimal and focus on the quantity (5%), but not necessarily the type of operation or reason to test. This was intentional in the 2012 Periodic Residue Testing final rule to allow certifiers flexibility. However, more than a decade later it appears that there is an opportunity to shift from the mindset of using testing as a tool for verifying an operation's compliance to more of a verification tool for fraud detection, which currently impacts the organic sector. With this shift, it seems necessary to indicate that the 5% of operations tested must include a portion selected based on risk criteria, while also maintaining the allowance for random selection as this is an important deterrent.

What do OFPA and the regulations state?

- OFPA (7 U.S.C. 6506(a)(6))[1]: Requires certifiers to conduct periodic residue testing to determine the presence of prohibited substances and report violations (as appropriate).
- 7 CFR 205.670(d)[2]: Requires certifiers to conduct sampling and testing from a minimum of 5% of the operations it certifies, annually.

Background and Discussion

The mandated 5% of operation testing by certifiers annually was added to the regulations as a result of the 2012 Periodic Residue Testing final rule, which became effective on January 1, 2013. This was in response to an audit of the NOP, which was conducted in March 2010 by the USDA Office of Inspector General (OIG). OIG found "that none of the four certifying agents visited conducted periodic residue testing. The OIG indicated that these certifying agents noted that they considered residue testing to be required by the regulations only under certain circumstances."[3]

The stated purpose of the 2012 Periodic Residue Testing final rule is to "implement the requirements of the OFPA (section 6506) for periodic residue testing by certifying agents. Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP regulations and by discouraging the mislabeling of agricultural products."

Section 6506(a)(6) of OFPA states: "A program established under this chapter shall require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants and to require certifying agents, to the extent that such agents are aware of a violation of applicable laws relating to food safety, to report such violation to the appropriate health agencies."

The Agricultural Marketing Service (AMS) stated that its primary objective was to align the NOP regulations with the requirements for testing under OFPA.

[1] Organic Foods Production Act of 1990, Section 6506

[2] 7 CFR 205.670(d)

[3] 2012 Periodic Residue Testing Final Rule (77 FR 67239, November 9, 2012]

The final rule explains the various options considered by AMS to ensure that certifiers are conducting a minimum level of residue testing, ranging from the status quo to testing upwards of 25% of operations annually.

Additionally, the final rule explained that all types of testing would be eligible to be counted toward the 5% mandate, including testing of operations chosen at random. Furthermore, the final rule stated, "certifying agents have the discretion to select operations for residue testing based on criteria such as size of operation, quantity of products produced, previous compliance issues, or other risk factors. Certifying agents are knowledgeable about the risk factors affecting the operations they certify; therefore, it is appropriate for a certifying agent to determine what operations should be tested under this action."

Public Comment Summary

In the comments received on the Fall 2025 discussion document, there was strong stakeholder alignment to retain the minimum requirement of 5% of operation for testing . Most commenters indicated that certifiers should incorporate both risk-based and random testing as part of an effective residue testing program to determine an operations compliance with the regulations, implementation of their OSP, as well as to determine fraudulent activity. Commenters did not agree with the leaning of the subcommittee in selecting operations for sampling and testing solely based on risk, noting that the potential for testing from a random selection is a good deterrent.

Conclusion

The Certification, Accreditation, and Compliance Subcommittee (CACS) recommends that NOP revise §205.670(d) to include language that certifiers must select operations, as part of their testing program, using a combination of risk-based criteria (e.g., more likely to have residues, high risk assessment score, complaint, investigation) as well as random selection (e.g., location convenience, using a random selection generator), that aligns with their client make up. Meaning if a certifier certifies many high-risk operations or is the recipient of several complaints and investigations, we'd expect that a larger portion of their 5% would have been selected due to risk vs. a certifier that has a lower-risk operation and is not fielding many complaints or investigations. CACS does not want a certifier to select operations due only to risk nor do we want a certifier to select operations only at random. We also don't want a certifier to select only one operation due to risk and then the rest randomly when they have many high-risk operations. The Subcommittee discussed specifying a certain percentage of the 5% that needed to be selected due to risk but ultimately did not. Lastly, CACS acknowledges that the regulations state that when a certifier certifies fewer than 30 operations then they must test at least one operation annually. CACS recommends that this one operation be selected based on risk.

Certifiers conducting all testing at their own expense

Since the original publication of the NOP regulations, the cost of testing has been required to be absorbed by the certifier. This was reinforced in the 2012 Periodic Residue Testing final rule. While this is technically true, in practice, many certifiers offset the costs of testing across their client base by including this in their base certification fees. This means that operations that are not tested are subsidizing those that are being tested.

What do OFPA and the Regulations State?

- §205.670(b) & (c)[4]: Requires that residue testing be conducted by the certifier at their own expense.

Background and Discussion

Due to the regulatory reference above, certifiers are required to absorb the costs of the testing described in §205.670(c). This requirement dates back to the original publication of NOP regulations. In the preamble of the December 21, 2000, final rule (65 FR 80548), it states in the Residue Testing section, "The cost of such testing will be borne by the applicable certifying agent and is considered a cost of doing business. Accordingly, certifying agents should make provisions for the cost of preharvest or postharvest residue testing when structuring certification fees."

Certifiers have expressed feeling constrained by this requirement. Testing is expensive, so to manage costs, certifiers sometimes choose the least-expensive testing plans instead of selecting operations based on risk or other criteria.

Suppose certifiers could pass the costs of testing along to specific certified operations tested as part of increased oversight activities deemed necessary (e.g., complaint, investigation, high-risk operation). In that case, certifiers may increase the number of samples collected, or at least the selection of operations would be less impacted by cost implications. Also, it should be noted that in the current system, certifiers are likely still "charging" certified operations for testing conducted indirectly, meaning general certification fees paid for by all operations incorporate the amount to be spent on residue testing. This change to how testing fees are assessed could alleviate certification fees unnecessarily billed to low-risk operations.

Additionally, it is our understanding that certifiers are implementing this requirement inconsistently. Some pass along the cost to operations for complaints and investigations, and do not count this towards their 5%, which appears compliant (i.e., haven't received a notice of noncompliance). In contrast, others have received a noncompliance for passing the costs along in the same situations.

Public Comment Summary:

In the Fall 2025 discussion document, CACS posed two questions pertaining to cost. The first asked stakeholders to provide feedback on whether certifiers should be allowed to charge operations for the cost of testing when the testing is being conducted due to a complaint or as part of an investigation, while still counting these as part of their minimum of 5% of operations tested.

There was mixed feedback. Some stakeholders stated that they didn't support the allowance for certifiers to pass along costs to operations in these scenarios. Those in favor of keeping the status quo noted:

- 5% minimum testing should be viewed as a standard cost of providing certification services.
- Passing along costs isn't always equitable (i.e. the operation tested due to a complaint may not be the operation responsible for the contamination).
- Challenging for operations to include this as a budgeted expense since complaints and investigations are unpredictable.

[4] 7 CFR 205.670(c)

- Lack of support for passing along the cost for complaints or investigations but should be allowed to pass along the costs for follow-up testing.

While there was opposition, more stakeholders were in favor of updates to the regulatory text to allow certifiers to directly charge operations tested but only when the test is being conducted as part of a complaint or investigation. Additionally, several commenters in favor indicated that an operation should only be charged if the complaint is valid/credible and contamination is determined to be caused by an intentional application or failure of an operation to adhere to their OSP (i.e. results in a noncompliance or adverse action). For example, if an operation didn't follow their cleanout procedures on equipment used in both nonorganic and organic production, which results in a positive test result.

The second question sought feedback on the implementation of a tiered certification fee schedule where higher-risk operations pay more than lower risk operations. We received mixed feedback on this topic as well. Some commenters pointed out that the current regulations already allow certifiers the flexibility to set up their fee schedule in a tiered manner (i.e., higher risk operations pay more).

CACS asked for additional considerations on the topic of cost of testing. We received the following comments:

- Certifiers shouldn't conduct testing. Rather, testing should be conducted by NOP.
- NOP should work with state departments of agriculture to conduct testing.
- There is an inherent conflict of interest that certifiers are responsible for testing their paid clients.
- Certifiers should be credited on their accreditation fees by NOP for fees associated with testing.

Conclusion

CACS recommends that NOP revise the regulatory text at §205.670(b) & (c) to allow certifiers to charge operations tested only when the:

- test is being conducted as part of a credible complaint or investigation; and
- contamination is determined to be caused by an intentional application or failure of an operation to adhere to their OSP (i.e., results in a noncompliance or adverse action).

Public access to results

There are two mentions of public access to results in the regulations. However, they are not aligned. Additionally, as the NOSB has been discussing the topic of residue testing, the idea of a database of results has been brought up, as a project is currently under development.

What do OFPA and the regulations state?

- OFPA (7 USC 6506(a)(9))[5]: Requires public access to certification documents and laboratory analyses that pertain to certification

[5] OFPA 6506(a)(9)

- §205.670(f)[6]: Requires that the results of all residue testing be available for public access, unless part of an ongoing investigation

- §205.504(b)(5)(iii)[7]: Requires that certifiers have procedures in place that, upon request, the results of residue testing conducted during the current and three preceding calendar years be made available.

Background and Discussion

Since the two regulatory citations listed above are not tied together, it is unclear what the intent of §205.670(f) is/was. Is the intent of §205.670(f) to make available results in accordance with §205.504(b)(5)(iii), or was §205.670(f) intended to make these results available in some other manner?

Additionally, the idea of a database (e.g., ORG-Tracker by Heartland Health Research Alliance) to compile and analyze residue test result data has been brought up by public comments, as industry stakeholders are currently developing such a project. The idea of a database was addressed in the 2012 Periodic Residue Testing final rule. At the time, AMS stated, "It is not AMS' intent to assemble data and draw conclusions based on statistical sampling techniques, as the sampling performed by certifying agents will vary considerably due to the worldwide diversity of operations which are certified to the NOP. Certifying agents have the discretion to sample from higher-risk operations, which may yield results that are not representative of all organic operations." This does not appear to be the current reality of testing, as many certifiers conduct random sampling rather than sampling based on known risks.

Additionally, between the proposed rule to the final rule, AMS amended the reporting requirements under section §205.670 "to reduce the reporting burden on certifying agents." AMS stated, "This rule eliminates the requirement that certifying agents must submit all residue testing results to the Administrator or the State organic program's governing State official. AMS does not intend to consolidate residue testing data from certifying agents and does not need reporting of residue testing results as the mechanism to ensure that certifying agents are meeting the requirement of periodic residue testing."

Based on the previous stance from NOP, it is unclear whether the landscape has changed to make the compilation of data more beneficial than it was in 2013, following the implementation of the Periodic Residue Testing final rule.

In this proposal, CACS is recommending that NOP update the requirement that 5% of operations be selected based on either risk or randomly selected. 5% annual minimal testing conducted by each certifier doesn't equal many operations, however, if the information can be aggregated and shared across all certifiers, there can be meaningful data and information to extract to continuously improve testing programs.

Public comment summary

Most commenters indicated that §205.504(b)(5)(iii) and §205.670(f) should be linked together. However, one commenter stated that it wouldn't be enough to link these two and raised questions regarding

[6] 7 CFR 205.670(f)

[7] 7 CFR 205.504(b)(5)(iii)

certifiers compliance with §205.504(b)(5)(iii) and if that truly met the public access requirements at §205.670(f).

Most commenters were in favor of some sort of centralized database in order to discern patterns/trends in crops and regions, which would then inform a certifiers testing program including risk evaluation and selection of subsequent testing. Additionally it was noted that over time this data could help with UREC determinations. Most in favor thought that full public access would be required based on the current regulations. Some indicated that a database could be structured to allow different access for different users. One commenter indicated that they've received feedback that there is the perception that compliance activities are not occurring in organic certification, in large part due to the lack of publicly available data - even with the availability to request this information. Some indicated their preference for anonymized and aggregated data.

While most commenters were in favor, there were others that were concerned. Their concerns are as follows:

- Data can be misconstrued and tell lots of different stories, especially if one can only see the violation and not the indication of a corrective action
- Certification costs may go up if there is an additional administrative burden to certifiers to provide these data
- Questions regarding who is responsible for maintaining and providing data
    - If this becomes an accreditation requirement then it would seem that NOP would need to be responsible, and certifiers would be required to provide the data
- Potential for litigation

Conclusion

CACS recommends that the two regulatory requirements to make results available to the public (§205.504(b)(5)(iii) and §205.670(f)) be linked together. By adding a reference to 205.504(b)(5)(iii) in 205.670(f) it makes it more clear to members of the public the way in which results will be made public - by the procedures required of certifiers in 205.504(b)(5)(iii) and not some other manner.

For example (red text is proposed text):

> §205.670(f): "Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation, pursuant to §205.504(b)(5)(iii).

Additionally, while it doesn't seem viable for NOP to be responsible for maintaining a residue test result database at this time, CACS encourages industry partners (e.g., ORG-Tracker, certifiers, Accredited Certifiers Association (ACA), etc.) to continue to develop a centralized database of residue results and incentive certifiers to participate.

Downstream Notification of Noncompliant Organic Products to Buyers

Transparency is the foundation of the organic program and a key driver of consumer trust. The Strengthening Organic Enforcement (SOE) rule increased traceability expectations across supply chains, prompting further discussion on formalizing the notification of downstream buyers when crops or products with exclusion-level contamination have entered the stream of commerce.

Stakeholders largely supported this concept when presented in previous discussion documents, and this proposal refines the idea of downstream notification, aiming to ensure that contamination events are communicated appropriately—balancing consumer protection, regulatory integrity, and fair treatment of certified operations acting in good faith.

What do OFPA and the regulations state?

The Organic Foods Production Act (OFPA) and the current USDA National Organic Program (NOP) regulations authorize residue testing, enforcement actions, and supply chain traceability requirements. However, neither explicitly mandates nor defines protocols for notifying downstream supply chain recipients (e.g., processors, retailers) when noncompliant organic products enter commerce.

- **OFPA (7 U.S.C. 6503)[8]:** Authorizes the Secretary to develop program-wide rules ensuring product integrity.
- **OFPA (7 U.S.C. 6505)[9]:** Grants power to suspend or revoke certifications.
- **OFPA (7 U.S.C. 6511)[10]:** Authorizes residue testing and prohibits the sale of products exceeding 5% of EPA tolerance.
- **7 CFR 205.501(a)(13)[11], 205.501(a)(21)[12] & 205.504(b)(7)[13]:** As revised by the SOE rule, requires information sharing among certifiers to enforce the organic regulations and determine compliance, along with the requirement that certifiers implement supply chain traceability audits.
- **7 CFR 205.662–205.668:** Define certifier enforcement responsibilities but do not cover downstream notifications.

Background and Discussion

While traceability and noncompliance procedures exist, there is currently no mechanism requiring certifiers or certified operations to notify downstream buyers or handlers when a product is determined to be noncompliant. This creates potential enforcement inconsistencies and limits transparency. Gaps include:

- Lack of authority for certifiers to alert third parties due to confidentiality requirements
- Absence of product disposition guidance post-notification
- Unclear roles for NOP, certifiers, and operators in managing post-market events
- No infrastructure to support timely or consistent alerts

[8] Organic Foods Production Act of 1990, Section 6503
[9] Organic Foods Production Act of 1990, Section 6505
[10] Organic Foods Production Act of 1990, Section 6511
[11] 7 CFR 205.501(a)(13)
[12] 7 CFR 205.501(a)(21)
[13] 7 CFR 205.504(b)(7)

As an example, below is a best practice scenario for supply chain reporting following detection of prohibited pesticide residue:

> An organic almond grower conducts residue testing and receives laboratory results indicating the presence of a prohibited pesticide substance, rendering the affected almond lots not eligible for sale as organic under 7 CFR Part 205.
>
> 1. Grower Notification and Lot Identification
>   Upon confirmation of the non-compliant residue result, the grower:
>   - Identifies the specific almond lots impacted
>   - Notifies their USDA-accredited certifying agent
>   - Notifies all buyers who received the affected lots that the product is not eligible for organic sale
> 2. Downstream Buyer Notification Response
>   One of the notified buyers, Processor A, has received affected almond lots and used them in the production of almond flour. Processor A:
>   - Reviews receiving records and production logs
>   - Identifies all almond flour production runs that included the affected almond lots
>
>   Processor A determines that the almond flour produced from the affected lots is not eligible for organic status and:
>   - Notifies its USDA-accredited certifying agent
>   - Notifies all buyers who purchased the implicated almond flour
>   - Provides affected lot numbers, production dates, and scope of impact
> 3. Certifier Oversight and Documentation
>   The certifying agents for both the grower and Processor A:
>   - Review documentation and traceability records
>   - Verify that appropriate notifications and product status changes were made
>   - Ensure that the implicated products are removed from organic sale channels or relabeled as non-organic, as applicable
> 4. Reporting to the National Organic Program
>   Where required, certifying agents report the incident to the NOP, including:
>   - Description of the residue finding
>   - Affected products and supply-chain scope
>   - Corrective actions taken to protect organic integrity

Downstream communication should function as a targeted accountability tool, not a broad notification requirement. Most stakeholders support the concept of notifying downstream supply chain partners in cases of confirmed noncompliance—especially for willful violations or residue levels exceeding thresholds—as a means to enhance accountability, prevent further distribution, and uphold consumer trust. Transparency has been emphasized repeatedly as a core value of the organic program, with many noting that such notifications could drive internal testing, risk-based fraud prevention, and alignment with global standards like the EU's traceability model.

Public comments consistently emphasized that notification should be limited to situations involving material risk to organic integrity—specifically, willful violations or residues exceeding action thresholds—while avoiding unnecessary disruption to compliant operations and markets. At the same time, commenters noted that current systems place disproportionate responsibility on certifiers and producers, while downstream buyers often remain insulated from accountability once a certificate is presented.

However, stakeholders have also raised concerns about the need for a formalized process to prevent confusion and protect compliant actors. Key risks include business disruptions, unclear product handling procedures, legal liability, and a lack of legal authority to implement recall and stop-sale. Particular concern about managing cases involving non-pesticide contaminants (e.g., PFAS or GMOs) and trace-level detections have been identified. Stakeholders stress the importance of clearly defining roles and responsibilities to ensure consistency and avoid fragmented enforcement.

While broadly supported by stakeholders, several areas need careful consideration when developing a downstream notification system:

- Infrastructure Gaps - no standardized hold/recall system currently exists in organic.
- Liability and Oversight - Questions remain about who holds responsibility for issuing and enforcing stop-sale notifications.
- Supply Chain Disruption - Unintended consequences may arise if downstream users unknowingly process noncompliant ingredients.
- Scope of Contaminants: Notification protocols must address more than pesticides.
- Fairness: Retailers and processors may bear reputational or financial harm despite acting in good faith.

To mitigate these risks, a structured, data-driven, and risk-based approach to avoid overburdening compliant operations is necessary.

Downstream notification should reinforce buyer due diligence obligations rather than substitute for them. Organic integrity cannot rely solely on possession of an organic certificate or import certificate. Buyers—particularly importers, brokers, and first domestic handlers—serve as critical control points in complex supply chains and must exercise independent due diligence when anomalies, price signals, or risk indicators are present. Notification mechanisms should therefore be designed to prompt corrective action and enhanced scrutiny by buyers, not to create a false assurance that risk is fully addressed upstream.

2025 Fall Public Comment Summary:

Stakeholders overwhelmingly supported downstream notification when confirmed noncompliant organic products have entered commerce, particularly when residue levels exceed action thresholds or willful violations occur. This transparency was viewed as essential to protecting organic integrity, strengthening fraud prevention, and maintaining consumer trust. Commenters expressed less support for automatic notification in trace, borderline, or potential UREC cases, cautioning that notification without clear context could create confusion or unnecessary disruption.

Stakeholders emphasized that downstream notification must be supported by clear procedures and infrastructure, including defined roles and accountability, guidance on product disposition, and a risk-based framework to avoid overreach. Overall, downstream communication was widely viewed as a critical fraud deterrent that improves visibility into enforcement actions, helps buyers refine fraud prevention plans, supports SOE traceability goals, and promotes greater vigilance in sourcing organic inputs.

Q1: Should other types of positives trigger downstream notification beyond results above 5% of thresholds?

Most commenters supported requiring downstream notification when residue test results exceed established action thresholds (e.g., greater than 5% of an EPA tolerance) or result in a noncompliance or adverse action. These situations were viewed as presenting a clear risk to organic integrity and warranting notification to prevent further distribution or use of noncompliant product.

Commenters expressed less support for automatic notification in cases involving trace detections, potential UREC, or results below action thresholds, noting that notification without sufficient context could create confusion or unnecessary market disruption. Overall, stakeholders emphasized that downstream notification should be risk-based, tied to confirmed noncompliance, and applied consistently.

Beyond product control, commenters repeatedly emphasized that a central purpose of downstream communication is to inform organic operations so fraud prevention plans can continuously improve. Stakeholders noted that without visibility into actual residue events, buyers and operators cannot refine sourcing decisions, risk assessments, or testing strategies—"you don't know what you don't know." One certifier reported that approximately 26% of residue tests conducted as part of their annual 5% sampling identified residues above acceptable levels, illustrating the value of information-sharing in strengthening fraud detection across the supply chain.

Q2: What should downstream buyers be required to do upon receiving notification?

Commenters generally supported clear, limited, and scenario-specific expectations for downstream buyers that align with the purpose of notification.

- **When contaminated product remains in the buyer's possession:**
  Stakeholders supported holding, segregating, and refraining from further use or sale of the product, consistent with existing traceability, recordkeeping, and cooperation requirements.

- **When contaminated product is no longer in the buyer's possession:**
  Commenters generally did not support retroactive enforcement or penalties for buyers acting in good faith. Instead, notification in these cases was viewed as informational—supporting internal risk assessments, supplier oversight, and updates to fraud prevention plans—rather than triggering corrective actions.

Across both scenarios, commenters stressed that the effectiveness of downstream notification depends on clear roles, defined responsibilities, and consistent procedures. Commenters emphasized that its primary value lies not only in stopping noncompliant product, but in enabling the organic sector to identify patterns, close gaps, and strengthen prevention efforts over time.

A small number of commenters cautioned that downstream notification could create unintended business disruption or liability if applied too broadly, particularly where the source of contamination is unclear or outside the control of the selling operation. These commenters emphasized the need for clear thresholds, defined roles, and standardized procedures to avoid confusion, reputational harm, or inconsistent enforcement. Importantly, these comments did not oppose downstream notification in principle, but stressed that it should be risk-based and narrowly applied.

Public comments consistently supported clearer expectations at this stage of the supply chain, noting that enforcement outcomes are more effective when accountability is applied to decision-makers controlling market access.

Conclusion:

Downstream notification is a vital step toward safeguarding the organic label. CACS recommends that NOP establish regulatory authority for downstream notification of noncompliant organic products so that they exclude a product from sale as organic once identified. With broad stakeholder support for the need of transparency, this targeted regulatory addition—grounded in OFPA (7 U.S.C. 6503, 6505, and 6511)—would close existing policy gaps, strengthen accountability, and protect organic integrity by ensuring that downstream notification of noncompliant organic products is included in the organic regulations. A new regulatory section would define the scope, responsibilities, and processes for downstream notification, benefiting both organic certificate holders, the organic community, and consumers.

CACS recommends NOP revise the regulatory text to require notification of downstream buyers when either of the following occur:

- Residues exceed action thresholds (e.g., >5% of EPA tolerances)
- Willful violations have occurred as determined by a certifier or NOP

CACS further recommends that NOP develop the notification mechanics, infrastructure, and safeguards, as noted in the table below, through an Advance Notice of Proposed Rulemaking (ANPR).

Component	**Regulatory Action Needed**	**OFPA/NOP Basis**
Notification Req. & Roles	Define Who and What	OFPA (7 U.S.C. 6505), SOE
Certified Operation Support	Require cooperation and records. ID downstream buyers to support notification	OFPA (7 U.S.C. 6503, 6505, 6511); 7 CFR 205.103 and § 205.504(b)(7))
Confidentiality & Liability	Clarify protections for downstream actors	OFPA (7 U.S.C. 6501, 6503, 6505, 6511) (program purpose, administration, enforcement) + stakeholder input+ stakeholder fairness
Infrastructure & Oversight	Direct NOP to manage and monitor the notification infrastructure	OFPA (7 U.S.C. 6503), NOP compliance
Regulatory Coordination	Align terminology for consistency and clarity	7 CFR 205.662 (noncompliance); §205.501(a)(21) & §205.504(b)(7) (traceability audits)

This approach reflects strong stakeholder support for downstream notification triggers, while appropriately reserving system design and implementation details for NOP.

Unavoidable residual environmental contamination (UREC) Definition (§205.2)

Organic certification is built on a process-based standard, grounded in transparency and accountability. While many consumers associate organic products with the absence of synthetic residues, trace contamination—often from environmental sources outside a farmer's control—can occur despite rigorous compliance with organic practices. As detection technologies improve, even the smallest residues can be identified, prompting the need for clearer, scientifically based policy to distinguish which residues are unavoidable residual environmental contamination (UREC).

Certifiers use EPA/FDA thresholds to assess pesticide residue levels. Still, in cases where no tolerance exists, a default of 0.01 ppm is applied to the pesticide, as instructed in NOP 2613: Responding to Results from Pesticide Residue Testing.[14] This has placed an undue burden on producers who operate in good faith yet face contamination from environmental factors. CACS explored updating regulatory text to ensure compliance evaluations align with modern agricultural realities—balancing certification integrity with environmental unpredictability.

What do OFPA, Organic regulations, and other references state?

- OFPA (7 U.S.C. 6511(c)(2)(B))[15]: Recognizes the inevitability of minimal residues not resulting from an operation's practices.
- Senate Report (1990)[16]: Clarifies intent to allow minor contamination not stemming from organic practices, suggesting tolerance levels between 1-10% of EPA levels.
- NOP Final Rule Preamble[17]: Commits to developing science-based UREC thresholds. Until such standards are formalized, FDA action levels apply for defining permissible contamination thresholds.
- 7 CFR 205.2[18]: Defines unavoidable residual environmental contamination (UREC) and drift

These references underscore the importance of protecting organic integrity without penalizing producers for truly unavoidable contamination.

Background and Discussion

The current §205.2 definition of unavoidable residual environmental contamination (UREC) is: "Background levels of naturally occurring or synthetic chemicals present in the soil or in organically produced agricultural products below established tolerances."

[14] NOP 2613: Responding to Results from Pesticide Residue Testing, Section 5.3.3

[15] Organic Foods Production Act of 1990, Section 6511

[16] Senate Report July 1990, S. 2830, pp 299-301

[17] Preamble to the Final Rule, pg. 155

[18] 7 CFR 205.2

During the Spring 2025 NOSB meeting, CACS proposed a revised UREC definition to reflect the modern agricultural environment. While stakeholders acknowledged the intent, many felt the draft required refinement.

To reiterate, a major driver for CACS is to explore options to provide better guidance to certifiers on how to evaluate residues that are seemingly low-level and are present, despite the operation carrying out reasonable and required prevention measures as reflected in their Organic System Plan. These situations often occur where no EPA tolerance exists, triggering default actions that may unfairly penalize compliant producers.

Is it reasonable to consider contamination due to atmospheric drift (i.e., contaminated rainwater) or other types of contamination that are outside of the operation's control, even when operators have implemented contamination prevention strategies, such as UREC? Should this be defined as something else, and then a process be established to address these types of contamination events?

Examples of Contamination Events

Inadvertent – indirect – unavoidable - contamination refers to the unintended introduction of a prohibited substance onto a certified organic operation due to environmental movement—such as wind, water, or volatilization—from a source not under the control of the certified operator.

- This may include cases where the origin cannot be traced or proven, such as dicamba or 2,4-D drift, and where all mitigation strategies were followed.

CACS also explored revising and modernizing the definition of drift. Still, the definition appears to be adequate to capture drift events, which are also unavoidable and indirect, such as atmospheric drift due to dicamba.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof. (§205.2)

CACS determined that even if the definitions for UREC or drift were revised, the challenge remains in the pathway to evaluation. Thresholds are based on the type of residue along with the crop it's found on, but the FDA and EPA tables do not contain these data Therefore, the default for pesticides is 0.01 ppm. With this in mind, CACS aims to elevate some of the recommendations from the Spring 2025 Proposal: Residue Testing for a Global Supply Chain: Guidance. Gaps in the EPA and FDA tables will continue to exist; therefore, CACS wants to elevate the need for the change to occur in how certifiers are evaluating and responding to results per the instructions in NOP 2613 (see appendix at end of this document for an excerpt in the spring 2025 proposal on guidance updates for NOP 2613).

2025 Spring Public Comment Summary – UREC

Public commenters emphasized the need for clearer guidance to address unavoidable, low-level residues outside an operator's control, while expressing mixed views on revising the regulatory definition of UREC. Stakeholders broadly agreed that operations should not receive noncompliances solely due to trace UREC-related residues when appropriate prevention measures are in place, and supported risk-based testing and clearer guidance to consistently address inadvertent drift in modern agricultural systems.

2025 Fall Public Comment Summary:

Q: Are there other solutions that CACS should consider, beyond the Board's previous recommendations, to revise NOP 2613, to help organic operations and certifiers navigate the presence of low-level residues due to circumstances outside of the operations' control (e.g., atmospheric drift)?

Many commenters supported the Board's previous recommendations and emphasized that **updating NOP 2613 is the most appropriate and effective mechanism** to improve consistency and fairness in these cases, rather than revising the regulatory definition of UREC. Stakeholders noted that when no EPA tolerance or FDA action level exists for a crop, default compliance responses can produce inconsistent outcomes and unnecessary burden for operations acting in good faith.

A minority of commenters cautioned that updates to NOP 2613 must be carefully framed to avoid **perceptions of weakened residue enforcement** or inconsistent application across certifiers. These commenters emphasized maintaining strong prevention expectations, clear documentation requirements, and consumer confidence, noting that flexibility should be paired with **clear decision criteria and oversight**.

Conclusion

Stakeholder feedback highlighted the need for clarity around contamination scenarios that fall outside the certified operation's control—especially those involving atmospheric drift.

Based on stakeholder comments, the majority of stakeholders favored preserving the UREC definition while creating a new, well-defined framework for evaluating inadvertent indirect drift. This approach offers clarity and fairness without altering the foundational regulatory language of UREC. It allows the organic community to acknowledge the reality of unavoidable environmental contamination while still enforcing rigorous standards for prevention and compliance.

CACS urges the NOP to implement the Board's previous recommendation to improve NOP 2613 instruction for responding to results when no tolerance exists for a particular crop to assist certifiers in further working with organic producers who experienced inadvertent indirect contamination due to modernized drift (e.g., atmospheric drift).

Additionally, stakeholders overwhelmingly supported updating NOP 2613 with the NOSB 2025 Spring Recommendation. Updates should emphasize:

- When noncompliances should not be issued for confirmed UREC or drift events involving trace residues below 0.01 ppm and without EPA tolerances
- How certifiers should distinguish between trace UREC or drift contamination and noncompliance due to operational negligence
- The continued requirement for operators to implement robust contamination prevention strategies
- Consideration of regionally specific environmental factors when determining what constitutes "unavoidable" contamination

By modernizing the guidance, NOP can provide certifiers with clear, science-based tools to handle UREC and drift events consistently while supporting both integrity and fairness within the organic program.

CACS reemphasizes their recommendation to update NOP 2613 guidance, consistent with the NOSB Spring 2025 recommendation, to provide certifiers with clearer direction for evaluating residue findings when:

1. residues are detected without an established EPA tolerance or FDA action level; and
2. contamination is the result of indirect, unintentional applications of unknown origin (e.g., volatile drift events), rather than intentional application or failure of an operation's Organic System Plan.

Overall Document Conclusion

Mandatory testing of 5% of operations

- Challenge: Some certifiers report that their current testing programs are not finding many positives. However, this is likely due to the types of operations being selected by certifiers to test, which can currently include anyone (i.e., does not need to be based on risk), as well as the types of tests being performed.

- Proposal: Revise the regulatory language to require that the mandated 5% of testing of operations be selected based on risk as well as randomly.

Cost of testing

- Challenge: Certifiers must bear the cost of all residue testing. If the selection requirements change to require that a portion of operations be selected based on risk, this is likely to increase costs. Without the ability to directly pass costs of testing on to operations, certifiers are likely to increase the certification costs for all of their certified operations, which is not equitable.

- Proposal: Revise the regulatory language to allow certifiers to pass along the cost of residue testing in certain circumstances (e.g., credible complaints or investigations) and when the contamination is determined to be caused by an intentional application or failure of an operation to adhere to their OSP (i.e. results in a noncompliance or adverse action).

Public access to results

- Challenge: Two regulatory sections address public access to results, but they are not aligned.

- Proposal: Revise the regulatory language to link the two sections of the regulations together.

Downstream Notification to Buyers

- Challenge: The regulations do not require notification to downstream buyers when a product yields a positive residue result upstream, thereby preventing a noncompliant product from entering the stream of commerce.

- Proposal: Revise the regulatory text to include a framework for downstream buyer notification, enabling the removal of noncompliant products from the stream of commerce in a timelier manner. Subsequently update the guidance regarding expectations for buyer response, clarification of importer and first handler obligations, buyer accountability when a trigger event occurs.

UREC

- Challenge: The current framework that certifiers and organic farmers must use to respond to the presence of pesticide residues in some situations negatively impacts organic farmers who have implemented and followed the contamination prevention strategies in their OSP, and residues are still present. This is often due to atmospheric drift and the fact that certifiers must default to 0.01ppm when assessing the residue, as there is no EPA tolerance for that crop.

- Proposal: Revise NOP 2613 as previously recommended to include a different framework for certifiers to evaluate and respond to the presence of residues when there isn't an EPA tolerance for the crop that yielded positive results, as 0.01ppm doesn't seem to work or be fair in some circumstances.

Subcommittee Vote
Motion to accept the proposal on Residue Testing for a Global Supply Chain: Regulation Review (§205.670 & UREC)
Motion by: Kathryn Deschenes
Seconded by: Amanda Felder
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Appendix: Excerpt from Spring 2025 proposal: Residue Testing for a Global Supply Chain – Guidance Documents 2613

We expand on the issues identified above and propose solutions below.

Issue: Detection without Tolerance Level – When detected pesticides are not registered for the crop on which they are found at any level above 0.01 ppm, the current guidance indicates that certifiers should exclude the crop from the organic marketplace and alert the appropriate authorities, including the EPA and FDA. This approach assumes that any detection of a prohibited pesticide when there is no established tolerance indicates that the product no longer qualifies for organic status and that there is a human health and safety concern. This approach is problematic in the following circumstances:

Drift or Inadvertent contamination: The current guidance does not allow certifiers to factor drift or inadvertent contamination events versus fraudulent activities into their assessment if there is a positive detection but no EPA tolerance or FDA action level. The current guidance also does not provide clarification to certifiers for evaluating whether the presence of a residue is due to unavoidable residual environmental contamination (UREC). Certifiers are assumed to equate this to less than 5% of EPA tolerances. This approach is problematic when there is no EPA tolerance.

For example, §180.129 o-Phenylphenol lists the tolerance for cucumbers at 10 ppm. This means that tests could show residues of up to 0.5 ppm (5% *10 ppm = 0.5 ppm) for cucumbers, and they'd still be allowed to

be sold as organic. However, broccoli is not listed in this table, so if a test came back positive for broccoli for o-Phenylphenol, it could not exceed .01 ppm. This is seemingly unfair to an organic operation in an inadvertent drift scenario, in that produce that might be in very close proximity (no difference in the operation's buffers, etc.) could have very different outcomes by having to rely solely on the inclusion of crops in the EPA tables.

NOSB further explores UREC in our "Residue Testing for a Global Supply Chain: Regulation Review Discussion Document," which includes revising the current definition.

Solutions: NOSB proposes that NOP explore the following policy solution options:

A. Utilize 40 CFR Subpart 180 paragraph (d) "Indirect or inadvertent residues":

    a. Recognize the values in 40 CFR Subpart 180 paragraph (d) "Indirect or inadvertent residues" as equivalent to 5% of EPA Tolerance for the purpose of responding to residue tests to determine organic compliance (i.e., 5% of the tolerance listed in (d) should not be taken given that these are already at inadvertent levels; evaluate compliance directly against values as they appear in (d)); and,

    b. Provide guidance to stakeholders for the process of requesting EPA to establish tolerances in paragraph (d) in cases where there isn't a current tolerance listed in paragraph (d) for that substance.

B. Utilize crop group structure: NOSB requests that NOP provide guidance to certifiers on how to utilize the crop group structure for the purpose of determining organic compliance including but not limited to:

    a. Adding additional crops (that are missing) to crop groups with like characteristics.

    b. State that if a crop is listed for a particular substance, all the crops in the corresponding crop group would have the same tolerance (e.g., for o-phenylphenol, cucumbers have a tolerance of 10 ppm). Since cucumbers are part of crop group 9 - cucurbit vegetables, all crops listed in crop group 9 would have the same tolerance as cucumbers).

C. Explore if other reliable data sets could be used to set action and inaction thresholds as an alternative to .01 ppm. These may include, but are not limited to, the USDA Pesticide Data Program or the Dietary Risk Index.

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
E-Commerce Labeling Proposal
Spring 2026

Introduction:
A petition was submitted to the NOP requesting a regulatory amendment to expand the "certified organic by * * *" requirements to include online e-commerce platforms, ensuring that full information panels are displayed at the point of sale. While this approach could enhance transparency, it presents challenges because certain online retailers are exempt from certification. Stakeholder input was received during the comment period for the rescheduled Fall 2025 meeting. CACS recommends that the NOP provide guidance on e-commerce labeling practices that align with other federal labeling guidance.

Background:
On April 16, 2025, Organic Eye submitted a petition for rulemaking to the USDA. The petition requests that NOP amend the USDA organic regulations to require online retailers/resellers to provide consistent certification information to consumers; specifically: to require "certified organic by * * *" statements. This information is readily available in brick-and-mortar stores (on the product's label); however, it is not always available online, where a full product label may not be visible to the buyer. The petition requests a requirement for online vendors and/or third-party resellers to provide a visible image of the packaged, organic product's information panel or a statement identifying the organic certifier of the product on the webpage.

The NOP asked the Board in a Memo to review Organic Eye's petition and if appropriate, submit feedback or a recommendation to NOP. As such, the CACS reviewed OFPA and the organic regulations to verify the NOP's authority regarding the petition.

A discussion document was prepared for the Fall 2025 meeting, but due to the postponement of that meeting and abbreviated rescheduled meeting in January 2026, the discussion document received public comments in the docket but was not discussed at a meeting. Public comments submitted to the Fall 2025 docket are considered here.

Since the convening of the NOSB in January 2026, the Food and Drug Administration released 2026 Human Foods Program Priorities and Guidance Agenda which includes "Food Labeling for Online Grocery Shopping Platforms; Draft Guidance for Industry." This signals that the FDA intends to, but is not bound to, develop guidance on this topic.

Discussion:
E-Commerce labeling practices
As online shopping continues to surge, the importance of providing clear, accurate, and comprehensive labeling information on e-commerce platforms has never been greater. Consumers increasingly rely on

digital product listings to make informed decisions about the items they purchase.

Current labeling practices across e-commerce retailers remain inconsistent. While some platforms excel in transparency—offering detailed product descriptions, high-resolution images of packaging, and full labeling information including nutrition facts, ingredient lists, and third-party certifications—others fall short. In many cases, consumers are presented with only minimal product descriptions and generic images that fail to convey critical details. The lack of standardized labeling protocols across platforms means that two listings for the same product may offer vastly different levels of information, depending on the retailer.

Encouragingly, some e-commerce platforms have begun to adopt more rigorous and transparent labeling practices. These include displaying images of the product's information panel, explicitly naming the certifying body for organic claims, and ensuring that digital listings mirror the physical product's packaging. Despite these improvements, such practices are far from universal and challenging for some products, such as produce.

Another key challenge lies in the regulatory landscape: retailers are often exempt from organic certification requirements, which limits accountability. The dynamic nature of product labeling—driven by reformulations, regulatory updates, and marketing changes—may make it difficult for retailers to maintain up-to-date and accurate information.

What do OFPA and the Regulations State?

OFPA:

The Organic Food Production Act (OFPA) 7 U.S.C. 6505 establishes a foundational principle for organic labeling: only agricultural products that are produced and handled in full compliance with organic standards may be labeled or marketed as "organically produced." It further prohibits any labeling or marketing information that suggests a product was produced using organic methods unless it meets these standards. This provision is critical in maintaining the integrity of the organic label and ensuring consumer trust across all sales channels.

Specifically, OFPA states:

> 7 U.S.C. 6505(a)(1)(B): No person may affix a label to, or provide other market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with this chapter.
>
> 7 U.S.C. 6505(a)(2)): USDA standards and seal -- A label affixed, or other market information provided, in accordance with paragraph (1) may indicate that the agricultural product meets Department of Agriculture standards for organic production and may incorporate the Department of Agriculture seal.

The USDA National Organic Program (NOP) regulations provide specific definitions for key terms that

govern how organic claims are communicated:

> **Label.** A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product. (7 CFR 205.2)
>
> **Labeling.** All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.(7 CFR 205.2)
>
> **Market Information.** Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product. (7 CFR 205.2)

The definitions are broad and inclusive, suggesting that digital product listings, e-commerce descriptions, and online promotional materials may fall under the scope of labeling and market information for the purposes of verifying organic compliance.

7 CFR 205.303 and 205.304 Packaged Product Labeling (*focusing on "Certified Organic By **" Statement Requirements)*:

NOP regulations (7 CFR 205.303(b)(2) & 205.304(b)(2) require that organic products (in all labeling categories) include a "Certified organic by [certifying agent]" or similar statement on the information panel of the physical package. This statement must appear below the name of the handler or distributor and may include the certifier's business address, website, or phone number. The text of 7 CFR 205.303(b) & 205.304(b) states that this is specifically required for "agricultural products in packages." While this requirement ensures transparency in physical retail environments, it does not explicitly extend to digital product listings or e-commerce platforms. As a result, many online retailers and resellers—particularly those exempt from organic certification—do not currently have specific responsibility to display certifier information as the "Certified organic by * * *" requirement is specifically tied to physical packaging. Therefore the addition of the statement on other "labeling" outside of physical packaging would be outside of current requirements and require changes to regulations.

Additionally in our discussions, CACS noted that 7 CFR 205.303(a) and 205.304(a) covers specific items that "may" be included on market information, which would apply to websites and e-commerce sales platforms. However, these are not required as currently written.

7 CFR 205.101 Exemptions from certification:
Extending the requirement to display "Certified organic by * * *" statements to e-commerce platforms could introduce new compliance obligations for entities that are currently exempt from organic

certification—namely, retailers and resellers. These businesses are not required to be certified under USDA organic regulations, even when selling certified organic products. But, exempt operations are not without obligations. As specified within 7 CFR 205.101(i), exempt operations are currently required to keep certain records. Additionally the regulations currently include a labeling section (7 CFR 205.310) that does apply to certain types of exempt operations. Therefore, exempt operations are not without responsibility to uphold integrity and their role in displaying accurate information regarding certifier information could be within a reasonable scope of duties.

FDA Labeling Governance

While the USDA retains authority over organic labeling, the majority of food labeling jurisdiction lies with the FDA. A review of FDA's actions related to e-commerce labeling provides valuable context for understanding how labeling requirements may apply to digital platforms—particularly in grocery store apps and online shopping environments. Although not directly tied to the petition's request, this regulatory backdrop helps clarify the extent to which USDA may assert jurisdiction over labeling practices in e-commerce.

In a 2007 "Dear Manufacturer" letter, FDA acknowledged that internet-based information—including websites offering truthful and non-misleading content about food products—can play a meaningful role in helping consumers make informed nutritional choices. FDA encouraged manufacturers and distributors to ensure that claims made online are consistent with current labeling laws and regulations, reinforcing the expectation that digital representations of food products should align with physical packaging standards.

Importantly, FDA has stated that in certain circumstances, online content disseminated by or on behalf of a regulated company may meet the definition of "labeling" under Section 201(m) of the Federal Food, Drug, and Cosmetic Act. For example, if a company promotes a regulated product on its website and enables direct consumer purchases, the website itself is likely considered labeling. FDA has also emphasized in warning letters that if a website is referenced on a product's physical label, the site may be subject to labeling requirements. In these cases, websites are treated as written, printed, or graphic matter that supplements or explains the product and is used in its distribution and sale.

FDA has taken steps to explore the implications of e-commerce labeling. In 2021, the agency hosted the "FDA's New Era E-Commerce Summit" and opened a public comment docket (https://www.federalregister.gov/documents/2023/04/24/2023-08543/food-labeling-in-online-grocery-shopping-request-for-information) to gather input. In 2023, FDA issued a formal Request for Information (RFI) on food labeling in online grocery shopping platforms, with the stated goal of improving consumer access to consistent and accurate nutrition, ingredient, and allergen information for packaged foods sold online. Despite these efforts, FDA has not yet issued formal guidance or regulatory updates specific to e-commerce labeling but signaled in their 2026 agenda that they intend to develop industry guidance titled, "Food Labeling for Online Grocery Shopping Platforms; Draft Guidance for Industry."

This evolving landscape underscores the need for USDA to consider how its own labeling requirements—particularly for organic claims—should apply to digital platforms. As FDA increasingly recognizes online

content as labeling, USDA may have a stronger foundation to assert oversight over organic labeling in e-commerce environments, especially where consumer-facing claims are made without the physical product present.

USDA National Organic Program (NOP) Labeling Governance

Brick and Mortar:

The USDA National Organic Program (NOP) is responsible for overseeing the labeling of organic products to ensure compliance with national standards. The NOP ensures that products labeled as "organic" meet the requirements of 7 CFR Part 205 and are labeled appropriately, including the presence of the “Certified organic by * * *” statement on packaging. The USDA NOP has jurisdiction over the labeling of organic products, ensuring that all products comply with the established standards for organic production and handling.

The NOP also works to maintain the integrity of the organic label by conducting compliance and enforcement activities. This includes investigating complaints about organic products and taking action against businesses that are found to be non-compliant. Such actions can range from issuing warning letters to revoking certification and imposing fines.

E-Commerce Labeling:

The USDA National Organic Program (NOP) governs organic labeling through regulations such as 7 CFR 205.303(b)(2) and 205.304(b)(2), which require that packaged organic products display the name of the certifying agent on the physical label. However, these requirements do not explicitly extend to e-commerce platforms, where online retailers and resellers are often exempt from organic certification. As a result, there is no consistent federal mandate requiring the display of certification information—such as the “Certified organic by * * *” statement—on digital product listings.

Discussion

The USDA NOP plays a critical role in ensuring that consumers can trust organic claims across all retail environments, including the rapidly expanding e-commerce marketplace. While the NOP has clear authority over the labeling and marketing of certified organic products, the unique structure of digital retail—where content is often controlled by third-party platforms rather than certified operations—introduces practical limitations to mandating new online labeling requirements through regulation alone.

Although expanding labeling or market-information requirements into the digital space may support greater consistency and help safeguard organic integrity, imposing a mandatory “Certified organic by [Certifier]” statement on e-commerce listings could pose significant implementation challenges and may not ultimately yield meaningful consumer benefit. Retailers selling organic products online, particularly fresh produce with rapidly rotating stock, would face substantial operational burdens in maintaining accurate certifier information—especially where products are unpackaged and therefore not subject to the certifier-statement requirement in physical retail settings.

Guidance will support transparency, and allow time for alignment with FDA guidance on online marketing.

Stakeholder Comments

The public comments reflect a broad and consistent set of themes regarding the e-commerce organic labeling proposal. Overall, commenters strongly support transparency in online labeling and agree that consumers should have access to essential information—such as the USDA Organic seal, ingredient lists, allergen statements, and nutrition facts—when shopping online. However, some stakeholders oppose expanding the regulatory requirement to include the full "Certified organic by* * *" statement on e-commerce product listings. They note that consumers rarely look for or understand this statement, while the burden of displaying and maintaining it across numerous digital retail platforms would be high and often outside the control of certified operations. Many comments emphasize that online retailers, not manufacturers, control product pages, making enforcement impractical and potentially unfair. Across the board, commenters urge the NOP to wait for or align with FDA's ongoing work on digital labeling to avoid conflicting regulatory regimes. Instead of new mandates, commenters overwhelmingly recommend voluntary best-practice guidance, education for retailers and brands, and improved digital data-sharing systems as a more feasible and consumer-aligned approach.

Summary of Proposal

CACS recommends that the NOP provide guidance—rather than pursuing rulemaking—on e-commerce labeling practices, with the goal of improving clarity and consistency in how organic claims are presented online. Such guidance should:

- Outline recommended best practices for displaying the USDA Organic seal and core labeling elements on product listings, including displaying images of full product labels with the "Certified organic by * * *" statement where possible
- Encourage accurate and timely updates by retailers and platforms
- Reinforce expectations for truthful organic claims across digital channels

Importantly, this approach would allow the NOP to harmonize its recommendations with FDA's forthcoming guidance on digital labeling, promoting coherent federal policy and minimizing conflicting obligations for industry.

Subcommittee Vote
Motion to accept the proposal on E-Commerce Labeling
Motion by: Kathryn Deschenes
Second by: Cat McCluskey
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Pear Ester
Spring 2026

Summary of Petition and Background Information on Pear Ester

In September 2023, the National Organic Program received a petition from Trece Incorporated requesting the addition of Pear Ester (i.e., Ethyl-2E,4Z-Decadienoate), a semiochemical material, to the National List as a synthetic allowed for use in crop production [7CFR§205.601(j)]. Semiochemicals are bioactive molecules released by an organism to signal or provoke a behavioral or physiological response Signaling may be between members of the same species or between two or more distinct species (2024 TR, lines 282-284). Pheromones, kairomones and allomones are sub-categories of semiochemicals. Pear ester was previously allowed for use in organic crop production under the synthetic pheromone classification until its correct reclassification as a kairomone. Even though pheromones and kairomones are both semiochemicals, they differ in a couple of significant characteristics. Pheromones are volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior (EPA, 2011).

Pear ester is synthesized by a condensation reaction between two chemicals that are by-products of petroleum processing. The prevalent process for manufacturing pear ester is the condensation reaction between the eight-carbon allyl alcohol, oct-1-yn-3-ol (CAS No. 818-72-4), and triethylorthoacetate (CAS No 78-39-7). The condensation product is heated with propanoic acid as a catalyst, and the subsequent Johnson-Claisen rearrangement gives ethyl 2E, 4Z-decadienoate. It is a convenient one-step synthesis with good yields (2024 TR, lines 552-556).

Pear ester appears on the FDA list of Substances Added to Food (*formerly EAFUS*) for use as a flavoring agent or adjuvant food additive. The EPA has registered pear ester formulations for pest management (2024 TR, lines 268-272). This behavior-altering chemical (i.e., semiochemical) is particularly useful in the management of the codling moth *Cydia pomonella* – an economically significant pest that principally affects apple, pear, and walnut crops (2024 TR, lines 98-99). The proper classification of pear ester as a kairomone instead of a pheromone rendered its continued use under the pheromone category untenable in organic crop production. The petition is aimed at providing organic crop producers with pest management tools that were available to them prior to the reclassification of pear ester as a kairomone instead of a pheromone.

The 2024 technical report (TR) on pear ester has detailed information on significant improvements in pest management outcomes from the incorporation of pear ester relative to results obtained with the use of pheromones alone. The report covers various uses of pear ester in codling moth management, including:

(a) As lures in traps to monitor populations of codling moth in orchards. These traps help to determine the "biofix point," which is the date when codling moths first appear in monitoring paths (2024 TR, lines 121-122). Pear ester monitoring traps provide information for determining action thresholds and the timing of treatments.
(b) In mating disruption efforts. Research findings show mating disruption dispensers loaded with both codling moth sex pheromone and pear ester can be more effective than dispensers with pheromone alone.

Available data shows that pear ester exerts significant economic impacts on pear and apple growers. The positive economic impact of pear ester is exerted through its documented direct impact on mass trapping, mating disruption and proper timing of treatments (including pesticide applications). These interventions result in significant reductions in fruit damage. The improved effectiveness of traps and monitoring tools when pear ester is combined with pheromones is well documented.

Subcommittee Review Fall 2024
Subcommittee discussions were based on a discussion document that was informed by the 2024 technical report on pear ester. Discussions covered pertinent elements of the petition (to add pear ester to the national list). Discussions also included the previous misclassification of kairomones as pheromones and the distinction between these behavior-altering chemicals. The essentiality of pear ester in apple and pear production was emphasized. There was a suggestion to explore the possibility of broadening the proposal to cover kairomones as a group instead of pear ester alone. All eight attendees voted to accept the discussion document on pear ester.

Fall 2024 Meeting Public Comments
Comments received at the Fall 2024 meeting were in favor of adding pear ester to the National List. A commenting organization stated that synthetic pear ester-based mating disruption products are Generally Recognized as Safe (GRAS) and are more effective in insect pest management in organic orchards relative to their alternatives. It was also pointed out that the chemical structure of synthetic pear ester is identical to the natural kairomone.

One commenter advised the Board to direct significant attention to determining whether the word "pheromones" was used in OFPA §6517.c.1.B.i to refer to only pheromones or if it could be interpreted to include other semiochemicals such as kairomones. The commenting organization was of the view that this determination will provide a basis (or otherwise) for continuation of the evaluation of pear ester in addition to helping to clearly articulate the Board's intent for handling future petitions involving semiochemicals. A historical context of negotiations that resulted in the inclusion of pheromones in OFPA was provided. The Crops Subcommittee was advised to determine the correct interpretation of pheromones in OFPA §6517.c.1.B.i. to ascertain whether it covered only materials that satisfy the technical definition of pheromones or if it included other semiochemicals. It was argued that the absence of internet-based resources and poor access to technical expertise during the negotiations pertaining to the inclusion of pheromones in OFPA may have led to the wrong interpretation of the intent of OFPA drafters. The commenting organization was of the view that if the drafters of OFPA had access to the information available in the 2024 technical report on pear ester, OFPA §6517.c.1.B.i. would have highly likely contained the term "semiochemicals" instead of "pheromones."

One of the comments was for the Board to make a distinction between pear ester that is released from traps and those that are microencapsulated in polyamide materials that are then sprayed. The commenting organization considers the use of pear ester in traps to be consistent with OFPA unlike its use in microencapsulated formulations. The commenter stated that polyamide particulates are microplastics and must be evaluated as such.

According to the commenting organization, the Board needs to consider the following pieces of information in its deliberations on pear ester: (a) the essentiality of microplastics in microencapsulated pesticide formulations, and (b) the publication by Alijagic et al. (2024) about the need to investigate potential health risks to individuals exposed to polyamide microplastics.

The Board was asked to consider the delivery mechanism in its deliberations on pear ester. An annotation to restrict the use of pear ester to traps was recommended.

Another commenting organization acknowledged the efficacy of semiochemicals in insect pest management but stressed the importance of guardrails that permit the use of synthetic materials that are identical to natural kairomones. In the perpetual quest for more effective pesticides, this guardrail would prevent the development of products that exert unintended/unexpected adverse impacts on non-target organisms in the farm ecosystem because they differ significantly from natural kairomones. The comment endorsed the

use of pear ester in trapping and monitoring insect pests but opposed the broadcast application of microencapsulated formulations which release microplastics in the organic environment.

Fall 2024 NOSB Board Meeting Review
There was widespread support for adding pear ester to the National List. Board members sought information from public commenters on whether there were other kairomones (i.e., apart from pear ester) that were in use in insect pest management. This was to inform the NOSB's decision on whether to pursue the addition of pear ester alone or kairomones as a group to the National List. The Board did not receive any information that justified the addition of kairomones as a group.

Category 1: Classification/categorization
There is a need for clarification and/or pursuit of supporting documentation on the intent or correct interpretation of the word "pheromone" in OFPA §6517.c.1.B.i. A section of the organic community is requesting information on the interpretation that informed the removal of pear ester from the National List. The current position/trajectory of the Crop Subcommittee (CS) is to proceed with a proposal to add pear ester to the National List until a determination that the drafters of OFPA intended to refer to semiochemicals instead of "pheromones" in particular. This approach is informed by the fact that even though kairomones and pheromones are both semiochemicals, they are technically different. The removal of pear ester from the National List represents a previous (correct or incorrect) determination that OFPA drafters did not intend to refer to semiochemicals in general. The CS will proceed with the proposal while it pursues documentation and/or clarification of the intent of OFPA drafters on the use of pheromones and other semiochemicals.

Another item that will feature prominently in discussions on pear ester is its categorization based on the various delivery systems used in deploying them. This will inform the possible introduction of an annotation to distinguish between systems that may be consistent and inconsistent with OFPA.

Category 2: Adverse Impacts of Pear Ester

Human Health Impacts
Pear ester is a Generally Recognized as Safe (GRAS) food additive. In 2013, the EPA exempted it from the need to establish food tolerance for residues in or on food crops at 40 CFR 180.1323. The EPA concluded that "there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposures to ethyl-2E-4Z-decadienoate (pear ester)" (78 FR 53051, August 28, 2013) (2024 TR, lines 889-892). Pear ester has low acute toxicity to mammals, and the oral LD_{50} for rats is 4,027 mg/kg. This number means pear ester is nearly non-toxic. Additionally, pear ester is an FDA-approved food additive, and average human consumption in the U.S. is about 3 µg per day (2024 TR, lines 876-880). According to the EPA, pear ester also has low chronic toxicity and is not likely a developmental toxicant or a mutagen. It is not on the EPA list of carcinogens or on the IARC carcinogen list. The EPA reported in 2013 that pear ester had not been evaluated for endocrine disruption (2024 TR, lines 882-884).

Even though the 2024 technical report on pear esters found no publications indicating harm to humans from pear ester or polyamide particulates, the products safety data sheet states that it may cause allergy or asthma symptoms or breathing difficulties if inhaled. Contact with skin or eyes may cause irritation. It must be noted that the food tolerance exemption provided by the EPA does not include an evaluation for occupational exposure. The maximum label amount is about 400 µg pear ester/day, which is well below the acute toxicity of 4027 mg/kg. Pear ester vapors are not likely a health problem for orchard workers (2024 TR. lines 909-911).

Exposure to Polyamide Particulates

Sprays of about 30 g/ha decadienoic acid (DA) ethyl ester (pear ester) commercially known as DA MEC™ are applied to tree canopies with an air- blast sprayer (2024 TR, lines 913-914). Even though exceedingly tiny amounts of DA MEC™ are used, the sprays contain a large number of small polyamide particles. Each tree canopy receives about five hundred million microencapsulated pear ester particles. There might be a respiratory hazard from inhaling plastic microparticles when the spray is applied by air blast sprayer to individual trees. However, effects of exposure to the polyamide spherical capsules in the spray have not been evaluated by the EPA. Given the 4-hr re-entry restriction, the greatest acute risk is probably during spray applications with an air blast sprayer. But the DA MEC™ label does not require respiratory protection for workers (2024 TR, lines 916-921). It is important to note that the maximum 8-hr worst case chronic exposure would be about 0.0357 mg/m^3 or 36 µg/m^3. This exposure is below the U.S. 24-hr particulate standard of 150 µg/m^3 for PM 10 (89 FR 16202, May 6, 2024) (2024 TR, lines 941-942).

Given the fact that sprayable microencapsulated pheromone particles can be washed out of tree canopies by wind, rain, and overhead irrigation sprays, pear esters are assumed/expected to meet the same fate (2024 TR, lines 935-936).

Environmental and Ecological Health Impacts
The EPA did not require testing for bird, fish, and aquatic invertebrate toxicity because pear ester is expected to quickly disperse and degrade in the environment. However, the pear ester safety data sheet from Boudakian Research states that pear ester is “very toxic to aquatic life with long lasting effects” (2024 TR, lines 650-653). The substance is, however, exempt from testing for toxicity to bird, fish, and aquatic invertebrates. According to the safety data sheet, pear ester is a marine toxicant and hazard. Environmental damage may be mitigated by the low application rate of 12 g DA MEC™/acre or 30 g/ha. That is about 0.27 mg DA MEC™/ft^2. That is a small amount, but each ml of the usual diluted field spray contains about 260,000 particles (2024 TR, lines 862-865). Once applied, microcapsules probably stay on the leaves until dislodged by wind and rain which is the case for microencapsulated sprayable pheromones (2024 TR, lines 857-858).

When particles are dislodged by rain, they likely become part of runoff from an orchard (2024 TR, lines 857-860). Once the microencapsulated particles reach water, fish or other aquatic creatures might ingest them. No density information is given , but likely the polyamide particles are less dense than water. The pear ester contained in the microparticles is an aquatic hazard (2024 TR, lines 869-871). The 2024 technical report found no information on the environmental effects of pear ester polyamide microcapsules. There is no published information on the effects of these particles on earthworms. Birds can be exposed by feeding on earthworms that ingest polyamide microcapsules. However, again, the amounts of pear ester involved are exceedingly small. Because of its volatility, pear ester dissipates quickly in the environment. Manufacturers encapsulate volatile components of spray formulations to limit volatilization and produce products that have a lasting effect (2024 TR, lines 87-88).

The EPA did not require the product manufacturer to submit environmental toxicity tests of microencapsulated pear ester (2024 TR, lines 872-874).

Category 3: Alternatives/Compatibility
Performance of Alternatives
It is important to note that codling moth management performance of natural alternatives to synthetic pear ester tend to be enhanced when combined with the synthetic product. Products such as granulosis virus, Spinosad, BT products and the use of degree day methods are employed against the codling moth. The performance of these alternatives is, however, enhanced by pear ester in monitoring traps to determine the biofix point and, thus, the correct and most effective timing of pesticide applications.

Spring 2025 Public Comments

Public comments were generally in favor of adding pear ester to the National List. An environmental and public health advocacy organization stated its support for the listing only if an annotation was introduced to limit the use of the semiochemical to traps and disallow its use in microencapsulated forms. It cited findings by Alijagic et al. (2024) that "the increasing use of polyamide microplastics may pose a potential health risk for the exposed individuals, and it merits more attention." The commenting organization warned the NOSB against over-reliance on Environmental Protection Agency (EPA) registration documents that state EPA conclusions rather than data on environmental risk. It went further to state that the world would have been less contaminated if the EPA were doing its job to protect humans and the biosphere from the negative impacts of pesticides. This advocacy group further differentiated between the use of pear ester in traps and its spray application in polyamide microcapsules. It stressed the fact that the polyamide capsules are microplastics which it had previously tasked the NOSB to work towards eliminating from organic production and handling. It listed adverse human, environmental, and ecological effects of microplastics. According to the commenting organization, unlike traps, microplastics are essential to the microencapsulated formulations. It stated its belief that "the use of pear ester in traps may be consistent with OFPA, but the use in sprays does not fit into any of the OFPA categories and poses unnecessary risks." The organization encouraged the Crops Subcommittee to investigate information on the relative effectiveness of the use of pear ester in traps and in sprays. A coalition of various stakeholders in the organic industry expressed their support for listing pear ester with an annotation prohibiting its use in microencapsulated polyamides. The organization mentioned further evidence that the charges on microparticles function as "collectors" for other pollutants in addition to their own detrimental effects. In summary, the commenting organization requested annotation(s) that have the following elements:

- Requirement to use forms of synthetic pear ester that are identical to the natural versions. Preclude the use of microencapsulated polyamides, and
- Ensure no direct contact with crops or soil.

In answering the NOSB's question on whether there were kairomones other than pear ester that were in use in insect pest management, a materials review organization (MRO) stated that the totality of kairomones and other semiochemical products is not necessarily identifiable through databases such as the National Pesticide Information Center (NPIC)'s database, NPRO (https://npic.orst.edu/NPRO/). The organization attributed this to the fact that kairomones and other semiochemicals are often exempt from EPA registration requirements. It cited the work of Murali-Baskaran et al., who in 2018 published a list of substances that can behave as kairomones. The list included tricosane, linalool-L, alpha-pinene, caryophyllene, myristic acid, alpha-humulene, octacosane, and methyl salicylate. The MRO stated that even though it had reviewed materials containing some of these substances, the reported role of the substances may not have been as kairomones due to multiple uses/functions of some of these chemicals. The commenting organization cited a publication by Nigg et al. (2022) which reported that at least one research group classified ammonium carbonate as a kairomone for attracting fruit flies. The commenting MRO stated the need for a technical report that reviews literature on chemicals used as kairomones in research and those used in commercial products.

According to an organic crop producer who stated support for the addition of pear ester to the National List, farmers find it challenging to control codling moths even in conventional orchards so organic farmers need as many tools as they can in their toolbox to maintain an acceptable level of control of the pest in orchards. According to the commenting farmer, failure to control the codling moth could cause over 80% of their apple and pear orchards to withdraw from organic certification and go back to conventional farming to avoid the significant risk that the pest poses to them. The farmer also stated that the availability of alternative pest management materials or practices is a decision-making factor that must be evaluated critically because these alternatives may not necessarily be effective against targeted pests. Another farmer concurred about the difficulty of controlling the pest (even on conventional farms), the need to have as

many tools as possible against it, and the risk of farms reverting to conventional production in the absence of effective tools against the pest. The farmer stated that in the Pacific Northwest, the codling moth situation had become bad enough to necessitate the creation of a codling moth task force made up of research, industry, university, and growers in the quest for better management of the pest.

A farmers' association wrote to state its support for the listing of pear ester as a "pheromone" provided there is an annotation that restricts its use to traps with no contact with soil or crops. It requested the NOSB to clarify that kairomones and pheromones that are identical to natural kairomones are the only types that are allowed. This statement is meant to prevent the production of novel forms of the material produced through irradiation, genetic manipulation, or other means. According to the farmers' association, pear esters should not be allowed in the spray form due to adverse impacts of the polyamide material (used in microencapsulation) on human, environmental, and ecological health.

A manufacturer of a relevant behavior-based pest management tool provided additional information on pear ester products. It stressed that lures never touch or come into contact with the crop and mating disruption products using pear ester in passive dispensers that are housed in solid delivery systems. The commenting manufacturer stated some of the pest management advantages of using pear ester-based products. It emphasized the use pattern for solid products which only allow for pear ester to emit as a gas, preventing the presence of the product in water residues. It stated that the microencapsulated products are not water-soluble, and label instructions specify full coverage sprays that must be complete but do not allow "runoff." It stated that the polyamide encapsulating agent is introduced into the environment at a low rate. The commenting organization admitted that microplastic contamination is a real issue because of possible adverse effects on humans, crops, and other organisms. It, however, stated that polyamide plastics are currently allowed as inerts in organic production. It cited the fact that the 2004 EPA list includes polyamide resins (CAS RN: 63428-83-1) as a List 4 material. The pest management material manufacturer stated that while polyamide does not appear on the NOP's list of inert ingredients that are currently believed to be in use on organic operations (known as Appendix A), it is technically allowed under §205.601(m)(1).

A coalition of wholesalers stated its support for the addition of pear ester to the National List but stated that the motion to do so in the Spring 2025 NOSB packet referenced §205.601(j). The coalition asserts that pear ester should be listed at §205.601(f) which is titled, "As insect management," whereas §205.601(j) is titled, "As crop or soil amendments." It also mentioned that the loss of the most effective organic codling moth treatment occurred in 2014 when streptomycin and tetracycline were delisted. It stressed the increased importance of pear ester in the management of codling moths. On the issue of essentiality and the availability of alternatives, the coalition of wholesalers emphasized the fact that moth control materials allowed for organic production are less effective than their conventional counterparts. It stated that this fact made trapping and monitoring programs critically important to organic producers. It further stated the increased effectiveness of permitted moth management methods such as granulosis virus, Spinosad (insecticide), Bt (insecticide) products, and degree day models when they are used in combination with pear ester. It called for a technical clarification of the regulatory status of semiochemicals other than pheromones, describing it as important to the long-term viability of the listing of pear ester and, thus, its availability to organic orchardists. It cited a publication titled, "*Role of kairomone in biological control of crop pests – A review"* by Ramasamy Kanagaraj Murali-Baskaran, Kailash Chander Sharma, Pankaj Kaushal, Jagdish Kumar, Packirisamy Parthiban, Sengottayan Senthil-Nathan, and Richard W. Mankind, which was not included in the bibliography of the technical report on pear ester. The study is said to contain information about the development of other types of kairomones and delivery systems that may increase their effectiveness in field applications.

A retailer echoed widespread support for the addition of pear ester to the National List and concerns about the use of microencapsulated polyamides as a dispersal method for pear ester. It listed adverse

environmental and human health impacts of plastic contamination. It stated its belief that spraying of plastic materials is counter to the spirit of organic, which prioritizes soil health and holistic management practices. It called for an annotation to prohibit the use of microencapsulation polyamide materials if pear ester is to be added to the National List.

A certifier stated its support for the addition of kairomones to the National List as an addition to the allowance of pheromones for use as insect management under §205.601(f). It currently approves six different kairomone materials under the previous approval as pheromones and has forty clients using one or more of these products.

A regional horticultural organization is stating its support for the listing of pear ester as a kairomone and emphasized the fact that the synthetic material is identical in chemical structure to the natural version. The commenting organization stated that this was the justification for the EPA not requesting environmental toxicity tests from the pear ester product manufacturer. It listed the codling moth as the principal pest among thirty-three insect pests that feed directly on tree fruits in the Pacific Northwest. Increasing populations of the pest, which is classified as a quarantine pest, has been reported by tree fruit growers in the Pacific Northwest. The commenting organization stated that 80 to 90 percent crop losses are typical if larval feeding is left uncontrolled. The use of semiochemicals in Integrated Pest Management (IPM) programs enable growers to apply fewer sprays than would otherwise be necessary. The regional organization stated that it was only aware of pear ester and acetic acid as the kairomones currently used in managing codling moths in the Pacific Northwest. It suggested that the Crops Subcommittee reach out to certifiers for information on any kairomone-based materials listed in the Organic System Plan (OSP) of organic growers. It also offered to compile a comprehensive list of kairomones to support a future NOSB decision to tackle kairomones as a class.

A trade association stated its staunch support for the expanded use of pear ester in organic production of fruit trees and management of pests; it described pear ester tools as absolutely critical and safe pest management tools for growers. It highlighted products that combine both groups of semiochemicals as the only ones that help growers to assess and manage both male and female codling moths. It also stated that pear ester products also enable growers to gain a better understanding of codling moth locations and population density. These pieces of information are critical in determining when and where to apply insecticides. The trade association stated that there were no documented risks of harm to the environment or human health pertaining to pear ester. The trade association underscores that pear ester tools are absolutely critical as safe pest management tools for growers.

Questions for Stakeholders (presented for public comment in the Spring 2025 proposal)
The CS has the following specific questions for stakeholders and welcomes any additional perspectives, solutions, and information related to pear ester.

1. Is there additional/new research-based information on the environmental and human health impacts of pear ester used in microencapsulated formulations and in traps?

Spring 2025 NOSB Board Meeting Review
The Board voted to send the proposal back to subcommittee for further work to consider an annotation to prohibit microencapsulated versions.

Subcommittee Review Fall 2025
The subcommittee presented an updated proposal for the Fall 2025 Meeting.

Fall 2025 Public Comments

Comments were generally in support of the addition of pear ester to the National List. These comments can be classified into three distinct groups. These include those in support of the proposal as presented, those in support of the addition of pear ester to the National List but against the specific wording of the annotation, and those that were against the inclusion of an annotation.

Some organizations simply declared their support for the proposal and the prohibition of micro-encapsulated formulations. This includes certifiers, a coalition of organic stakeholders, a group of organic farmers, an environmental and public health advocacy organization, and a regional coalition of various organic and regenerative agricultural stakeholders as well as an organization involved in advocacy, certification, education. The environmental and public health advocacy group stated that the use of pear ester in sprays poses unnecessary risk and does not fit into any of the OFPA categories. The group of farmers made an additional request that the Board clarify that only synthetic kairomones and pheromones that are identical to their natural counterparts are allowed. A certifier requested that the Board pursue a technical report and broader examination of semiochemicals. This is based on its belief that certified operations were interested in using kairomones other than pear ester. A community-owned food market submitted a written comment in support of the prohibition of microencapsulated forms of pear ester. It addressed a Spring 2025 comment that argued against the restriction of microencapsulated polyamides. The community owned market stated that information accumulated over the past twenty plus years on plastic contamination negates the argument that microencapsulation has historically been allowed. According to the organization current information enables a retrospective look and more informed decisions on all generally accepted uses of plastics in organic agriculture.

As stated previously, some commenters took issue with the annotation in the version of the proposal submitted for the Fall 2025 meeting. Several individual commenters and organizations were against the annotation which inadvertently disallowed the use of pear ester in passive dispensers for mating disruption of codling moth. The specific wording of the annotation was “use of pear ester is limited to passive traps/monitors and not for use in microencapsulated formulations.’’ Similar comments were received from a regional horticultural council, different crop producer associations/groups, and a coalition of organic wholesalers. The regional horticultural stated the annotation should only prohibit the use of microencapsulated formulations instead of suggesting that the pear ester is not allowed for use in mating disruption.

The petitioner for addition of pear ester to the National List as a kairomone addressed concerns regarding the human health impact of the microencapsulation. The manufacturer stated that pear ester (including its use in spray applications) has already undergone a full regulatory evaluation in the United States. It stated that the EPA evaluated the full product (including the polyamide microencapsulation used in foliar sprays) and determined that the product presents no unreasonable risk to human health or the environment when used in accordance with the label directions.

An alliance of advocates for biological approaches to sustainability suggested that the Board considers the addition of the kairomone to the National List without any restrictions or consideration of formulation. The alliance also emphasized the fact that the petition was for the active ingredient in pear ester and not for specific products or formulations. It also cited the fact that polyamide resins are listed on EPA List 4 and therefore allowed under 7 CFR 205.601(m)(1). It therefore proscribed the application of extra scrutiny to polyamide resins.

A group of organic experts expressed support for the addition of pear ester to the National List but stated its concern that the proposed annotation might add unnecessary burdens and conflicts. The group considers the annotation unnecessary.

Fall 2025 Board Meeting Review
The fall 2025 board meeting was cancelled and rescheduled as a virtual shortened meeting. This topic was not included in the shorted meeting agenda.

Subcommittee Review Spring 2026
The subcommittee is presenting another updated proposal with more simplified annotation that addresses the comments received in fall 2025. This was necessitated by the Board's inadvertent prohibition of the use of pear ester in mating disruption of the codling moth. The rationale for this revision is to eliminate any ambiguity pertaining to the allowed formulations and uses of pear ester.

Subcommittee Votes
Motion to classify pear ester as synthetic
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Motion to add pear ester to the National List at § 205.601(f) with the following annotation: Microencapsulated formulations prohibited.
Motion by: Franklin Quarcoo
Seconded by: Amy Bruch
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2028
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
Spring 2026

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 coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances 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, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2026 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2026 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

Public comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at § 205.601, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic crop production.

For Comments that Do Not Support the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments that do not support a substance at § 205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;

2. unnecessary because of the availability of alternatives; and/or
3. inconsistent with organic crop production.

For Comments that Support the Continued Prohibition of § 205.602 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the § 205.602 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment; and
2. inconsistent with organic crop production.

For Comments that Do Not Support the Continued Prohibition of § 205.602 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at § 205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the § 205.602 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments Addressing the Availability of Alternatives:
Comments may include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices or natural substances that would eliminate the need for the specific substance;
- Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. Comments received after that date may not be reviewed by the NOSB before the meeting.

§ 205.601 Sunsets: Synthetic substances allowed for use in organic crop production:

- Chlorine materials
  - (i) Calcium hypochlorite
  - (ii) Chlorine dioxide
  - (iii) Hypochlorous acid - generated from electrolyzed water
  - (iv) Sodium hypochlorite
- Copper sulfate (§ 205.601(a)(3) & § 205.601(e)(4))

- Ozone gas
- Peracetic acid (§ 205.601(a)(6) & § 205.601(i)(8))
- Magnesium oxide
- EPA List 3 - Inerts of unknown toxicity

§ 205.602 Sunsets: Nonsynthetic substances prohibited for use in organic crop production:

- Calcium chloride
- Rotenone

Chlorine materials – Calcium hypochlorite

Reference: § 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR; 2025 TR (pending post)

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation; 10/2021 sunset recommendation

Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547), Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice 04/14/2023 (88 FR 22893)

Sunset Date: 05/29/2028

Subcommittee Review

Use

In addition to USDA, chlorine materials are regulated by FDA, EPA, and FSIS when used in organic production [2025 TR, line 429]. Calcium hypochlorite, a chlorine material, is an Environmental Protection Agency (EPA)-pesticide (PC Code 014701). The EPA approved the registration of calcium hypochlorite pesticides for use on crops, soil, and livestock to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals [2025 TR, lines 444-445]. It is an antimicrobial disinfectant and pesticide used to control harmful microorganisms and viruses on inanimate objects and surfaces primarily in indoor environments [2006 TR, lines 66-67, 85-86]. It is allowed for disinfecting and sanitizing food contact surfaces. An important annotation for the use of this and other chlorine materials is that residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields, should not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2) [2006 TR, lines 77-79]. Information provided by three NOP-accredited certifying agents revealed that only one certifier had approved the use of chlorine products in irrigation systems. The certifier stated that the most common chlorine product used for irrigation systems was calcium hypochlorite.

Calcium hypochlorite is an "indirect" food additive approved by the Food and Drug Administration (FDA). Calcium hypochlorite may be used as a final sanitizing rinse on food-processing equipment (21 CFR 178.1010). Calcium hypochlorite also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water at the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA.

Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Manufacture

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 [2006 TR, lines 151-152].

International Acceptance

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- Calcium hypochlorite is not explicitly mentioned in the regulations.

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

- Calcium hypochlorite is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Calcium hypochlorite is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Calcium hypochlorite is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used daily. Chlorine compounds are dermal, respiratory, ocular, and mucous membrane irritants. In addition, sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011 and 2025 Technical Reports (TR) (referenced above). In 1991 the US Environmental Protection Agency reported that calcium hypochlorite is highly toxic to freshwater fish and invertebrates [2025 TR, lines 718-

719]. In 1992 the EPA also stated that sodium and calcium hypochlorite were low risk to both upland game birds (quail) and waterfowl (ducks) [2025 TR, lines 733-734].

The EPA exempts calcium hypochlorite (40 CFR 180.1054), potassium hypochlorite (40 CFR 180 1300), and sodium hypochlorite (40 CFR 180.1235) from the requirement of a tolerance in food [2025 TR, lines 446-447].

In 2025 the US EPA reported that 88 of the 651 chlorine material incidents reported to the US EPA'S Incident Data System between September 1, 2010 and September 1, 2025 were due to calcium hypochlorite [2025 TR, lines 802-805]. Sodium hypochlorite accounted for 556 of the reported incidents. Most of the incidents involved humans and were classified as either minor or moderate. No human fatality and one animal fatality was recorded for Calcium hypochlorite.

Discussion
Subcommittee discussions during the sunset review of Calcium Hypochlorite's in 2021covered comments from various stakeholders on its essentiality as well as impact on human and environmental health. Below is a summary of discussions and public comments on calcium hypochlorite during its last sunset review in 2021.

Arguments in support of Calcium hypochlorite include its use in protecting food from contamination by human pathogens which is essential in safeguarding organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been deemed essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supported the continued listing of chlorine materials but encouraged ongoing discussion (at the time) on the listing of sanitizers and disinfectants for post-harvest handling and processing. Some public comments outlined the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment. It was said that further restructuring of the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used and would facilitate better organic education.

The CS, in 2021, stated its support for research priorities that investigate alternatives to chlorine compounds and encouraged the use of alternative, less toxic materials, when their use can meet strict food safety standards.

In the 2025 sunset review of another chlorine material (potassium hypochlorite), the CS received public comments that were not supportive of the proposed annotation requiring the use of chlorine produced via environmentally friendly methods in the synthetic production of chlorine materials.

Questions to our Stakeholders
None.

Chlorine materials – Chlorine dioxide

Reference: § 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials - For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(ii) Chlorine dioxide

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR; 2025 TR (pending post)

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation; 10/2021 sunset recommendation

Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice 04/14/2023 (88 FR 22893)

Sunset Date: 05/29/2028

Subcommittee Review

Use

In addition to USDA, chlorine materials are regulated by FDA, EPA, and FSIS when used in organic production [2025 TR, line 429]. 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 [2006 TR, lines 66-67]. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. The FDA permits direct food use of chlorine dioxide to wash fruits and vegetables. The maximum amount of ClO_2 allowed is 3 ppm for fruits and vegetables, followed by a potable water rinse, blanching, cooking, or canning [2025 TR, lines 482-485]. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water at the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases (2011 TR, lines 149-150).

Manufacture

To form chlorine dioxide, sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid ($Cl\text{-}H\text{-}O_3$) is reacted with methanol (CH_3OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate (2011 TR, lines 206-210).

International Acceptance

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

- Teat dips and udder wash are permitted. Substances, such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations. Chlorhexidine can be used as a post-milking teat dip if alternative germicidal agents and physical barriers have lost their effectiveness (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- Chlorine dioxide is not explicitly mentioned in the regulations.

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

- Chlorine dioxide is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Chlorine dioxide is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Chlorine dioxide is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used daily. Chlorine compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label

is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above).

The EPA established Maximum Residual Disinfectant Levels (MRDLs) of 4.0 mg/L for chloramines (as Cl_2), and 0.8 mg/L for chlorine dioxide (as ClO_2) (40 CFR 141.65(a). In addition, the EPA established Maximum Contaminant Levels (MCLs) for the chlorine disinfection by-products (DBPs) total trihalomethanes (TTHMs) of 0.080 mg/L and haloacetic acids (HAAs) of 0.060 mg/L (40 CFR 141.64(b)(1) [2025 TR, lines 495-498].

Discussion

Subcommittee discussions during the sunset review of Chlorine dioxide in 2021 covered comments from various stakeholders on its essentiality as well as impact on human and environmental health. Below is a summary of discussions and public comments on Chlorine dioxide during its last sunset review in 2021. Arguments in support of Chlorine dioxide and other chlorine materials include its use in protecting food from contamination by human pathogens which is essential in safeguarding organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been deemed essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supported the continued listing of chlorine materials but encouraged ongoing discussion at the time on the listing of sanitizers and disinfectants for post-harvest handling and processing. Some public comments outlined the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment. It was said that further restructuring of the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used and would facilitate better organic education.

The CS in 2021 stated its support for research priorities that investigate alternatives to chlorine compounds and encouraged the use of alternative, less toxic materials, when their use can meet strict food safety standards.

In the 2025 sunset review of another chlorine material (potassium hypochlorite), the CS received public comments that were not supportive of the proposed annotation requiring the use of chlorine produced using environmentally friendly methods in the synthetic production of chlorine materials. It was stated that this annotation would make it difficult to obtain chlorine materials that meet this requirement.

Questions to our Stakeholders

None

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: § 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iii) Hypochlorous acid - generated from electrolyzed water.

Technical Report(s): 1995 TAP (Chlorine materials); 2006 TR (Chlorine materials); 2011 TR (Chlorine materials); 2015 TR (Hypochlorous acid); 2025 TR (pending post)

Petition(s): 2015

Past NOSB Actions: 04/2016 recommendation to add; 10/2021 sunset recommendation

Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Hypochlorous acid (HOCl) is the most effective form of chlorine for killing microbial pathogens and parasites that pose food safety risks [2025 TR, lines 504-506]. In addition to USDA, chlorine materials are regulated by FDA, EPA, and FSIS when used in organic production [2025 TR, line 429]. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl_2). For organic food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions.

Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates 3-phosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 118-122].

Manufacture
When chlorine is added to water, it goes into solution as hypochlorous acid, a hydrogen ion, and a chloride ion (2025 TR, line 540). 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 [2015 TR lines 48-68].

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment,

storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- Hypochlorous acid is not explicitly mentioned in the regulations.

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

- Hypochlorous acid is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Hypochlorous acid is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Any substances other than hypochlorous acid water and sodium hypochlorite, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of hypochlorous acid water produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- Hypochlorous acid water is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Human Health and Environmental Issues

Hypochlorous acid, generated from electrolyzed water [2025 TR, line 59], is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at § 205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above). When formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at lower chlorine concentrations and is likely safer for health and the environment than other currently listed chlorine sanitizers. Toxicological experiments on model laboratory animals showed that hypochlorous acid salts are less toxic than chlorine dioxide or sodium chlorite [2025 TR, line 739]. In 1991 the International Agency for Research on Cancer stated that there was no evidence that hypochlorite salts or chlorinated drinking water are carcinogenic [2025 TR, line 786].

In 2025 the US EPA reported that 1 of the 651 chlorine material incidents reported to the US EPA'S Incident Data System between September 1, 2010 and September 1, 2025 were due to hypochlorous acid [2025 TR,

lines 802-807]. Sodium hypochlorite accounted for 556 of the reported incidents. Most of the incidents involved humans and were classified as either minor or moderate. No human or animal fatality was recorded for hypochlorous acid.

Chlorine disinfection byproducts (DBPs) are formed when chlorine in water reacts with natural organic matter. It is, however, important to note that not all toxic DBPs formed by chlorine products contain chlorine. Humic acid exposed to chlorine and hypochlorous acid disinfectants can also form benzene, aldehydes, alkanoic acids, carboxylic acids, and other non-halogenated DBPs when the free chlorine breaks the chemical bonds in the organic matter.
A laboratory experiment treated soil samples with a sodium hypochlorite solution and a hypochlorous acid solution to measure soil enzyme activity [2025 TR, lines 1280-1288]. Soil samples were treated with commercial disinfectants with low concentrations of 250 mg/L and high concentrations of 500 mg/L of each of the active ingredients. The researchers measured THMs after 24 hours. Hypochlorous acid generated higher levels of THMs with trichloromethane being the predominant DBP. They next measured urease, phosphatase, catalase, and sucrase activity at 7 days and 28 days. Phosphatase showed decreased activity with all treatments. Catalase, which is an oxygen scavenger, increased its activity. Urease activity decreased with the sodium hypochlorite treatments but increased with the low hypochlorous acid treatment. Plant available nitrogen in the form of ammonia is produced by urease activity. Sucrase activity was unchanged [2025 TR, lines 1280-1288]. Hypochlorous acid reportedly kills a broader range of microorganisms than any other approved sanitizer [2025 TR, lines 1296-1297] . Effective alternatives will often incur a higher cost, may require investment in new equipment, and in many cases will be less effective [2025 TR, lines 1297-1298].

Discussion
Subcommittee discussions during the sunset review of hypochlorous acid covered comments from various stakeholders on its essentiality as well as impact on human and environmental health. Below is a summary of discussions and public comments on hypochlorous acid during its last sunset review.

Arguments in support of hypochlorous acid include its use in protecting food from contamination by human pathogens which is essential in safeguarding organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been deemed essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supported the continued listing of chlorine materials but encouraged ongoing discussion at the time on the listing of sanitizers and disinfectants for post-harvest handling and processing. Some public comments outlined the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized “by specific use or application” with clear identification of the hazards to humans and the environment. It was said that further restructuring of the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used and would facilitate better organic education.

In the 2025 sunset review of another chlorine material (potassium hypochlorite), the CS received public comments that were not supportive of the proposed annotation requiring the use of chlorine produced using environmentally friendly methods in the synthetic production of chlorine materials. It was stated that this annotation would make it difficult to obtain chlorine materials that meet this requirement.

Questions to our Stakeholders
None

Chlorine materials – Sodium hypochlorite

Reference: § 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iv) Sodium hypochlorite

Technical Report(s): 1995 TAP; 2006 TR; 2011 TR; 2025 TR (pending post)

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation; 10/2021 sunset recommendation

Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547), Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice 04/14/2023 (88 FR 22893)

Sunset Date: 05/29/2028

Subcommittee Review

Use

Sodium hypochlorite is an Environmental Protection Agency (EPA)--registered pesticide (PC Code 014703). Sodium hypochlorite in aqueous solution is generally referred to as “bleach.” It 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 allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl_2).

Sodium hypochlorite is an "indirect" food additive approved by Food and Drug Administration (FDA). Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). Sodium hypochlorite also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium hypochlorite separates into sodium and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 117-122].

Information provided by three NOP-accredited certifying agents revealed that all three certifiers approved chlorine for post-harvest handling. They all approved sodium hypochlorite, acidified sodium chlorite, calcium hypochlorite, chlorine dioxide, and hypochlorous acid generated from electrolyzed water. Sodium hypochlorite was the most commonly used material for post-harvest handling, with calcium hypochlorite and chlorine dioxide also common, according to one certifier.

Manufacture

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 (Na_2CO_3) [2006 TR, lines 156-159].

International Acceptance

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- Sodium hypochlorite is not explicitly mentioned in the regulations.
-

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

- Sodium hypochlorite is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Sodium hypochlorite is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).
- Sodium hypochlorite (e.g., as liquid bleach) is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Any substances other than hypochlorous acid water and sodium hypochlorite, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite sodium chloride is permitted with the following criteria: limited to those obtained by electrolyzing the salt solution (limited to those using salt containing no less than 99% sodium chloride) (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of hypochlorous acid water produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- Sodium hypochlorite is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used daily. Chlorine compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006 and 2011 Technical Reports (TR) (referenced above). The EPA exempts calcium hypochlorite (40 CFR 180.1054), potassium hypochlorite (40 CFR 180 1300), and sodium hypochlorite (40 CFR 180.1235) from the requirement of a tolerance in food [2025 TR, lines 446-447].

A laboratory experiment treated soil samples with a sodium hypochlorite solution and a hypochlorous acid solution to measure soil enzyme activity [2025 TR, lines 1280-1288]. Soil samples were treated with commercial disinfectants with low concentrations of 250 mg/L and high concentrations of 500 mg/L of each of the active ingredients. The researchers measured Trihalomethanes (THMs) after 24 hours. Hypochlorous acid generated higher levels of THMs with trichloromethane being the predominant disinfection byproduct. They next measured urease, phosphatase, catalase, and sucrase activity at 7 days and 28 days. Phosphatase showed decreased activity with all treatments. Catalase, which is an oxygen scavenger, increased its activity. Urease activity decreased with the sodium hypochlorite treatments but increased with the low hypochlorous acid treatment. Plant available nitrogen in the form of ammonia is produced by urease activity. Sucrase activity was unchanged [2025 TR, lines 1280-1288].

Discussion

Subcommittee discussions during the sunset review of sodium hypochlorite covered comments from various stakeholders on its essentiality as well as impact on human and environmental health. Below is a summary of discussions and public comments on sodium hypochlorite during its last sunset review. Arguments in support of sodium hypochlorite and other chlorine materials include its use in protecting food from contamination by human pathogens which is essential in safeguarding organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have

been deemed essential to ensure food safety and to comply with food safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supported the continued listing of chlorine materials but encouraged ongoing discussion at the time on the listing of sanitizers and disinfectants for post-harvest handling and processing. Some public comments outlined the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment. It was said that further restructuring of the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used and would facilitate better organic education.

In the 2025 sunset review of another chlorine material (potassium hypochlorite), the CS received public comments that were not supportive of the proposed annotation requiring the use of chlorine produced using environmentally friendly methods in the synthetic production of chlorine materials. It was stated that this annotation would make it difficult to obtain chlorine materials that meet this requirement.

Questions to our Stakeholders
None

Copper sulfate

Reference: § 205.601(a)(3) Copper sulfate – for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent; and,

§ 205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
Technical Report: 1995 TAP (Copper Sulfate and Other Coppers); 2001 TAP; 2011 TR; 2022 TR
Petition(s): 2001
Past NOSB Actions: 10/2001 meeting minutes and vote; 11/2007 recommendation; 04/2011 recommendation; 10/2016 sunset recommendation; 10/2021 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 11/03/2013; Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Copper sulfate is used as an algicide for rice crops, as the growth of algal matting in flooded fields can dislodge young seedlings. It is broadcast aerially into the flooded rice fields by plane. Rice farmers also spray copper sulfate to control a freshwater invertebrate, *Triops longicaudatus*, otherwise known as tadpole shrimp. Tadpole shrimp are only detrimental to very young seedlings, as their burrowing activities can disrupt the seedling roots and the first emerging leaves.

Manufacture

Copper sulfate is manufactured by treating copper metal with hot concentrated sulfuric acid. Copper oxides can be treated with a more dilute sulfuric acid to produce copper sulfate. Copper sulfate is also known as copper vitriol.

International Acceptance

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

- Copper is permitted as a soil amendment. The following copper products may be used to correct documented copper deficiencies: **copper sulphate**, basic copper sulphate, copper oxide and copper oxysulphate. Copper ammonia base, copper ammonium carbonate, copper nitrate and cuprous chloride are prohibited. Shall be used with caution to prevent excessive copper accumulation in the soil. Copper build-up in soil shall prohibit future use. Visible residue of copper products on harvested crops is prohibited (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Copper is permitted as a production aid. **Copper sulphate**, copper hydroxide, copper octanoate, Bordeaux mix, copper oxychloride and copper oxide. Permitted for use as a wood preservative, or for controlling pests, including diseases. Shall be used with caution to prevent excessive copper accumulation in the soil. Copper build-up in soil shall prohibit future use. Visible residue of copper products on harvested crops is prohibited (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Copper sulphate** is permitted as an essential nutrient (source of copper and sulphur) and for topical use (foot baths) (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products: caustic soda; caustic potash; oxalic acid; natural essences of plants with the exception of linseed oil, lavender oil and peppermint oil; nitric acid; phosphoric acid; sodium carbonate; **copper sulphate**; potassium permanganate; tea seed cake made of natural camelia seed; humic acid; peroxyacetic acids with the exception of peracetic acid (Annex IV: Authorised products for cleaning and disinfection, EC No. 2021/1165).

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

- Copper in the form of copper hydroxide, copper octanoate, copper oxychloride, (tribasic) **copper sulphate**, cuprous oxide, Bordeaux mixture, and Burgundy mixture is permitted with the following conditions for use: need, prescription and application rates recognized by certification body or authority. As a fungicide on condition that the substance be used in such a way as to minimize copper accumulation in the soil (Table 2 - Substances for plant pest and disease control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Trace elements (e.g., boric acid; sodium borate; calcium borate; borethanolamin; cobalt-acetate; cobalt-sulphate; copper oxide; **copper sulfate**; copper hydroxide; copper silicate; copper carbonate; copper citrate; ferric oxide; ferric sulfate; ferrous sulfate; iron citrate; iron sulfate; iron tartrate; manganous oxide; manganese sulfate; manganese carbonate; selenic acid; selenous acid; sodium molybdate; molybdic oxide; zinc carbonate; zinc oxide; zinc silicate; and zinc sulfate) are permitted as calcareous and magnesium amendments of mineral origin with the following conditions for use: use restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert. Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant (Appendix 2: Fertilizers and soil conditioners, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Copper sulfate** is permitted with the following criteria: limited to the use for the preparation of Bordeaux mixture (Table B.1 - Agricultural chemicals, JAS 1605 Organic Products of Plant Origin).

Environmental and Human Health Issues

Copper sulfate is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In amphibians, increasing concentrations of copper can alter behavior, reduce growth rates and final size, and at higher concentrations can result in death. Copper also has algicidal effects and can disrupt the food chain in aquatic environments. For this reason, its direct introduction into flooded rice fields is contentious, particularly since rice fields serve as replacement wetlands for many birds and other fauna in agricultural areas like Northern California. Previous comments to the NOSB have highlighted specific concerns that the application rates in organic rice fields in California are several times higher than the amounts known to be toxic to native amphibian species.

In the soil, copper can concentrate heavily in the topsoil and over time, altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice is called into question.

Copper sulfate has been shown to be toxic to bees, particularly in tropical environments. At sub-lethal levels, the heavy metal also changes behavior and movement ability of bees (Rodrigues et al, 2016). Despite this, there are multiples statements on the National Pesticide Information Center (NPIC) and in US Environmental Protection Agency Office of Pesticide Programs documents stating that copper sulfate is virtually non-toxic to bees. This is an important issue to clarify. The role that bees play in the pollination of commercial crops globally should make the use of copper sulfate a concern to farmers and the general public alike.

Copper sulfate has been classified as a human carcinogen by the European Chemicals Agency (ECHA), with specific concern for renal cancers (Buzio et al, 2002). Chronic exposure to fungicidal sprays elevated the risk of renal cancers by almost 3 times. While copper binds to soils readily, copper contamination of drinking water sources would also be a concern.

When copper sulfate is applied to flooded paddies, the copper becomes fixed to soil particles after 7 or more days. Thus this use elevates soil copper levels but does not contaminate other water bodies when the field is drained.

Discussion

Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, its use has repeatedly been extended in all three jurisdictions, as there isn't yet a viable organic alternative for copper in certain applications. The EU, Canada, and Japan all exclude copper sulfate for organic rice production but allow it as a fungicidal spray in organic orchards and vineyards.

In terms of copper sulfate use in rice paddies to control tadpole shrimp, it appears that there may be ways to circumvent the need for chemical control. The tadpole shrimp emerge from eggs and most hatch within 1-3 days of flooding. Tadpole shrimp primarily cause injury to the rice through chewing young roots and shoots and disrupting the roots with burrowing activities (Tindall and Fothergill, 2012). The shrimp do not injure older seedlings once they have reached the water surface and roots are well established in the soil.

In fact, at this later stage in seedling development, the tadpole shrimp can be beneficial to the crop by controlling algae and mosquitos.

Transplanting in older seedings eliminates any threat from algal mats to the delicate young seedling stage, as do practices such as dry seeding the rice or ensuring that the rice is seeded directly at the time of flooding. Transplanting seedlings has been the preferred method of rice production throughout most of human rice cultivation but is much more expensive than direct seeding. In Asian rice cultivation, the tadpole shrimp are often deliberately introduced as a means of controlling algae and mosquitos. The current approach of flooding the fields and then direct wet-seeding didn't gain popularity until broad chemical use was implemented and was demonstrated to marginally reduce costs and increase yields.

An important issue for this use of copper sulfate on organic farms is the annotation requirement that, "application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent." The 2022 TR indicates that available soil copper levels have been shown to increase dramatically over time in some situations [n 1114-1117, 1210-1223[. While copper is an element and does not break down when added to the soil, it does leave the soil in harvested crops and leachate. In addition, it may be tightly adsorbed to soil particles and not show up on a soil test. Soil test copper levels appear to increase rapidly when multiple heavy applications are used over years. In order to fulfill this requirement, the original soil baseline copper level needs to be compared to current levels by the certifier. While pesticide applications of copper can be a source of increasing soil test copper levels, manure applications can also include even larger amounts of copper [TR ln 2519-2524].

The maximum label application rate for one product (Brandt Copper Sulfate Crystals, 25.1% copper) is 10.88 lb. per acre-foot for algae control and 27.2 lb. per acre foot for tadpole shrimp control. At a typical maximum paddy water depth of 5 inches, this translates to 11.3 lb. of copper sulfate per acre or 2.8 lb. of elemental copper for shrimp control.

A Swiss study showed yearly copper leaching rates of only 2.65 to 11.7 grams per hectare in dryland grain systems, less than an ounce per acre (Wiggenhauser et al., 2024). If these rates are close to what happens in organic rice soil systems, copper will be accumulating over time. Since some of the total copper is strongly held by the soil particles, soil test results will likely not increase as quickly as total soil copper.
It is necessary to research alternate algicides and other means of controlling tadpole shrimp.

It appears that to date there is sufficient evidence to conclude that:

1. Use of copper sulfate in rice fields can cause environmental damage,
2. Alternative seeding practices could eliminate the need for copper sulfate as both algae and tadpole shrimp cease to be problematic once seedlings are established and
3. International standards do not allow spraying of copper sulfate for organic rice production.
4. It is not feasible to apply amounts of copper sulfate that will not raise soil copper levels over time

NOSB Subcommittee Review Much of the Crops Subcommittee's review of copper sulfate centered on public comments and on interviewing stakeholders after the Spring 2021 NOSB meeting. There were in excess of twenty-five written and oral comments with the overwhelming majority in favor of keeping copper sulfate on the National List. Two of the organizations most opposed to the use of copper sulfate did not advocate immediate delisting, but rather, strongly urged the program to: Get serious about "Continuous Improvement" and to put some real effort into finding alternative methods or materials that would limit or end its use.

Questions to our Stakeholders

1. How do certifiers verify compliance with this annotation?
2. Are there practical alternatives for algae and tadpole shrimp management in paddy rice?
3. Are there practical methods to remediate high soil copper levels?
4. What are common organic rice rotations? Is rice ever grown in successive years?
5. If so, is copper sulfate allowed to be applied to rice in successive years, alternating control of algae and tadpole shrimp?

References

- Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.
- Rodrigues C, Krüger A, Barbosa W, Guedes R (2016) Leaf fertilizers affect survival and behavior of the Neotropical Stingless Bee Friesella schrottkyi (Meliponini: Apidae: Hymenoptera) , Journal of Economic Entomology, 109(3):1001–1008.
- Tindall K, Fothergill K (2012) Review of a new pest of rice, Tadpole Shrimp (Notostraca: Triopsidae), in the midsouthern United States and a winter scouting method of rice fields for preplanting detection. Journal of Integrated Pest Management 3 (3):B1–B5.
- Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.
- Wiggenhauser, Matthias, David Illme, Ernst Spies, Annelie Holzk, Volker Prasuhn, Frank Liebisch (2024). Cadmium, zinc, and copper leaching rates determined in large monolith lysimeters. Science of the Total Environment 926.
- Willer, Helga & Yussefi, Minou. (2007). The World of Organic Agriculture - Statistics and Emerging Trends 2007.

Ozone gas

Reference: § 205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.
Technical Report: 2002 TAP; 2021 TR
Petition(s): 2001
Past NOSB Actions: 09/2002 meeting minutes and vote; 11/2007 recommendation; 12/2011 recommendation; 10/2016 sunset recommendation; 10/2021 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

Ozone gas is a strong oxidant and works by oxidizing plant tissue and bacterial membranes. The primary use of ozone globally is as a water treatment. In this capacity, ozone oxidizes organic and inorganic compounds, improving water quality when used as a broad-scope disinfectant. It is used in organic crop production primarily as a sanitizer for water, equipment, and post-harvest handling systems to reduce microbial contamination. It is applied as a processing aid or treatment agent and does not persist in the environment, as it rapidly decomposes to oxygen. Ozone is found in the atmosphere at levels of 0.05 ppm, but at levels of 0.5 ppm in cities with smog.

Manufacture
Ozone occurs naturally, mostly in the upper atmosphere. Naturally occurring ozone is often the product of ultraviolet radiation on atmospheric oxygen. Producers generate most ozone by applying a low-current electrical discharge (corona discharge) to atmospheric oxygen. Increasingly, producers generate ozone through the electrolysis of water. Ozone can also be manufactured photochemically by exposing oxygen in air or water to ultraviolet light. Ozone is an unstable gas in the air and even more so in water, so it must be produced on site.

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

- Teat dips and udder wash are permitted. Substances, such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and **ozone**, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's *Food and Drug Regulations. Chlorhexidine can be used as a post-milking teat dip if alternative germicidal agents and physical barriers have lost their effectiveness* (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

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

- With regard to disease prevention, the following rules shall apply: (i) ultraviolet light and **ozone** may only be used in hatcheries and nurseries (Disease prevention, EC No. 2018/848).

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

- **Ozone** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Ozone** is permitted (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Ozone** is permitted (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Ozone** is permitted with the following criteria: limited to the use for disinfecting the processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Ozone** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Human Health and Environmental Issues
When ozone gas is used for water treatment, it oxidizes or disinfects many components that impact water quality and could result in crop iron deficiencies. It will oxidize iron and manganese, which precipitate as ferric and manganese hydroxides. Ozone partially oxidizes organic matter to forms that are more easily biodegradable. It is also germicidal against many types of pathogenic organisms including viruses, bacteria, and protozoa. It is rated as a strong irritant via inhalation, and is irritating to skin, eyes, and mucous membranes. Exposure to atmospheric ozone generated from on-site production can be minimized through

equipment maintenance. Ozone is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (FDA) without limitations other than current good manufacturing practices. Ozone systems that inject directly into irrigation lines use relatively low concentrations of ozone and there is little potential for off-gassing. In water, ozone decomposes rapidly and the only decomposition product is oxygen, as opposed to chlorine, which can generate trihalomethanes. Cleaning of irrigation lines should not lead to problems with soil structure because most of the ozone is contained in the irrigation tubing.

Discussion
Ozone is still in active use by the organic community. Public comments during the last sunset review supported relisting ozone, and the Board unanimously approved its relisting.

Questions to our Stakeholders

1. Is ozone gas necessary for organic crop production, and for what specific uses (e.g., water sanitation, post-harvest handling, equipment sanitation)?
2. Are there effective organic alternatives available that could reasonably replace ozone for these uses?

Peracetic acid

Reference: § 205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label; and,

§ 205.601(i)(8) Peracetic acid - for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008
Past NOSB Actions: 11/2007 recommendation; 11/2009 annotation change; 12/2011 sunset recommendation; 10/2016 sunset recommendation; 10/2021 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 10/09/2008 (73 FR 59479); Annotation change 05/28/2013 (78 FR 31815); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
In organic crop production, peracetic acid, or PAA, is used to disinfect equipment. It can also be used as a disinfectant to treat seeds or asexually propagated planting material. It can be used to disinfect pruning equipment to help prevent the spread of the fire blight bacterium and is also used in one of the hydrogen peroxide formulations for control on the tree canopy of this same disease (2016 TR, lines 91-98, 731-734). PAA is also used in formulations of hydrogen peroxide, allowed at a concentration of no more than 6%, for use in organic crop production (2016 TR, lines 20-24). Peracetic acid was relisted during the 2016 sunset review for Handling and the 2017 sunset review for Livestock. Peracetic acid is an unstable oxidizing agent, which makes it an effective sanitizer (2016 TR, line 38).

First industrially developed in 1950, it has historically been used to treat fruits and vegetables to reduce spoilage from bacteria and various fungi. It is used to treat bulbs, to disinfect potting soil, clean irrigation

equipment, and as a seed treatment to inactivate fungi or other plants diseases. Additionally, in organic crop production, it is also used as a bactericide/fungicide in wash waters to help decrease *Escherichia coli O157:H7* on some fruit and vegetable crops. With the removal of two antibiotics previously allowed for use in organic crop production to assist in fire blight reduction, use of this substance as part of a rotational control and fire blight prevention program has increased in recent years, according to information provided by some organic stakeholders during public comment periods.

Manufacture
According to the 2016 Technical Report (TR), solutions of peracetic acid, hydrogen peroxide, acetic acid, and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Most commercially available PAA solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1, 1-diphosphonic acid) or dipicolinic acid (2, 6-dicarboxypyridine) to slow the rate of oxidation or decomposition (2016 TR, lines 46-48, 342-344).

PAA appears to be a straightforward material in that it is made from, and decomposes back to, acetic acid, oxygen, and water. PAA is a very strong oxidizing agent and can be produced by the interaction between methyl (or acetaldehyde) and air, or by mixing acetic acid and hydrogen peroxide (methyl itself derives from plants, commonly coffee, bread grains, and ripe fruit). It can also be produced within laundry detergents and is considered a more effective bleach than hydrogen peroxide.

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

- **Peracetic (peroxyacetic) acid** is permitted as a production aid. Formulations of **peracetic acid** may include unreacted residual reagents and catalysts, such as hydrogen peroxide, acetic acid and sulphuric acid. Permitted for: a) pest control; and b) disinfecting and cleaning seeds and plant stock (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Peracetic (peroxyacetic) acid** is permitted. On food and plants: **peracetic acid** may be used in wash or rinse water. **Peracetic acid** may also be used on food contact surfaces (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

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

- The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products: caustic soda; caustic potash; oxalic acid; natural essences of plants with the exception of linseed oil, lavender oil and peppermint oil; nitric acid; phosphoric acid; sodium carbonate; copper sulphate; potassium permanganate; tea seed cake made of natural camelia seed; humic acid; **peroxyacetic acids with the exception of peracetic acid** (Annex IV: Authorised products for cleaning and disinfection, EC No. 2021/1165).

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

- **Peracetic acid** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Peracetic acid** is permitted (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

- Citric, **peracetic acid**, formic, lactic, oxalic and acetic acid are permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Peracetic acid** is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

If misused, peracetic acid can irritate eyes, skin, and breathing [2016 TR, lines 683-684].

Discussion

Peracetic acid was registered by the EPA for indoor antimicrobial use in 1985 [2016 TR, lines 382-383]. In the December 2011 NOSB recommendation for the 2013 sunset review of peracetic acid for the two Crops listings at § 205.601(a)(6) and § 205.601(i)(8), the Board clarified the annotation change from the 2009 recommendation and supported it.

The original recommended annotation change was:

§ 205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

§ 205.601(i)(8) Peracetic acid—for use to control fire blight bacteria. Permitted in hydrogen peroxide formulations at concentrations of no more than 5%.

This annotation was later implemented by the NOP with a slight change. The recommended 5% limit was changed to a 6% limit, based on information provided during public comment stating the recommended 5% limit was too low compared to percentages in use at the time. This point of concern was discussed at the Spring 2011 NOSB meeting, and it was decided that this slight increase in the percentage was necessary to adequately accommodate use rates.

While there does appear to be other materials that could be used as possible alternatives, peracetic acid is selected for use by many organic crop producers for many reasons: it is a strong oxidizing compound, it works well in cold conditions, it does not give off chlorine into the environment, it is used as part of a rotation process in fire blight disease control, and it is the more benign of the sanitizers and disinfectants since it reverts back to acetic acid, oxygen, and water in the environment (2016 TR, lines 600-601). It has also been described as a no-rinse material. This information was provided during public comment and can be found in the 2016 TR.

Concerns about the various forms of peracetic acid mentioned in the 2016 TR were raised during public comment submitted for the Spring 2016 NOSB meeting. The NOSB determined the majority of those other sources (that were raising a concern) would not be allowed for use in organic crop production or other currently allowed uses, as currently shown on the National List. Several commenters mentioned that all sanitizers and disinfectants should be looked at to determine need and to prioritize allowed uses. The NOSB determined this request was outside of the scope of this specific sunset review and would need to be addressed as a separate issue/topic.

Other public comments mentioned that the implementation of the Food Safety Modernization Act (FSMA), which oversees an enhanced approach to food safety at the farm and handling levels, places an even higher degree of necessity in having this material and/or other sanitizers available for use in organic crop production.

There was overwhelming support for the continued listing of peracetic acid for use in organic crop production. While a few commenters took a neutral position, there were no commenters, either during the written or oral public comment periods, that were specifically opposed to the relisting of peracetic acid. Based on the information provided (comments, new TR, etc.), discussion during public comment periods (in-person, webinar, and written), and Subcommittee review and discussion, the NOSB determined this material satisfies the OFPA evaluation criteria and the Crops Subcommittee supported the relisting of peracetic acid. Additionally, peracetic acid was relisted during the 2016 sunset review for Handling and the 2017 sunset review for Livestock.

There is widespread use of peracetic acid by many stakeholders, and it is generally considered to be critical to the sanitizer, cleaner, and disinfectant toolkit as one of the most benign and effective materials available for crop-specific uses. Many certifiers report that it is a sanitizer in increasingly widespread use.

Organic producers consider peracetic acid essential to ensure food safety and compliance with food safety regulations under FSMA. Stakeholders broadly support the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List so that cleaners, sanitizers, and disinfectants have a designated category would help to ensure certified operations understand which cleaners, sanitizers, and disinfectants may be used, and it would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of cleaners, sanitizers, and disinfectants, and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA, 2021).

Questions to our Stakeholders
None

Magnesium oxide

Reference: § 205.601(j)(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.
Technical Report(s): 2021 TR
Petition(s): 2013
Past NOSB Actions: 05/2014 NOSB recommendation to add; 10/2021 sunset recommendation
Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Magnesium oxide (MgO) is a synthetic substance approved for organic crop production to control the viscosity of a clay suspension agent for humates. MgO occurs as the mineral magnesia and in its hydrated form – magnesium hydroxide – as the naturally occurring mineral periclase. Magnesium oxide appears to be a fairly benign compound with a wide range of uses, including as an antacid and laxative (milk of magnesia) and in lots of industrial processes such as in producing cement, abrasive materials, and furnace linings.

MgO is neither a strong acid nor a strong base. Instead, it acts as a buffering agent when in an aqueous solution. Buffering agents are materials that create an effective resistance to change in pH of an aqueous solution when a strong acid or base is added.

Manufacture

Magnesium oxide is a naturally occurring compound that is found in the mineral periclase. There are several manufacturing processes used to produce MgO. However, most commercially available magnesium oxide is formed by calcinating magnesium carbonate-containing minerals (e.g., magnesite, hydro-magnesite) [2021 TR, lines 421-424].

Magnesium can also be sourced from other mineral sources in the form of magnesium chlorides and silicates, which can be converted to magnesium hydroxide via acid-base and metathesis reactions. Magnesium hydroxide sourced as brucite or by the chemical processing of other magnesium-containing minerals is calcined to form magnesium oxide [2021 TR, lines 424-428].

Magnesium oxide is also produced from seawater and salt lake brine sources. While magnesium is a common elemental component of brine, magnesium oxide is not present in brine sources due to its water insolubility. Magnesium chloride is the primary source of magnesium within brine and is converted to magnesium hydroxide using the same reactions used to process mineral sources of magnesium chloride. Additionally, brine may be treated with sulfuric acid to remove carbonates, reducing calcium in the final product. Magnesium oxide from brine is also obtained by calcination of magnesium hydroxide [2021 TR, lines 430-437].

NOP guidelines classify substances produced by the "heating or burning of non-biological matter (e.g., minerals) to cause a chemical reaction" as synthetic (NOP 5033). Based on this classification, all commercial sources of magnesium oxide are considered synthetic, formed by calcination (heating) to liberate carbon dioxide (Equation 3) or water (Equation 8) [2021 TR, lines 440-443].

International Acceptance

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

- Minerals, trace minerals, and elements are permitted with the following origin/usage conditions: non-synthetic chelated or sulphated minerals. Examples include oyster shell, calcium chloride and **magnesium oxide**. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are permitted for medical use (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).

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

- Crude potassium salt is permitted. The minimum content of nutrients (percentage by weight): 9% K_2O; potassium expressed as water-soluble K2O; **2% MgO**; **magnesium in the form of water-soluble salts, expressed as magnesium oxide** (Annex II: Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- **Magnesium oxide** is permitted as a feed material of mineral origin (Annex III: Authorised products and substances for use as feed or in feed production, EC No. 2021/1165).

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

- **Magnesium oxide** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Magnesium oxide** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Magnesium oxide** is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

The 2021 TR states that, at the time of publication, the authors found no studies on magnesium oxide's environmental persistence or toxicity. The insoluble nature of magnesium oxide makes it unlikely to contaminate water systems, and its insolubility results in low bioavailability within terrestrial environments [2021 TR, lines 448-451, 462-463]. Moreover, when used as approved within organic agriculture, magnesium oxide is applied in limited quantities as a viscosity control additive, making environmental contamination unlikely [2021 TR, lines 479-480].

The Code of Federal Regulations (CFR), Title 21, Part 184 (Direct food substances affirmed as generally recognized as safe) lists magnesium oxide at § 184.1431 as an ingredient used in food with no limitation other than current good manufacturing practice and affirms the ingredient as generally recognized as safe (GRAS) as a direct human food ingredient [2021 TR, lines 131-135].

The original petitioner noted that magnesium oxide is safely used in numerous applications for other materials because it is considered non-hazardous, environmentally safe, and non-toxic. Some of the applications include:

- wastewater treatment,
- toxic metal removal,
- adsorption of dyes and excess phosphorus from industrial wastewater,
- odor control,
- treatment of acid mine drainage,
- nontoxic flame retardant for clothing,
- flue gas desulfurization, and
- hazardous spill clean-up.

Magnesium oxide and the hydrated form of magnesium hydroxide have been used safely for over a century as a laxative and antacid (milk of magnesia).

Discussion

This is the second sunset review for magnesium oxide since it was added to the National List. A previous technical report covered its use in livestock production, and in 2021 the NOSB requested and received a technical report specific to its use in crop production. The petition and TR describe magnesium oxide as a material used to modify clays so that humic substances can remain suspended in aqueous solutions without recrystallizing, preventing nozzle plugging and improving the stability and viscosity of liquid humate products.

In 2021 the NOSB reviewed the limited stakeholder comments, but most were generally supportive of maintaining the listing. Commenters affirmed that magnesium oxide is currently used for its petitioned purpose and that humates continue to play an important role in organic agriculture by stimulating biological activity, supporting nutrient cycling, improving soil structure, and enhancing water retention and root development. Stakeholders also reiterated that while several non-synthetic materials—such as dolomitic limestone, wood ash, periclase, brucite, or pelletized humates—are cited as potential alternatives, they are either not commercially available or do not meet the chemical or physical specifications needed to suspend humates in solution.

During the 2021 public discussion, one commenter suggested adding an expiration date for reevaluation of the material, though such a change would require annotation outside of the sunset process. Questions

were raised regarding the use of nonsynthetic acids in place of sulfuric acid during manufacturing. Environmental considerations shared during the meeting focused on the use of sulfuric or hydrochloric acid in production, which can release carbon dioxide; however, stakeholders noted that without magnesium oxide, dry humates would likely need to be applied, raising concerns about dust exposure.

Questions to our Stakeholders

1. Are there any commercially available nonsynthetic or less-processed alternatives that can perform the same viscosity-control function for liquid humates as magnesium oxide? If so, please describe their availability, performance, and limitations.
2. Is magnesium oxide still necessary for its currently approved use in organic crop production?

EPA List 3 – Inerts of unknown toxicity

Reference: § 205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/2002 meeting minutes and vote (see pheromones); 11/2007 recommendation; 05/2012 recommendation; 08/2015 recommendation to change annotation at 7 CFR § 205.601(m); 10/2016 sunset recommendation; 10/2021 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 10/09/2008 (73 FR 59479); Sunset renewal notice effective 10/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

The annotation for EPA List 3 inerts limits their use in organic crop production to passive pheromone dispensers. The dispensers are generally manufactured as either tubes that contain pheromones or as an impregnated substance containing the pheromone. Passive pheromone dispensers may be used to trap and monitor insect populations, or they may be used for control of a pest through pheromone mating disruption. For trapping, the pheromone-impregnated dispenser is placed in a trap, and the insect catch is monitored to determine when an economic threshold is reached, and the particular insect needs to be controlled. For pheromone mating disruption, the dispensers are tied to branches of trees or placed in such a manner that they are distributed throughout an area being covered by the pheromones. Throughout the season, the design of the pheromone dispensers regulates the volatilization of pheromones into the air. Once in the air of the production area, the pheromones act to disrupt mating by interfering with the insect communication systems. A wide variety of insects, mostly *Lepidoptera*, can be managed with pheromones including codling moth, peach twig borer, peach crown borer, leafrollers, pink bollworm, boll weevil, gypsy moth, and others. When they are placed in the production area, the pheromone dispensers are not in contact with the organic product being grown but are instead suspended from the trees or plants. Since the pheromone dispensers do not contact the product grown, there is no movement of the pheromones into the product. Passive pheromone dispensers are different from other forms of dispensers such as microencapsulated products, which are sprayed throughout the production area and could be in direct contact with the fruit or other product being grown.

Manufacture

Manufacture varies based on which List 3 inert is being used, so will not be addressed.

International Acceptance

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

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

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

- The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation: (a) safeners, synergists and **co-formulants** as components of plant protection products (General production rules, EC No. 2018/848).
- In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and **co-formulants** as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848 (Annex I: Active substances contained in plant protection products authorised for use in organic production, EC No. 2021/1165).
- In relation to products and substances used in traps or in dispensers of products and substances other than **pheromones**, the traps or dispensers shall prevent the products and substances from being released into the environment and shall prevent contact between the products and substances and the crops being cultivated. All traps, including **pheromone traps**, shall be collected after use and shall be safely disposed of (Annex II: Detailed production rules, EC No. 2018/848).
- **Pheromones and other semiochemicals are permitted with the following conditions**: only in traps and dispensers (Annex I: Active substances contained in plant protection products authorised for use in organic production, EC No. 2021/1165).

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

- The above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production. In addition, the following criteria should be applied in the evaluation process: b) if they are used for the purpose of plant disease or pest and weed control: they should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available; and their use should take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees; and substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion); however, if they are products used, in exceptional circumstances, **in traps and dispensers such as pheromones**, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts; their use may be restricted to specific conditions, specific regions or specific commodities (Section 5: Requirements for inclusion of substances in Annex 2 and criteria for the development of lists of substances by countries, CXG 32-1999).
- Pests should be avoided by good manufacturing practice. Pest control measures within storage areas or transport containers may include physical barriers or other treatments such as sound, ultra-sound, light, ultra-violet light, **traps (pheromone traps and static bait traps)**, controlled temperature, controlled atmosphere (carbon dioxide, oxygen, nitrogen), and diatomaceous earth (Handling, Storage, Transportation, Processing and Packaging, CXG 32-1999).
- **Pheromone preparations are permitted in traps** (Table 2 - Substances for plant pest and disease control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Organic crop production ensures that **co-formulants** (e.g. **inerts** and synergists) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins (Main objectives and detailed requirements of the COROS, IFOAM NORMS 2014).
- **Pheromones – in traps and dispensers only** are permitted (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Sex pheromone agents** are permitted with the following criteria: limited to the agent containing a substance having the pheromone action of insects harmful to crops as the active ingredient (Table B.1 - Agricultural chemicals, JAS 1605 Organic Products of Plant Origin).
- **Pheromone agents** are permitted with the following criteria: limited to chemical agents containing a substance having insect pheromone as the active ingredient; excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS 1605 Organic Products of Plant Origin).
- **Pheromones** are permitted with the following criteria: limited to those chemical agents containing substances with insect pheromone actions as the active ingredients; not permitted for use in plant products for controlling pests and diseases (Table C.1 - Chemical agents, JAS 1606 Organic Processed Foods).
- **Pheromones** are permitted with the following criteria: limited to those chemical agents containing a substance with insect pheromone action as the active ingredient; excluding the cases where it is

applied to the plant products for the purpose of controlling pests and diseases (Table B.1 - Chemical agents, JAS 1607 Organic Feed).

- **Pheromones** are permitted with the following criteria: limited to those chemical agents containing a substance with insect pheromone action as the active ingredient; excluding the cases where it is applied to the plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS 1608 Organic Livestock Products).

Human Health and Environmental Issues

Passive pheromone dispensers used to monitor insects are crucial to integrated pest management programs in that they help to determine the size and impact of insect populations. The use of passive pheromone dispensers for mating disruption often precludes the need for other chemical controls. When used with adequate sanitation practices, monitoring, biocontrol methods, and environmental controls, pheromones can be effective in controlling certain *Lepidoptera* insects. Without pheromone use, and despite the other natural controls listed, insecticides may be needed for control of a specific pest insect. Insecticides may either be natural or synthetic, but would most often be applied directly to the product being grown and might require preharvest intervals. While pheromones are very specific to individual insect species, other insecticides may be broader spectrum and affect more species than those requiring control and may have more detrimental environmental impacts.

Other potential environmental issues relate to the number of pheromone dispensers containing List 3 inerts used per acre. Often, maximum applications are in the range of 400 dispensers per acre. Information from the package of one manufacturer lists 8% other ingredients which may include List 3 inerts, and that the total amount of pheromone applied per acres is 50 grams. Given the small amount of pheromone applied, there is a very small volume of List 3 inerts applied to any given acre. This application rate is very low when compared to the amounts of allowed List 4 inerts applied in spray materials or the number of synthetics applied in allowed newspaper mulch. While application of any material to organic acreage should be considered, it is also important to consider the scale of the application. In addition, the ingredients other than pheromones are heavier than the pheromone itself and remain inside the dispenser. Thus, the List 3 inerts are not dispersed into the atmosphere and do not have direct crop contact. The manufacture of pheromones may have possible environmental impacts, but because these materials are grouped together as List 3 inerts, these impacts cannot be independently categorized.

Discussion

For reference, the old EPA lists can be found at: https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists.

As noted in the 2020 review of List 4 inerts, the List 3 inerts listing is also outdated because EPA no longer maintains these lists. Thus, the process to review materials for addition or removal is broken. The listing for List 3 inerts is more specific than that for List 4 inerts in that it is limited to only those materials needed for and used in passive pheromone dispensers. These dispensers do not come into direct contact with the agricultural products being produced, whether they are used for trapping or mating disruption.

At the Fall 2024 NOSB meeting, the Board passed a recommendation to NOP modernizing the listing for inert substances used in organic pesticide formulations. The proposal provided NOP with two options:

1. Allow all inert ingredients that are exempt from the requirement for a tolerance.
2. List inert ingredients currently allowed in pesticide products individually.

The substances used in passive pheromone dispensers that are found on List 3 are included in both of these options. NOSB does not anticipate any disruptions to the allowance of pheromone products when NOP pursues rulemaking using either of these options. As the organic industry awaits rulemaking action on inert

ingredients used in organic pesticide products, the existing allowances will be maintained to ensure there are no disruptions to the availability of passive pheromone products for organic farmers.

Questions to our Stakeholders
None

Calcium chloride

Reference: § 205.602(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
Technical Report: 2001 TAP; 2021 TR
Petition(s): 2005; 2015
Past NOSB Actions: 09/1996 minutes and vote; 11/2006 annotation change (failed); 11/2007 sunset recommendation; 12/2011 sunset recommendation; 10/2016 sunset recommendation; 10/2021 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Calcium chloride is used to manage almost three dozen physiological disorders on crops. These include reduction of cork spot on pears, bitter pit in apples, fruit cracking on developing figs, rain cracking in cherries, blossom end rot on tomatoes, and tipburn on Chinese cabbage [2001 TAP, lines 156-175]. Application of foliar calcium sprays relieves calcium physiological disorders because these are local deficiencies due to calcium transport problems. Local availability of calcium in new shoots and fruits can help solve the problem [2001 TAP, lines 197-198]. Application of nonsynthetic calcium chloride in organic crop production is limited to foliar sprays to treat a physiological disorder associated with calcium uptake.

Manufacture
According to the 2001 TAP, calcium chloride can be produced from a number of sources by various methods. Some of these are naturally occurring, some require extraction and beneficiation that is not considered by most reviewers to be a chemical reaction, and some are entirely synthetic. Calcium chloride extracted from brine is generally considered nonsynthetic, although certain steps to purify the brine may be considered synthetic [2001 TAP, lines 8-11]. The TAP goes on to explain that calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic. However, Dow (a major supplier) and other producers use synthetic chemicals during the purification of the brine [2001 TAP, lines 62-64]. Industrial production of calcium chloride occurs mainly through 1) the hydrochloric acid method, 2) the Solvay process, and 3) the Dow process. Productions by the Solvay process and by reaction of a calcium source with hydrochloric acid are both clearly synthetic [2001 TAP, lines 11-12].
Calcium chloride from naturally occurring brine is nonsynthetic as long as there are no manufacturing steps (see NOP 5033: 4.6 Extraction of Nonorganic Materials) that change the classification to synthetic.

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

- **Calcium chloride** derived from naturally occurring brines and not chemically treated is permitted (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Sodium chloride, **calcium chloride** or potassium chloride; shall be mined or derived from sources of natural brine. The effluent from ion exchange water softener regeneration may be used. For pest control (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Minerals, trace minerals, and elements are permitted with the following origin/usage conditions: non-synthetic chelated or sulphated minerals. Examples include oyster shell, **calcium chloride** and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are permitted for medical use (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- **Calcium chloride** is permitted for: a) milk products; b) fat products; c) soybean products; and d) fruits and vegetables (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

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

- **Calcium chloride** solution is permitted only for foliar treatment of apple trees, to prevent deficit of calcium (Annex II: Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- **Calcium chloride** is permitted for addition to milk-based products as a coagulation agent (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- **Calcium chloride** is only authorised for the processing of products of plant origin and sausages based on meat as a coagulation agent (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- **Calcium chloride** is permitted as a processing aid in primary yeast (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).

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

- **Calcium chloride solutions** are permitted for leaf treatment in case of proven calcium deficiency (Table 1 - Substances for use in soil fertilizing and conditioning, CXG 32-1999).
- **Calcium chloride** is permitted for use in foods of plant origin (fruits and vegetables including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera; seaweeds; nuts and seeds; soybean products excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10; soybean protein products; fermented soybean products) and foods of animal origin (dairy products and analogues excluding products of food category 02.008.2; processed meat, poultry, and game products in whole pieces or cuts; processed comminuted meat, poultry and game products; edible casings (e.g., sausage casings)) (Table 3 - Ingredients of non-agricultural origin, CXG 32-1999).
- **Calcium chloride** is permitted for use in plant products as a coagulation agent (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).
- **Calcium chloride** is permitted for use in livestock and bee products as a firming, coagulation agent in cheese making (For livestock and bee products, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Limestone, gypsum, marl, maerl, chalk, sugar beet lime, **calcium chloride** are permitted as calcareous and magnesium amendments of mineral origin (Appendix 2: Fertilizers and soil conditioners, IFOAM NORMS 2014).
- Chloride of lime (**calcium chloride**) is permitted (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).

- **Calcium chloride** is permitted as an additive and as a processing and post-harvest handling aid (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).
- Chloride of lime (calcium oxychloride, **calcium chloride**, and calcium hydroxide) is permitted (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Calcium chloride** is permitted (Table A.1 - Fertilizers and soil improvement substances, JAS 1605 Organic Products of Plant Origin).
- **Calcium chloride** is permitted with the following criteria: limited to the use in processed products of plant origin (as a coagulant) and in cheesemaking (as a coagulant), or the use in edible fats & oils, processed vegetable products, processed fruit products, prepared legumes/beans, dairy products, or processed meat products (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Calcium chloride** is permitted (Table B.1 - Additives for alcohol beverages, JAS 1606 Organic Processed Foods).

Human Health and Environmental Issues

The 2001 TAP describes that, when used as a foliar spray, calcium chloride probably has low potential for interaction or interference with other materials used in organic farming [2001 TAP, lines 295-296]. It has a low toxicity to mammals, though it can be a skin, eye, and breathing irritant. When used in foliar applications, it should not affect beneficial insects. It should not persist on foliage and any amount not absorbed by the plant should be washed off with rain. Calcium chloride is extremely soluble in water, and low concentrations from foliar use should not build up in soil, unless it is used in low rainfall areas with minimal irrigation. Any water-soluble calcium chloride not absorbed by plant roots would drain into surface waters or be leached into groundwater [2001 TAP, lines 300-308]. Additionally, during manufacture from brines, the liquid brines are pumped out from underground, and do not present the kind of problem usually seen with strip mining. The only toxic chemicals involved are chlorine and bromine, and they are handled so that environmental contamination is low. The chlorine is recycled, and bromine is isolated as bromide or bromine and is sold as a chemical product. Excess lime added in processing is isolated as part of the final calcium chloride. The magnesium hydroxide produced is used to prepare other magnesium salts and magnesium metal by electrolysis. It is not dumped into the environment. The sodium chloride isolated in the process is sold as table salt or for chemical production. Spent solutions are recycled and pumped back underground to isolate a new concentrated brine [2001 TAP, lines 311-319]. Finally, calcium chloride obtained from natural salt brines has a significant amount of sodium chloride, usually about 3-4%. Sodium chloride has a high salt index and should not be applied to soil. Application to soil could lead to chloride phytotoxicity [2001 TAP, lines 355-358].

Discussion

This is a unique § 205.602 material in that, while not completely prohibited for use, is restricted via an annotation. Since it is only allowed for a very specific use (foliar application to treat a calcium uptake disorder), material review organizations list it with the restriction to reflect the very narrow permitted use. Certifiers are responsible for verifying that growers use it in a manner consistent with the restriction.

In 1996, the NOSB originally voted to allow calcium chloride for use to control bitter pit in apples and as an emergency defoliant for cotton; the material was categorized as nonsynthetic and was not included in sections § 205.601 or § 205.602. In 2003, calcium chloride was subsequently added to National List at § 205.602 as a non-synthetic substance prohibited for use in organic crop production with the current

annotation: “brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.” In 2005, the NOSB rejected a petition to remove the prohibition for use as a soil-applied non-synthetic substance due to high chloride and solubility concerns. The Board received another petition in 2015 to remove the prohibition on direct soil applications but determined it to be ineligible as no new substantive information was presented to warrant reconsideration of the petition.

The NOSB has consistently concluded that brine process calcium chloride is a mined substance of high solubility, and, as such, its use is subject to the conditions established on the National List of non-synthetic materials prohibited for crop production. The foundational principle for placing high solubility materials such as calcium chloride on the prohibited non-synthetic materials list is described in § 205.203(d) – Soil fertility and crop nutrient management practice standard: A producer may manage crop nutrients...in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients. The NOSB has established that the potential for overuse of this natural substance resulting in subsoil, surface water, and ground water contamination warrant continued limitation through the annotation restrictions.

Relisting calcium chloride as a restricted non-synthetic material was widely supported in previous public comments. Calcium chloride is a material needed to combat physiological disorders of many commodities that typically cannot be resolved with other calcium products. Many previous commenters stated that calcium chloride is necessary to ensure quality of many crops and significant losses would occur if the substance were not relisted. The current annotation restricting the use to foliar sprays to treat a physiological disorder associated with calcium uptake is also supported to prevent soil buildup of chloride.

Questions to our Stakeholders
None

Rotenone

Reference: § 205.602(f) Rotenone (CAS # 83-79-4).
Technical Report(s): N/A
Petition(s): N/A
Past NOSB Actions: 10/2012 NOSB recommendation to add; 10/2021 sunset recommendation
Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559); Sunset renewal notice 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Rotenone is a potent non-synthetic botanical pesticide that is also used as a piscicide. Historically, farmers have used this extract as a foliar spray to control pests on vegetables, berries, tree fruit, nuts, and forage crops.

Manufacture
Rotenone is commonly derived from the roots of various tropical plants native to Southeast Asia, South America, and East Africa.

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

- **Rotenone** is not explicitly mentioned in the regulations.

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

- **Rotenone** is not explicitly mentioned in the regulations.

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

- Preparations of **rotenone** from *Derris elliptica, Lonchocarpus,* and *Thephrosia* spp. are permitted with the following conditions for use: Need recognized by the certification body or authority. The substance should be used in such a way as to prevent its flowing into waterways (Table 2 - Substances for plant pest and disease control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Rotenone** (*Derris elliptica, Lonchocarpus* spp. *Tephrosia* spp.) is permitted with the following conditions for use: not near waterways. Subject to approval by the CB (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Rotenone** is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

Adverse health effects from rotenone have been well documented since the NOSB reviewed botanicals in 1994. In 2004, the EPA required an inhalation neurotoxicity study to investigate the possibility of rotenone leading to Parkinson's Disease-like symptoms at high-dose exposure in animals. Instead, the companies distributing and selling rotenone products voluntarily cancelled all food-use registrations, except for piscicidal uses.

Discussion

Rotenone is found to have adverse environmental and health impacts, a lack of essentiality, and an incompatibility with organic principles. Therefore, the NOSB unanimously passed a recommendation in October 2012 to add rotenone to the National List at § 205.602 as a non-synthetic substance prohibited for use in organic crop production.

During the last sunset review of rotenone, public comments also supported the continued listing as a prohibited natural substance in organic crop production. The Board unanimously voted to maintain the rotenone listing on § 205.602.

Questions to our Stakeholders

None

National Organic Standards Board
Materials Subcommittee
2026 Research Priorities Proposal
Spring 2026

Executive Summary

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture, a process originally established by the Board in 2012. The NOSB requests that integrated research be undertaken with consideration of the whole-farm system in multiple regions, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

As part of this year's process, the Livestock, Crops, and Handling Subcommittees have made an effort to categorize and differentiate highest priority topics from ongoing topics. In addition, stakeholder comments for the Fall 2025 meeting emphasized the need for research on topics that covered multiple sectors. In response to that, the NOSB is adding a new category called "Interdisciplinary", which incorporates those previously classed as "General."

BACKGROUND

The NOSB revisits the list of priorities each year. The list is made meaningful by input through the written and oral public comments shared with the Board, through the expertise of the Board itself, and through interactions throughout the year with those engaged in some dimension of the organic farm-to-fork continuum. When the NOSB has determined that a priority area has been sufficiently addressed, it is removed from the list. Priorities are also reviewed and updated each year to more accurately reflect the current need for new knowledge.

The NOSB encourages collaboration among laboratories, federal agencies, universities, foundations, organizations, business interests, organic farmers, and the broader organic community to address pressing issues in organic agriculture and processing/handling. We especially encourage university researchers to conduct non-intrusive studies on working organic farms.

The NOSB encourages integrated, whole-farm research into the areas described below.

Motion to accept the 2026 Research Priorities proposal
Motion by: Andrea Hatziyannis
Seconded by: Cat McCluskey
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

SUMMARY LISTS (see following sections for expanded explanations)

INTERDISCIPLINARY RESEARCH PRIORITIES

1. Increasing access to organic foods
2. Barriers to transitioning to organic production
3. Whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming system choices
4. Research-based information on the economics of organic certification, and production as well as profitability of organic enterprises.
5. Information on the impact of organic enterprises on regional economies
6. Organic yield gaps and system-level productivity
7. Measuring and improving the effectiveness of research extension programs
8. Research-based information on farmer mental health and quality of life
9. Information on the availability, quality, and cost of farm labor
10. A comprehensive study of National List sanitizers used in all phases of organic production and handling.
11. Organic agroforestry and perennial-based systems.

CROPS

Top priorities for organic crop research

1. Assess the extent and impact of plastic use in organic crop production and identify ways organic producers can lead in reducing it and aligning with consumer concerns
2. Side-by-side trials of approved organic pesticide products, both synthetic and natural, and cultural methods, in multiple regions, with a request for collaboration with the IR4 project.
3. Develop alternatives to eliminate the use of Per- and Polyfluoroalkyl (PFAS) substances and implement remediation strategies to mitigate contaminated areas.
4. Assess the extent, economic impact and potential compensation mechanisms for GMO contamination and prohibited pesticide drift, such as from Dicamba, on organic crops.
5. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming system choices.

Ongoing organic crop research topics -- Inputs

6. Develop NOP-compliant, biobased, biodegradable film mulches and hydromulches that control weeds, conserve moisture, and protect the soil. Include studies of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
7. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments and their contribution to soil health.
8. Holistic soil research to quantify soil biodiversity and activity.
9. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding supply.
10. Conduct a comprehensive review of the positive and negative impacts of copper products in pest management.
11. Increase the availability and supply of organic seeds by developing cultivars with improved performance. More breeding of cover crops is also needed. Also, conduct regional comparative trials to evaluate the performance and quality of organic varieties, seeds and planting stock.

12. Investigate the occurrence and fate of prohibited substances such as antibiotics, heavy metals, and pesticides in compost.
13. Investigate contaminated inputs from non-organic sources.
14. Investigate plasticizers and other additives to paper and their behavior in the environment.

Ongoing organic crop research topics -- Systems

15. Practices that reduce greenhouse gas emissions and that contribute to farming systems' resilience in the face of climate change.
16. Factors impacting organic crop nutrition, and comparison of organic and/conventional crop nutrient profiles.
17. Organic no-till and low-till practices for diverse climates, crops, and soil types.
18. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
19. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
20. Strategies for the prevention, management, and control of problem insects, diseases, and weeds in the context of a changing climate, with an emphasis on predicting new pest problems and systems-based approaches.
21. Studies of the effects of long-term (2+ years) use of in-situ plastic weed barriers/landscape fabric on soils in greenhouse and container growing systems. This includes changes in nutrient levels and biodiversity above and below the soil level, as well as any needed remediation measures once the plastic has been removed.
22. Research-based information on corn and soybean trade deficits: assessment of imports and exports to determine the causal factors and viable solutions to unfavorable trade disparities; organic traceability and supply chain technology; market data and supply/demand transparency.

LIVESTOCK

Top priorities for organic livestock research

1. Elucidate the barriers to increased domestic organic pork and beef production and markets.
2. Develop balanced organic livestock rations incorporating high percentages of diverse, regionally adapted grain crops to complement corn and soybeans, creating more marketing opportunities for robust crop rotations.

Ongoing organic livestock research topics

3. Prevention and management of parasites in all livestock species across regions, including evaluation of natural parasiticides and methodologies such as nutritional programs, herbs, essential oils, homeopathic remedies, diatomaceous earth, pasture rotation, pasture species selections, mixed species grazing, and use of genetic within and between breeds.
4. Evaluate natural alternatives to DL-Methionine in a systems approach for organic poultry feed program.
5. Develop dairy programs that address climate change mitigation strategies while maintaining production capacity and maximizing effective forage rotations.
6. Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas and water for Per- and Polyfluoroalkyl (PFAS) substances.\
7. Barriers to increased organic insect production.

FOOD HANDLING AND PROCESSING

Prioritized order within categories; categories not ordered by priority. See Expanded Explanation section for more detail, as applicable.

Improving methods and practices for organic handling and processing

1. Best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, and processing facilities to support prevention measures.
2. Effect of various types of food packaging on organic products, including suitable alternatives to packaging that contain any of the following: phthalates, plasticizers, per- and polyfluoroalkyl substances (PFAS), BPA (Bisphenol-A), and antimicrobial nanoparticle surface coatings. Additionally, PFAS research should include testing for total organic fluorine as well as specific PFAS materials.
3. Evaluation of postharvest physiology of organic fruit and effective decay management practices to address unique post-harvest issues.
4. Environmental, economic, and health benefits of organic handling and processing for society, communities, businesses, and/or individuals.

Expanding market opportunities for organic products – e.g., consumer expectations, products based on rotational crops, etc.

5. Evaluation of the essentiality of § 205.605(a), § 205.605(b), and § 205.606 substances and the suitability of organic alternatives (i.e., including commercial availability) in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.
6. Alternatives to conventional celery powder for curing organic meat.
7. Consumer food product development research for crops integral to organic farming systems (e.g., rotational crops).
8. Multi-product stream crops with potential for use in organic products, including organic produce items with strong pigment levels that could be sold for direct consumption and processed into organic colors.
9. Opportunities and barriers to organic alcohol production from rotational crops
10. Phosphates used in processed foods

Complete (or full) materials review

11. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.

MATERIALS/GMO

1. Fate of Genetically Engineered Plant Material in Compost
2. Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material
3. Assess the Genetic Integrity of Organic Crops At-Risk
4. Prevention of GMO Crop Contamination: Evaluation of effectiveness
5. Testing for Fraud: Developing and implementing new technologies and practices
6. Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods

EXPANDED EXPLANATIONS

INTERDISCIPLINARY RESEARCH PRIORITIES

1. **Increasing Access to Organic Foods**
   What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing organic food. Research should be funded that builds on an understanding of constraints by asking what community, market, and policy-based incentives would enhance access to organic foods.

2. **Barriers to Transitioning to Organic Production**
   What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic production? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

3. **Whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming system choices**
   This can include the full spectrum of crop, livestock, and integrated systems as well as soilless systems.

4. **Research-based information on the economics of organic certification, and production as well as profitability of organic enterprises**.
   Production budgets and profitability analyses can be broken down for specific sectors, farm scales, and crops. Some are well-studied, and literature reviews could be worthwhile. Conditions and conclusions vary over time as relative prices change. How important is the perception of integrity or its lack in the market? Farmers will benefit from this information.

5. **Information on the impact of organic enterprises on regional economies**
   Ground-breaking studies have been done in this area and need to be expanded and followed up.

6. **Organic yield gaps and system-level productivity**
   These studies have been done for specific crops and regions. More needs to be done on diversified farm operations, including those with both crops and livestock.

7. **Measuring and improving the effectiveness of research extension programs**
   How to ensure that results from these Research Priorities are fully shared with farmers and other organic stakeholders? The Extension system appears to be losing funding and is unable to reach many organic farmers. Alternative information outlets may be biased or oriented toward product sales. Farmer-to-farmer networks need to be studied and optimized as well. Organic farming is under multiple threats, and the entire organic community needs accurate and timely information.

8. **Research-based information on farmer mental health and quality of life**
   Much research has been done on farming stresses and their effects on mental health. More needs to be done, and results circulated to farmers and farm service providers.

9. **Information on the availability, quality, and cost of farm labor**
   The availability and quality of farm labor is in flux. Farmers and lawmakers need to fully understand the situation.

10. **A comprehensive study of National List sanitizers used in all phases of organic production and handling.**
    Holistic studies are needed on all phases of sanitizer use in organic food production, processing, and distribution, including disinfection of irrigation, maple, and dairy lines; dairy bulk tanks and trucks; post-harvest treatments; processing equipment and packing lines, etc. Suggested topics:
    - Effective alternatives to current sanitizers. Effectiveness of sanitizers includes both reduction of pathogenic organisms and reduction of post-harvest spoilage.
    - effects on occupational and consumer human health and the environment
    - optimizing rotational use strategies for various situations and purposes
    - Collaboration among researchers, agencies that regulate sanitizers and food safety, and NOP with the goal of developing an alternative process for evaluating sanitizers and sanitation practices for use by organic operations
    - Is there a measurable transfer of sanitizer residue to organic food following the sanitization of food contact surfaces? If residues are not found, is it even necessary for the National List to regulate surface/environmental sanitizers? (Residue studies should not be limited to only National List materials but should also include sanitizers such as quaternary ammonia compounds.)
    - What amount of sanitizer/disinfectant remains on or in various organic products after a processing or packing step that includes direct treatment with a sanitizer such as immersion in a water bath treated with a sanitizer?
    - Could the development of robust, post-harvest handling standards better identify which sanitation, disinfectants, or treatment practices impact organic integrity? Could expanded handling standards assist in regulating and enforcing the use of sanitizers instead of, or in addition to, the National List?
    - Could restructuring the National List to separate sanitizers from ingredients and processing aids create a pathway to development of an alternative set of evaluation criteria for sanitizers?
    - What would the impact on handlers and processors be if any specific sanitizers were removed from the National List?

11. **Organic agroforestry and perennial-based systems**.
    There has been a dearth of research into the organic establishment and management of agroforestry, permaculture, and woody perennial conservation buffers. These systems offer multiple ecosystem benefits including enhanced soil health and organic matter, improved nutrient cycling and reduced input needs, improved water quality, increased biodiversity, and improved microclimate for crops and livestock. In addition, woody perennial buffer plantings can protect organic crops from pesticide and GMO pollen drift from neighboring non-organic farms. These benefits need to be quantified and optimized.

CROPS

Top priorities for organic crop research

1. **The extent and impact of plastic use in organic crop production**

Both consumers and producers are concerned about the use of plastics in organic agriculture. The Crops Subcommittee is requesting research and information on the following:

- Statistics on current use (acreage and quantity) of crop production plastics, including mulches, drip tape, containers, row covers, tarps, high tunnels, greenhouses, etc.
- What is the turnover and fate of these plastics? This information is needed for the U.S. and major production areas such as Mexico, Spain, Chile, Holland, Canada, etc.
- What are the effects of breakdown products, airborne releases, and microplastics on soil organisms and crop plants? What is the fitness cost to beneficial microbial/fungal communities due to the presence of plastics, resins, and other breakdown substances in soil and compost?
- What are the economics of alternatives?
- If approved biodegradable biobased mulch films are developed, how many organic farmers would switch to them, and what would impact overall plastic usage?
- Can longer-term mulches, such as landscape fabric, reduce overall plastic use if allowed to remain in place over several years?
- What are the best first steps to reduce plastic use in organic production?

2. **Efficacy Comparisons of Inputs and Practices for Organic Production**

Organic farmers need to have information from side-by-side trials between allowed and petitioned synthetic inputs versus non-synthetic alternative inputs or practices. During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions.

The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

3. **Per- and Polyfluoroalkyl (PFAS): Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas.**

Background: There is a need for increased research examining PFAS substances. PFAS is a broad term that contains thousands of chemicals used in consumer, commercial, and industrial products. There is evidence that PFAS substances, also known as “forever chemicals,” contaminate farmland, water, food, consumer goods, and more. PFAS substances can negatively

impact human health and animal health in direct and indirect ways over time. Many researchers and scientists are looking into matters related to PFAS substances.
The NOSB is requesting additional research on the following:

- To find safe and eco-friendly alternatives so PFAS substances can be eliminated in the production of consumer, commercial, and industrial products to prevent any future contamination.
- To quantify the impact of PFAS substances on the environment, including agricultural land and water, and human and animal health.
- To utilize tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland. Explore measuring total organic chlorine to ensure that all PFAS variants are captured.
- To identify viable programs for addressing the financial and emotional costs of land that must be removed from production due to PFAS contamination.

4. **Assessing the economic impact of GMO contamination on organic crops**
   Background: Genetically engineered crops and organic crops can exist in adjacent fields. There are many risks, including cross-pollination, that are mitigated as best as possible by the growers involved, but much to the expense of the organic producer. Organic growers use borders, at a minimum of thirty feet, off-set planting timeframes to avoid cross-pollination (causing organic crops to be planted sometimes at undesirable times) and change cropping rotations, all to mitigate risk. In addition, dicamba drift from sources further away can damage crops.
   Research is needed on the following:
   - The total cost of GMO contamination on organic farms for the full range of crops with GMO varieties (including lesser-studied crops like apples, canola, summer squash, sweet corn, etc.). This would include recommended buffer requirements, recommended planting delays windows, testing costs, a variety of pollen receptivity restrictions, loss of sales, etc.
   - Are USDA coexistence provisions adequate?
   - Drifting chemicals can be considered “chemical trespassing.” Could pollen contamination be considered trespassing as well? Are there avenues for compensation for organic crops damaged or with reduced sale value due to contamination from other farms?

5. **Ecosystem service provisioning and biodiversity of organic systems**
   How do organic systems impact ecosystem service provisioning, both on-farm and off-farm through the materials and inputs sourced and used for production? For example, life-cycle analysis of environmental costs and benefits of inputs used for organic production, such as manure, seaweed, and fish-based soil amendments, would be beneficial. Additionally, what is the impact of diversified and agroecologically designed organic farming systems on biodiversity and ecosystem services within the farm and in its surroundings? Can farm-mapping be performed to quantify the impact of the location of a farm (in a broader landscape) and the arrangement of fields and non-crop habitats to enhance biodiversity and ecosystem service provisioning?

Ongoing organic crop research topics -- Inputs

6. **Biodegradable Bio-based Mulch Film--develop NOP-compliant, biobased, biodegradable film**

mulches and hydromulches that control weeds, conserve moisture, optimize temperatures, and protect the soil.

More studies are needed addressing the following bullets. Data from Europe, where BBMF mulches are allowed for organic production, may be particularly useful.

- How rapidly do these mulches fully decompose, to what extent do cropping system, soil type, and climate mediate decomposition rates, and does the percentage of the polymers in the mulch film affect the decomposition rate?
- Are there metabolites or breakdown products of these mulches that do not fully decompose?
- Do any of these mulches fully decompose?
- Do breakdown byproducts influence the community ecology and ecosystem function of soils, plants, and the livestock that graze on crops grown in these soils?
- As fragments degrade, do they pose a problem to terrestrial and aquatic wildlife? What are the environmental fates of micro- and nano-plastic fragments resulting from biodegradable mulch film degradation, and what hazards do they present to organisms that they interact with on the way to that fate?
- Do the residues of these films accumulate after repeated use?
- Are the testing protocols in place to ensure decomposition standards?
- Are there ways that paper mulches can be improved for commercial use?

7. **Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments**

   Vendors of organic amendments now offer a large and growing array of microbial inoculants, organic soil conditioners, and other materials claimed to improve soil health, crop vigor and quality, and combat weeds, pests, and diseases. There is an urgent need for impartial evaluation of these materials to help producers decide which products to use and to avoid unnecessary expenditures on products that are unlikely to yield benefits.

8. **Holistic Soil Research to Quantify Soil Biology**

   Organic farmers are presented with many alternative ways of assessing the health of their soil and its biological components. Which assessments give the most accurate and useful information to help farmers best manage soil over the short and long term?

9. **Identify Barriers and Develop Protocols for Organic Nursery Stock Production**

   The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. Research centered on the development of practical organic methods for the nursery industry to implement is needed, including:

   - Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.
   - New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
   - Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.
   - Evaluate the use of mycorrhizal inoculants in nursery production

10. **Comprehensive Review of Copper**

Systems research that identifies disease-resistant material and biological controls that can reduce the use of copper-based compounds where possible is needed. Use of copper has documented negative effects on human and ecosystem health. Continued strong efforts need to be made to reduce the reliance on copper in organic production.

- Develop alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Develop biological agents that work on diseases that copper is now used on.
- Research on tadpole shrimp and algae control in rice, and whether sodium carbonate peroxyhydrate or other materials are suitable copper alternatives in an aquatic environment.
- Research on movement and fate of applied copper in aquatic and field environments.
- Establish available and total copper threshold levels above, and identify which soil organisms are harmed, for different regions and soil types.
- Breeding plants that are resistant to the diseases that copper influences.

11. **Increase the availability and supply of organic seeds by developing cultivars with improved performance. More breeding of cover crops is also needed. Also, conduct regional comparative trials to evaluate the performance and quality of organic varieties, seeds and planting stock.**
    Investigate barriers to production and adoption of organic seed. Identify specific gaps and suggest solutions. In addition, rigorous, unbiased trials are needed to compare performance of different sources of organic and conventional varieties. These can reflect a range of common organic production practices, such as high or low nitrogen status or with and without plastic mulch.

12. **Research on the fate of prohibited substances in compost – antibiotics, heavy metals, pesticides, etc.**
    Can composting reduce or eliminate some undesired contaminants? Are some recalcitrant? Research is needed on the fate of what may be unavoidable contaminants in compost feedstocks.

13. **Investigate contaminated inputs from non-organic sources**
    In addition to PFAS and GMO drift, there are many other sources of contamination that can negatively impact organic farms and crops. Examples would be contaminants in manures and other fertilizers, irrigation water, etc. Research to identify these and whether they are avoidable needs to be ongoing.

14. **Investigate plasticizers and other additives to paper and their behavior in the environment.**
    Modern paper may contain many additives. The extent of these materials and their behavior in compost, the soil, and the environment needs to be studied.

Ongoing organic crop research topics -- Systems

15. **Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon)**
    A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although several researchers are examining this issue, additional work is needed to pinpoint specific strategies

that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security. Life cycle analysis of organic inputs and practices is critical. In particular, work is needed on comparing soil-based and soil-less systems, as well as the effects of farm scale on greenhouse emissions.

16. **Nutritional Value of Organic Crops**

    How do organic soil health and fertility practices - crop rotations cover crops, compost and other organic or natural mineral amendments, etc. - affect the nutritional value or "nutrient density" of organically produced crops? How do organic production and shipping methods (including methods of production, handling, and time in transport) influence the nutritional quality, taste, palatability, and ultimately preference for organic vegetables and fruits? There is a lack of sound, rigorously conducted studies of this kind. How can growers and handlers retain nutrition through post-harvest handling and transportation? Additionally, can providing organic producers with information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed to examine how organic crops compare to conventional crops with regards to nutritional value.

17. **Organic No-Till and Minimum Tillage**

    Organic no-till can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. Farmers are employing several different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.
    Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes, would all benefit from organic no till practices.
    Research areas that could be covered include:

    - Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
    - What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
    - How does organic no-till influence pest, weed, and disease management?
    - What potential pest problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
    - In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest, and disease management, as well as soil fertility?
    - What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
    - Do these systems affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?

- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life
  and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?
- Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to "inform" where reduced tillage practices are likely to have their greatest impact.

18. Managing Cover Crops for On-Farm Fertility

Growing cover crops and green manures is a foundational practice on many organic farms. In addition to conserving soil, increasing water holding capacity, and providing weed suppression, cover crops supply important plant nutrients and increase soil organic matter. As farmers seek to grow their own fertility, more research is needed on the efficacy of relying primarily on cover crops to meet production needs, particularly for horticultural crops. At present, there is inadequate data on the nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, subsequent planting time of the cash crops, and the preceding practices that define the legacy of individual fields. Further, there need to be more programs to breed seeds for cover crops.

19. Pathogen Prevention

Third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this hypothesis, more research, extension and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

20. Management of Problem Insects, Diseases, and Weeds

There is a large pool of research on the control of insects, diseases, and weeds using organic methods. Many controls use a systems approach and are quite effective. However, some arthropod pests, including new invasive species, are problematic, and in several cases the organic control options are very limited or nonexistent. The organic community needs more information on their biology, life cycle weak points, and natural enemies to implement targeted and systemic management.

Examples are:

- Spotted wing drosophila.
- Brown marmorated stinkbug,
- Spotted lanternfly,
- Swede midge,

- Leek moth, Corn rootworm beetle (northern and western),
- Cutworms (army, western bean, etc.),
- and others.

Disease management in organic fruit and vegetable production relies on a systems approach to succeed, but even with current systems plans in place, growers frequently struggle to manage commonly occurring blights and citrus greening. The NOSB underscores the need for systems research that addresses solutions to these and related diseases that are workable for farmers, that reduces adverse health effects on farmers and fieldworkers, and that also limits adverse effects on the soil and water in which the crops grow. To this end, we call for systems research that identifies disease resistant material and biological controls that limit the use of copper-based compounds and other fungicides where possible. Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops.

More research is needed on many of the crop/disease combinations, including:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Improved materials and methods for fire blight control in rosaceous crops.
- Evaluation of plant nutritional strategies to lessen disease impacts.

Further research into certain diseases in vegetables (including, but not limited to, early blight, late blight, downy mildews, etc.), fruits (including, but not limited to, apple scab, fire blight, peach leaf curl, little cherry disease, X-disease, grape botrytis, etc.), and soilborne or other diseases affecting organic crops that require mitigations such as approved fungicides or the increased use of copper.

Weed management is one of the greatest challenges to successful organic crop production. Development of integrated organic management strategies that effectively control weeds in specific cropping systems without excessive tillage continues to be a top research priority for organic producers. For instance, Canadian thistle, pigweed (including invasive palmer amaranth and water hemp), wild sunflower, giant ragweed, cocklebur, and other perennial weeds can be very difficult to control in reduced tillage systems. Research into new technologies, such as electroshock weeders, interrow mowers, camera-guided cultivators, laser-weeders incorporating AI (artificial intelligence) and robotics, propane flamers, etc., is critical to success in field crops, whereas tarping, solarization, and a new generation of hand tools have great potential in small- to medium-scale vegetable crops. For large scale vegetables as well as row-crop producers, strip tillage and compatible weed management tools including row cleaners, finger weeders, and high residue cultivators can combine reduced tillage and cover crops into one practice set.

Future cropping systems will utilize multiple elements of soil, crop, arthropod, disease, and weed management. The integration of tools, such as weed-suppressive cover crops and rotations, livestock grazing, flaming, beneficial insect habitat, intercropping, etc., into annual and perennial cropping systems needs more research.

21. **Studies of the effects of long-term (2+ years) use of in-situ plastic weed barriers/landscape fabric on soils in greenhouse and container growing systems. This includes changes in nutrient levels and biodiversity above and below the soil level, as well as any needed remediation measures once the plastic has been removed.**
    These systems may rely on liquid fertility inputs and landscape cloth in the exact location for 10 years or more. What happens to the soil under that woven landscape plastic? Is there an imbalance of soil nutrients? Is the soil compacted or in good condition? Once the landscape cloth is removed, is there any special remediation that needs to be done to this soil to allow crops to grow in it? How does long-term use of landscape cloth affect biodiversity both above and below the soil?

22. **Research-based information on corn and soybean trade deficits:**
    Assessment of imports and exports to determine the causal factors and viable solutions to unfavorable trade disparities will be very useful. Research on the use of organic traceability and supply chain technology will enhance the collection of accurate market data and generally improve supply/demand transparency.

    The potential for fraud in the international organic market is high, and many organic farmer stakeholders have stated that they are under financial duress due to it. There is a need for unbiased research utilizing all available data to identify any fraudulent sales and weaknesses in the international organic market.

LIVESTOCK

Top priorities for organic livestock research

1. **Elucidate the barriers to increased organic pork and beef production and markets**
   Production of organic pork has lagged behind chickens, eggs, and dairy. We request holistic investigations into what the barriers are including, but not limited to, markets, pricing, input costs, processing facilities, and production constraints such as lack of hardy breeds and housing/humane standards (including indoor and outdoor space standards as well as outdoor soil and vegetation requirements) and effective parasite management. Competition from non-organic pasture-raised, local, and other production claims should be included, as should evaluation of methods to avoid the need for farrowing crates. Similarly, the majority of organic beef marketed in the US appears to be imported. We request research into the reasons for this, and into how domestic production can be increased.

2. **Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation**
   The US organic livestock demand and consumption of organic corn and soybean meal in feed rations exceeds US production. To help encourage farmers to utilize robust crop rotation programs that are specific to their geographical region, give livestock producers more product availability/flexibility of ingredients, and reduce the dependence on corn and beans, there needs to be proven equitable rations in all livestock segments that include alternative energy and protein sources.

Ongoing organic livestock research topics

3. **Prevention and Management of Parasites**
   Livestock production places large numbers of cattle, sheep, goats, poultry, etc., in relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner that approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical. The research questions on prevention and management of parasites must be systems-based. What farm systems, bird and animal breeds, and herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, diatomaceous earth, or other treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems are best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?
   An area of particular concern is control of *Ascaridia galli* and *Heterakis gallinarum* in laying and replacement chickens.

4. **Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production**
   Methionine is an essential amino acid for poultry. Prior to the 1950s, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in compliance with NOP regulations §205.237(5)(b) which prohibits organic operations from feeding mammalian or poultry slaughter by-products to mammals or poultry, "We have seemingly made vegetarians out of poultry and pigs." As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

   Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the Spring 2015 Board meeting in La Jolla, California. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for:

   A. Evaluation of the merits and safety of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal, potato meal, fishmeal, animal byproducts, and other non-plant materials including insect protein in organic poultry production systems. Additional research on the more promising alternative methionine sources with the
      goal of bringing them into commercial production is also encouraged.

B. Evaluation of poultry breeds selection that could be adapted to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine.
C. Management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management; and
D. Using the European Union as a case study, assessing how EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. The fruition of these types of research topics could take years to achieve; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand.

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.

5. **Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized**
To further acknowledge the central role the certified organic industry will play in the fight against climate change, an opportunity exists to both empower the economic resilience of organic dairy farmers while harnessing the soil building potential of diverse perennial and annual forages, we encourage the research community to dedicate resources to the following needs:
    A. Identify an index of dairy cattle genetics to which producers could breed their existing herds and achieve a minimum of 12,000 lbs. of milk production per year on 100% forage diets. In considering the genetics selected, also identify animals bred for longevity as the more lactations on a cow, the more spread out the fixed costs of raising her as a heifer becomes.
    B. To assist dairy farmers in having the tools to consider a forage-based rotation for their herds, research and identify crop rotations that have three functions: produce high quality forage, maximize soil building, and provide the most profitable outcome for the dairy producer.

6. **Per- and Polyfluoroalkyl (PFAS): Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas**
Background: There is a need for increased research examining PFAS substances. PFAS is a broad term that contains thousands of chemicals used in consumer, commercial, and industrial products. There is evidence that PFAS substances, also known as "forever chemicals," contaminate farmland, water, food, consumer goods, and more. PFAS substances can negatively impact human health and animal health in direct and indirect ways over time. Many researchers and scientists are looking into matters related to PFAS substances.

The NOSB is requesting additional research on the following:

A. To find safe and eco-friendly alternatives so PFAS substances can be eliminated in the production of consumer, commercial, and industrial products to prevent any future contamination.
B. To quantify the impact of PFAS substances on the environment, including agricultural land and water, and human and animal health.
C. To utilize tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland. Explore measuring total organic chlorine to ensure that all PFAS variants are captured.
D. To identify viable programs for addressing the financial and emotional costs of land that must be removed from production due to PFAS contamination.

7. **Barriers to increased organic insect production**
   There is interest in producing organic insects for high-methionine chicken feed. Stakeholders have pointed out that insects, though technically livestock, do not fit well into NOP livestock regulations, including outdoor access requirements, etc. An overview of insect rearing practices and how they may be accommodated into organic systems is needed.

FOOD HANDLING AND PROCESSING

Prioritized order within categories; categories not ordered by priority.

Improving methods and practices for organic handling and processing

1. **Research on best practices** for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.

2. **Effect of various types of food packaging on organic products,** including suitable alternatives to packaging that contain any of the following: phthalates, plasticizers, per- and polyfluoroalkyl substances (PFAS), BPA (Bisphenol-A), and antimicrobial nanoparticle surface coatings. Additionally, PFAS research should investigate testing for total organic fluorine in addition to specific PFAS materials.

3. **Evaluation of postharvest physiology of organic fruit and effective decay management practices to combat unique post-harvest issues:**
   Many varieties of organic fruit on the market require specific post-harvest handling conditions (e.g., temperature, moisture, light). There are few items on the National List aimed at supporting decay management, but these may work better on some items than others and/or be restricted only for use on specific products. Research aimed at illuminating unique problems and effective strategies depending on the fruit type would be beneficial to organic fruit handlers.

4. **Research on the potential benefits of organic handling, including the environmental, economic, and health benefits that accrue to society, communities, businesses, and/or individuals from organic processing:**
   The current body of research compares the on-farm productivity and the profitability of organic farms relative to conventional operations. A smaller body examines handling of organic products, including studies of the supply chain. However, questions related to whether organic

handling facilities are less damaging to the environment or communities have not been addressed. It is well understood that lack of markets, including access to certified organic processing, remains a barrier to expansion of organic acreage and introduction of new organic crops and products. Improved access to information about the benefits of organic handling may help more processors enter the organic market and offer organic handling capacity.

Expanding market opportunities for organic products – e.g., consumer expectations, products based on rotational crops, etc.

5. **Evaluation of the essentiality of § 205.605(a), § 205.605(b), and § 205.606 substances:** In review of substances on the National List at 205.605 and 205.606 during the sunset process questions related to essentiality and commercial availability of organically produced substances, and if supplies are lacking knowledge of the barriers to organic production, are often the focus of the review by the Handling Subcommittee and of stakeholder comments. There are often commenters that blanketly state that all items should be removed from 205.606 - inferring that there should be the ability to produce all these substances organically. Therefore, it would be beneficial to comprehensively understand the status of essentiality of these substances and if organic alternatives exist; and if not what the barriers are that prevent a vibrant organic market for these substances.

6. **Alternatives to conventional celery powder for curing organic meat:** Celery Powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (note: products must still be labeled “uncured”). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

7. **Consumer food product development research for crops integral to organic farming systems (e.g., rotational crops).**

8. **Multi-product stream crops with potential for use in organic products, including organic produce items with strong pigment levels that could be sold for direct consumption and processed into organic colors.** Several nonorganic colors remain on the National List; while the crops named as the color source are grown organically, those crops may not be varieties appropriate for color production. Research on crops that are both directly palatable and potentially useful as organic color sources could give farmers additional flexibility and market opportunities and help the organic sector transition to use of exclusively organic colors.

9. **Opportunities for and barriers to organic alcohol production from rotational crops:** Organic (and nonorganic) farmers are increasingly incorporating new crops into rotations to support soil health and natural pest control, but the economics of this practice remain challenging where the rotation crops do not have strong existing markets. The organic spirits

sector could potentially incorporate some of these crops, but more research is needed on which crops and how to use them in alcohol production.

10. **Phosphates used in processed foods.**
    Phosphates appear in many different compounds used in processed foods. For example calcium phosphates provide unique functionality in organic baked goods and are used in a variety of other organic food products. Additionally, calcium phosphates provide two essential nutrients in food – calcium and phosphorus –and may be used as an alternative to replace sodium phosphate and lower the sodium content in food. Some research has alleged that phosphates are associated with adverse health effects, such as cancer and cardiovascular risk, and more research is needed for conclusive results. Currently these claims have not been validated and are not supported by current scientific literature. The risk of bioaccumulation of phosphorus in the human body and at what level does it produce adverse effects to the cardiovascular and renal system need to be researched.

Complete (or full) materials review

11. **Overarching ancillary ingredient review process for materials used in processing and handling:**
    The topic of ancillary substances contained in substances on 205.605 and 205.606 and how the NOSB should review them has been a topic of discussion since 2013 but has not reached a full resolution. The current process is to review individually during the petition or sunset review process. However, as noted by stakeholder comments this has the potential to result in different decisions due to the gap in time, available information and/or people responsible for conducting the review being different. It would be beneficial to analyze and compare different strategies for conducting ancillary substance review in a more comprehensive manner as opposed to the current individual review process that includes a cost/benefit analysis of each proposed review strategy.

MATERIALS/GMO

In previous years, the Materials Subcommittee prioritized the reduction of genetically modified content of breeding lines (2013) and seed purity from GMOs (2014), issues which are currently being addressed through a comprehensive stream of work on excluded methods. The following research priorities are among the areas that the excluded methods work continues to elevate.

1. **Fate of Genetically Engineered Plant Material in Compost**
   What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (Bacillus thuringiensis) after composting that would result in persistence in the environment or plant uptake?

2. **Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material**
   Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. **Assess the Genetic Integrity of Organic Crops At-Risk**
   Develop then implement methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. **Prevention of GMO Crop Contamination: Evaluation of effectiveness**
   How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows? Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen. Lastly, research is needed on a mechanism to provide conventional growers incentive to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally important.

5. **Testing for Fraud: Developing and implementing new technologies and practices**
   New technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

6. **Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods**
   First, identify the set of potential threats the use of excluded methods presents to organic businesses (farms and handlers). The potential threats include crop damage and cross contamination, but we recognize there might be others not yet identified. Second, estimate the costs the threats present to organic farms and organic handlers.

National Organic Standards Board
Policy Development Subcommittee (PDS)
Policy and Procedures Manual (PPM) Revision Proposal
Spring 2026

Introduction and Background

The Policy and Procedures Manual (PPM) was established to assist the National Organic Standards Board (NOSB) in the implementation of its duties under the Organic Foods Production Act (OFPA), and the USDA Organic Regulations (7 CFR Part 205). It contains operating procedures and policies for the NOSB. During the period since the last revision (April 2024), the Policy Development Subcommittee (PDS) has discussed changes to address actions the board can take when Board members do not participate in meetings and how to ensure the highest level of trust and transparency in our process when evaluating new substances for inclusion on the National List. The PDS has reviewed these suggested changes and proposes the following as listed in the table below.

Summary Table of Changes

Section/Page	Summary of changes (specific language included in ppm strikethrough appendix)
III. J (3)	Failure to participate Authorizes NOSB Chair to request Secretary remove board members for extreme non-participation.
IV. H Step 3	Clarifies 3rd party technical reviews should be conducted for all newly petitioned substances and narrows conditions when existing information and expertise can be relied upon to evaluate petitions for National List substances.
VII. B.	Process for Separate Annotation Changes at Sunset Review New section outlining the steps for annotation change proposals during substance sunset review process.
Throughout	Minor wording updates including replacing the term “Technical Report” with the abbreviation “TR.”

Subcommittee Vote

Motion to accept the Policy and Procedure Manual (PPM) updates.
Motion by: Nate Lewis
Seconded by: Allison Johnson
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 0

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
Revised November 19, 2008
Revised May 6, 2009
Revised November 9, 2009
Revised April 29, 2010
Revised October 28, 2010
Revised April 29, 2011
Revised December 2, 2011
Revised April 11, 2012
Revised April 26, 2016
Revised November 18, 2016
Revised October 25, 2019
Revised April 28, 2022
Revised May 1, 2024
Revised November 6, 2025

NATIONAL ORGANIC STANDARDS BOARD (NOSB)
POLICY AND PROCEDURES MANUAL

I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA), NOSB members are encouraged to review this manual in depth as well as to become familiar with the OFPA, the USDA organic regulations at 7 CFR Part 205, and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title (OFPA, Sec 2119 (a)).

C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations

- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List
- Communicating with the organic community, including conducting public meetings, soliciting and reviewing public comments
- Communicating, supporting and coordinating with the NOP staff

II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The NOSB charter is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

III. NOSB ADMINISTRATION

A. NOSB MEMBERSHIP

OFPA as amended (7 U.S.C. 6501 et. seq. 2018) specifies the membership composition of the NOSB as

follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation, or employees of such individuals;
- Two shall be individuals who own or operate an organic handling operation, or employees of such individuals;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products, or employees of such individuals;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;
- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. NOMINATION AND APPOINTMENT PROCESS

(NOSB Recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five-year term. The terms are staggered, and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved

travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

C. RESPONSIBILITIES OF THE NOSB

(OFPA, 7 USC 6518(k)):

(1) **In General**. The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.

(2) **National List**. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this title.

(3) **Technical Advisory Panels**. The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) **Special Review of Botanical Pesticides**. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.

(5) **Product Residue Testing**. The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

(6) **Emergency Spray Programs.** The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

Requirements. (OFPA 6518(l)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

(1) review available information from the environmental protection agency, the national institute of environmental health studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed national list;

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and

(3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

4. the effect of the substance on human health;

5. the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

6. the alternatives to using the substance in terms of practices or other available materials; and

7. compatibility with a system of sustainable agriculture.

Petitions. (7 USC 6518(n)) The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List.

Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair, and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

1. Chair

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings, and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Committee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Committee meetings
- Convenes and presides over NOSB meetings

- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

2. Vice chair

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Committee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

3. Secretary

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Committee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval
- Assists with the annual election of NOSB officers
- Monitors and notifies Subcommittee Chairs periodically of public comments posted to the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted.
- May delegate tasks to others, but retains responsibility for the official record

4. Administrative Team

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. This group is responsible for facilitating logistics and operations of the Board, including working with USDA staff for onboarding new members and providing outgoing board members with the opportunity to share experiences and feedback. The Administrative team meets via teleconference on an as-needed basis, to be determined by the Administrative Team. This team is not a subcommittee and makes no decisions. All items needing further discussion or action are

placed on the Executive Committee agenda and are recorded in the Executive Committee notes.

E. NOSB-NOP COLLABORATION

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to "establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation" of the Act. Section 6503 (a) of the OFPA requires that the Secretary "shall establish an organic certification program … and shall consult with the NOSB" (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord.

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly, the NOP, as required through OFPA, must consult and collaborate with the NOSB.

Teamwork and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance, and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ~~ES~~ Executive Committee calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB requires a high level of collaboration, and therefore NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics, and maintain organic integrity. Every aspect of this work must take place in a manner that clearly demonstrates mutual respect and positive intent.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope:** Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions to or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.

- **USDA and NOP Priority:** Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.

- **Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Committee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.

2. The NOP and Executive Committee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.

3. NOP confirms the final NOSB work agenda and provides written confirmation.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)

2. NOP requests to the NOSB

3. NOSB requests to NOP

4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List:** The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

- **Changes to annotation or classification of materials:** The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment.

- **Recommendation for modification of existing standards or new standards:** The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards:** The NOSB may provide comments on guidance or policy memos included in the Program Handbook or may also make recommendations for new guidance or policies.

- **Compliance and Enforcement:** The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review:** The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

G. DESIGNATED FEDERAL OFFICER

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Committee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling meetings of the NOSB

- Approving the semi-annual meeting agenda

- Attending the semi-annual meetings

- Adjourning the meetings when such adjournment is in the public interest

H. ADVISORY COMMITTEE SPECIALIST

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the

NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented.
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities.
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls.
- Ensuring NOSB members have all necessary materials and information to provide informed, structured, and timely recommendations to the NOP.
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments.
- Coordinating the NOSB nomination and chartering process.
- Facilitating training of NOSB members.
- Managing information reporting and communication between the NOSB and NOP.

I. ADDITIONAL ADMINISTRATIVE ITEMS

1. Official to whom the Committee Reports

The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer; the Agricultural Marketing Service's NOP Deputy Administrator.

2. Staff Support

The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

3. Estimated Number and Frequency of Meetings

The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.

4. Recordkeeping

Records of the NOSB shall be defined and handled in accordance with General Records Schedule 6.2 or other approved agency records disposition schedule. This schedule is available online at: https://www.archives.gov/records-mgmt/grs/grs06-2.pdf. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Requests for records should be handled in accordance with the GSA March 14, 2000 memo that is available online here: http://www.gsa.gov/portal/content/100785. Information about the NOSB is available online at: http://www.ams.usda.gov/rules-regulations/organic/nosb

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes

to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, documents provided to the board, a complete and accurate description of matters discussed and conclusions, and the outcome of voting. If not included in the minutes, a voting summary will be published that contains votes by member.

FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist." Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- **Freedom of Information Act** (FOIA; 5 U.S.C. 552). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. PROFESSIONAL AND ETHICAL STANDARDS

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

1. NOSB Member Professional Conduct Standards

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust.
- Put forth an honest effort in the performance of their NOSB duties.
- Make no commitments or promises of any kind purporting to bind the Government.
- Act impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings

- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.

- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any "specific party matters" (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP's Advisory Committee Specialist any specific party matter in which the member's immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB's advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2. Additional Standards of Conduct

NOSB members should adhere to the following basic "standards of conduct" while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).

- Do not use board appointments for private gain.

- Do not misuse internal non-public government information.

- Do not use government property and time improperly.

- Do not accept compensation for teaching, speaking, and writing related to your board duties.

- Do not engage in partisan political activities while performing your board duties or while in a federal building.

- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.

- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.

- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.

- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.

- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

3. Failure to Participate

The NOSB typically has a heavy workload and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fails to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that they cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Committee, and if necessary, encourage the Board member to resign. In cases of extreme non-participation that continues after the previous steps have been taken, the Chair may send a letter to the Secretary, requesting that Board member's removal from the NOSB. Reasons for this decision may include; repeated failure to participate in Subcommittee work, failure to communicate expected absences, or three or more unexcused public meeting absences.

K. DECLARATION OF INTERESTS/CONFLICT OF INTEREST

The Organic Foods Production Act (OFPA) prescribes seven interest groups/seats: farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumer and public interest groups, and retailers.

In 2022, USDA determined that eleven of the fifteen seats are classified as **representatives** under the Federal Advisory Committee Act (FACA), and four are classified as Special Government Employees (SGEs). Representatives are appointed to articulate the viewpoints and interests of a particular interest group, while SGEs are appointed to provide expert advice. Regardless of classification, all board members function as equals in providing advice to the Secretary in the development of standards for substances to be used in organic production and on any other aspects of the implementation of OFPA.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionally benefits you or a person associated with that member;

- Could impair your objectivity in representing your group; or

- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

1. Declarations of Interest/Conflicts of Interest Procedures

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

2. At the Subcommittee Level

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.

- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the Subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the Subcommittee.

- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

3. At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.

2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).

3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP, working with the USDA office of ethics, as needed, will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.

4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.

5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the Board chair, the DFO will state: "the following Board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etc.)."

6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." This is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.

7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state "recuse" when it is his or her time to vote.

IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc.

A. STANDING COMMITTEES AND SUBCOMMITTEES

The current standing Subcommittees are:

- Executive (EC)
- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)

- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

Executive Committee (EC)
The Executive Committee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Committee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACS)
The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)
The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)
The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)
The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)
The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the

annual work agenda of the MS.

In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees.

Policy Development Subcommittee (PDS)
The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

B. AD HOC SUBCOMMITTEES

At the discretion of the NOSB Chair, and with approval of the Executive Committee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a "joint" Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the Executive Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.

- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS

1. Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure minority opinions are given the opportunity to be represented in meetings, and in discussion documents and proposals.
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Committee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

2. Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair's absence

F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary. Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

1. After the election of NOSB Officers at the Fall Meeting:

1. **The new NOSB Chair takes Office**
   At the close of the meeting at which the election occurred, the newly elected Chair takes office.

2. **Appointment of Subcommittee Chairs**
   The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience.

3. **Appointment of Subcommittee Vice Chair**
   Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

Timeframe for Appointments
Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

4. **Review of Subcommittee Files**
   New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work.

Mentorship Period
The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

5. **Appointment of New NOSB Members:**
   The Board Chair will appoint each new NOSB member to the appropriate Subcommittees as soon as possible, so that all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members' interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

6. **Changing Subcommittee Appointments**
   Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Committee.

7. Filling a Subcommittee Chair and/or Vice Chair vacancy
If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. Development of proposals/discussion documents

Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

- A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.

- By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty-five (45) days prior to a scheduled NOSB meeting.

- When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view. A minority view should:

    - Be short and concise, and include reasons for opposing the Subcommittees recommendation;

    - Should not include any data or information not introduced on a Subcommittee call;

    - Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its proposal;

    - Will be included as a separate section at the end of the proposal/recommendation.

- The NOP will post the proposal or discussion document for public comment.

- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.

- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. Types of Proposals/Discussion Documents

(See Member Guide for examples) There are several formats for writing proposals and discussion

documents, based on the subject under review:

- Proposals related to substances: petitioned substances, sunset reviews, annotation changes, or classification changes.
- Proposals for policy or procedure changes
- Discussion documents
- Petitioned material discussion documents

3. Subcommittee Proposals and Discussion Documents

The following information should be included in proposals and discussion documents:

1. **Introduction**: A brief summary of the issue, or statement of the problem.
2. **Background**: An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
3. **Proposal**: A concise explanation of the recommended action.
4. **Subcommittee Vote**: The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, or agricultural/non-agricultural, and the other a motion to add to the National List.
5. **Public Comment:** A brief summary of the public comments.
6. **Minority View**: If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is “to assist in the development of standards for substances to be used in organic production” (OFPA 6518 (a)). “The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary …” (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 - year “sunset” review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions and NOP Guidance 3011 – National List Petition Guidelines, effective March

11, 2016.

In lieu of a formal petition, a Subcommittee (Livestock, Crops, Handling) of the NOSB may propose to add, remove, or amend a substance from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518(m) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H. Step 2 in this PPM.

1. Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.

2. Subcommittee (SC) determines sufficiency of the petition. If found insufficient, the subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

3. Subcommittee (SC) determines if a technical review (TR) is needed.

4. SC may develop a discussion document based on the petition and forward that document to the full board for posting, and to solicit public discussion.

5. Technical report is completed and sent to the subcommittee for review.

6. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.

7. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting ~45 days prior to public meeting.

8. The NOSB members analyze comments and vote on the proposal at the public meeting.

9. The NOSB chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition
During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.

- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);

- NOP documents this review using two checklists.

    - OFPA Checklist, NOP 3005-1

    - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and a petitioner.

Step 2: Subcommittee (SC) determines sufficiency of the petition
During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine if the petition is sufficient for SC review. This decision may be based on the following:

- Is there sufficient information in the petition for the SC to determine why or for what purpose the material is being petitioned?
- What is the petitioner's proposed wording for listing the material?
- Is the information presented in the petition clear and consistent so that a proposal may easily be developed?

If the petition is found insufficient, the Subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

Step 3: Subcommittee determines whether a Third-Party Technical Review (TR) is required
During this phase, which may occur simultaneously with the determination of petition sufficiency, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third-party ~~technical review~~ TR is required. ~~This decision is based on the following:~~ If the petition is for a new substance without a TR or an existing substance that has a TR that is over 10 years old, a new TR should be requested. If the petition is for an existing substance with a TR that is less than 10 years old, the subcommittee may determine that an additional TR is not required based on the following

considerations:

- Is there sufficient information in the petition that makes a TR unnecessary?
- Have the sources of information provided in the petition been vetted for potential conflicts of interest or bias that may obscure National List concerns?
- Do any previous TRs of other materials provide sufficient information?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.
- Is all the information available to the Subcommittee also available to the public?

If the Subcommittee decides a ~~Technical Review~~ TR is needed, the Subcommittee Chair will make the request to the National List Manager. The ~~SC~~ Subcommittee may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides a ~~Technical Review~~ TR is not needed, the Subcommittee Chair will inform the National List Manager~~.~~ and describe the information and expertise that will support the Subcommittee's recommendations and satisfy OFPA criteria. The Subcommittee shall include this information in any recommendations or proposals related to the petitioned substance.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a ~~Technical Review~~ TR. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)

OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))

The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations. In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 4: Subcommittee may develop a discussion document based on the petition and forward that document to the full board and post it for public discussion
At the discretion of the Subcommittee (SC), the SC may develop a discussion document to:

- Solicit public comment about the material prior to a proposal being developed
- Provide opportunity for full board discussion prior to a proposal being written
- Allow the petitioner to hear public and board comments, and give them an opportunity to submit petition addendums prior to a Subcommittee proposal and vote.

A petition discussion document is optional, but if used, could allow for full board discussion of a material while a technical review is in process, or, would aid the Subcommittee when writing a proposal.

Step 5: Third Party Technical Review
During this phase the NOP will:

- Assign a contractor to develop a ~~Technical Review (~~TR~~)~~ or Technical Advisory Panel (TAP). The third-party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 6: Technical Review Sufficiency Determination
During this phase the Subcommittee (Crops, Livestock or Handling) will:

- Review the draft TR to ensure that it:
    - Is consistent in format, level of detail, and tone
    - Is technically objective and free from opinions or conjecture
    - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
    - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
    - Is based on the best available information that can be obtained within the designated time frame
    - Is thoroughly supported using literature citations

- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving a TR, that it is sufficient. If a TR is found insufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor. Once a Technical Report is deemed sufficient, the NOP will post it on the NOP website.

Step 7: Review by the Subcommittee (Crops, Livestock or Handling)
During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Report, personal knowledge, public or board comments from the optional petition discussion document, and recommendations of a contracted panel of experts when utilized.

- Subcommittee members will prepare a written review of the substance according to the OFPA criteria.

- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural, non-agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend).

- The review, including a record of the Subcommittee vote, will be finalized as a proposal for the next meeting.

- All proposals must be submitted to NOP for posting ~45 days before the public meeting date.

Step 8: Action by Full NOSB
During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.

- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, receive ~~listen to~~ public comments (written, virtual, and in-person), and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the Subcommittee, and the Chair will open the motion for discussion. After discussion, board members will vote on the motion.

- Voting may be by show of hands, roll call, or by use of modern voting devices.

- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

Step 9: The NOSB Chair will review all final recommendations and submit them to the NOP.

2. Changes to annotations, classification of materials, or proposal to remove.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation, a reclassification of the substance, or removal of a substance. This may happen as a result of the sunset review process, or based on new information provided in a TR ~~Technical Review~~, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Committee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The Executive Committee considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

3. Additional considerations concerning Technical Reviews.

Basic principles that should be considered when consulting with a third-party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health, and its compatibility with organic principles.
- The decision to request a ~~Technical Report~~ TR needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee determines the completeness of the petition and whether a Technical Review is needed.
- The decision to define specific expertise of the third-party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.

- The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the ~~Technical Review~~ TR. All Federal contracts, including those issued by USDA/NOP to ~~Technical Report~~ TR contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract. Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf.

4. Definitions

Technical Report (TR)- A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Technical Advisory Panel (TAP) - Group of third-party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. PRIORITIZATION OF PETITIONS

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition or proposal to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1,** above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

Priority 2: A petition or proposal to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2,** behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

Priority 3: A petition to **add** a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as **Priority 3**.

Priority 4: A petition to **reconsider** adding a material that had previously been rejected by a Board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

VI. WITHDRAWAL OF A PETITION BY A PETITIONER

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the Subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. SUNSET REVIEW PROCESS

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition.”

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

A. STEPS IN THE SUNSET REVIEW PROCESS (see Member Guide for forms used in these steps)

Step 1: The NOSB Subcommittees submit the initial **Sunset Summaries** for posting, which may include requests for specific information. The NOP posts the summaries as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the

next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews,** which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass. At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances

Note: This is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation ~~or re-classifying a material~~, a standing work agenda item approved in May 2023 authorizes Subcommittees ~~may request~~ to develop a separate proposal that will be reviewed separately from the sunset review process~~.~~ and which is detailed below. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

B. PROCESS FOR SEPARATE ANNOTATION CHANGES AT SUSNET REVIEW

Step 1: Determine if substance is a candidate for an annotation change

- During the TR determination process, substances may be flagged if they appear to warrant a parallel (separate) annotation proposal during the following sunset cycle. This early identification allows the Subcommittee to begin preliminary consideration and wordsmithing of potential annotation changes and begin the process of securing relevant technical information that will inform the Subcommittee's recommendation.

Step 2: Draft sunset review and annotation language for Spring Meeting

- The Subcommittee will draft the sunset review and consider whether they would propose to remove the substance from the National List before proceeding to an annotation change document.

- The Subcommittee may include questions to stakeholders seeking recommendations for annotation changes, or draft annotation language in a separate document, based on previous stakeholder input, and request feedback.

- Each substance's sunset summary should include a dedicated section on annotation to prompt consideration and ensure any discussion is memorialized for future reference.

Step 3: Draft separate annotation change document for Fall Meeting

- For each proposed annotation change, the Subcommittee will draft a discussion document or proposal for the Fall Meeting in addition to the sunset review write-up. Each proposed annotation change will be:
    - Tracked as a separate work agenda item on the work agenda spreadsheet; and
    - Documented in the subcommittee notes table

Step 4: Consider timelines

- Annotation change proposals are not required to follow the same timeline as sunset reviews.
- Annotation changes do not need to be completed by the Fall NOSB meeting. The Subcommittee should anticipate that additional drafting or revisions may extend beyond the standard two-meeting sunset review timeline.

Step 5: Voting on annotation change proposals

- Full board votes on annotation change proposals occur independently from the sunset review and vote of the substance, although voting on annotation change proposals may occur at the same meeting as the sunset renewal vote.
- Should an annotation change proposal pass the full board, NOP may consider the proposal in its decision to renew substance listings and/or engage in rulemaking for changes to the National List.

VIII. NOSB PROCEDURES

A. BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples of these exempted meetings include; Subcommittee calls, assemblies for completing work, planning retreats, training, or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

B. CONDUCTING BUSINESS

1. NOSB public meetings in brief:

- Approximately 3 days long depending on workload.
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints.

- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by ~~the~~ NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas.

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases when extenuating circumstances prevent in-person participation, a virtual presence is permitted.

Decisive votes: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

Calculation of Decisive Votes

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

C. PARLIAMENTARY PROCEDURES

No procedures or business of the NOSB shall be taken in conflict with OFPA, FACA, or other pertinent laws (herein referred to as governing legislation). For parliamentary procedure, all motions and votes not covered under the governing legislation shall be governed by this Policy and Procedures Manual, if directly addressed. If procedures, motions, and votes are not directly addressed in the Policy and Procedures Manual, they shall be governed by Robert's Rules of Order Newly Revised. The NOSB adopted the use of Robert's Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA, and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include, but are not limited to: adoption of a proposal as presented by the Subcommittee,

non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

*1. *Substantive vs. non-substantive amendments.*

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests.
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal.
- The extent to which the effects of the recommendation differ from the effects of the proposal.

2. Procedure for submitting final recommendations to NOP.

Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

- Each proposal lead prepares the following documents:
    - A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
    - The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals are encouraged to submit written comments and may also present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

1. Comments before Public Meetings:

Written comment:

All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to consider comments in advance.

Commenters shall refrain from including personal attacks or remarks that might malign the character of any individual, entity, or organization.

Oral comments:

Individuals may have the opportunity to present oral comment at either a pre-meeting webinar or at the in-person NOSB meeting. Public notice of pre-meeting webinars will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Transcripts of such webinar meetings shall be made available to the public and to NOSB members.

2. Comments at In-Person Public Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.

- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to consider comments in advance.

- Persons will be called upon to speak according to a posted schedule. However, speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.

- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.

- Persons must give their name and affiliation for the record at the beginning of their public comment.

- Proxy speakers are not permitted.

- Public comments may be scheduled according to topic.

- Individuals providing public comment shall refrain from making any personal attacks or remarks that might malign the character of any individual, entity, or organization.

- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

3. Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)

- The NOSB and NOP seek public communication outside of biannual Board meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

- The NOSB may post draft discussion documents and proposals between public meetings for review and public comment. Timely submission of comments will assist the NOSB and its Subcommittees in revising such documents for subsequent NOSB review.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position.

- An NOSB member may self-nominate or may be nominated by another member of the NOSB.

- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Committee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term.

- Members may serve more than one term in any officer position.

Voting Schedule

- Officers shall be elected for one-year terms by majority vote at the Fall NOSB meeting.

- Newly elected officers will assume their positions at the conclusion of the Fall NOSB meeting, and assume the responsibilities thereof at that time.

- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

Counting of Votes

- Voting will be by secret ballot immediately following nominations for each office.

- Ballots for officers will be cast in the following order:

    1. Chair

    2. Vice Chair

    3. Secretary

- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations.

- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote.

- The Secretary will tally the votes and the Chair will verify the results~~.~~, unless the Secretary and/or Chair is running for an executive position, in which case, the Chair will delegate this responsibility.

- The first nominee to receive a majority of votes will be elected. If no nominee receives the majority of votes, the nominee with the least votes will be eliminated and a revote will occur with the remaining candidates. This process will be repeated until a nominee obtains a majority.

- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote.

- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.

- A nominee may withdraw at their discretion at any time.

- In the event there is only one nominee for office, the vote may be by acclamation.

G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB, or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.

- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.

- Speakers must be approved and invited by the NOP.

- If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

- Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.

- Speakers are expected to disclose any financial interests ~~that he or she has~~ that can be reasonably assumed to influence his or her presentation content.

2. Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Committee before they are submitted for approval to USDA, and

- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM as needed and, working in collaboration with the NOP, determine if any updates are necessary.

- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

X. APPENDICES

A. APPENDIX 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

1.2 An organic production system is designed to:

1.2.1 Optimize soil biological activity;

1.2.2 Maintain long-term fertility;

1.2.3 Minimize soil erosion;

1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;

1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;

1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;

1.2.7 Minimize pollution of soil, water, and air; and

1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

1.3.1 Providing good quality organically grown feed;

1.3.2 Maintaining appropriate stocking rates;

1.3.3 Designing husbandry systems adapted to the species' needs;

1.3.4 Promoting animal health and welfare while minimizing stress; and

1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;

1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;

1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;

1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and

1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.

1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.

1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.

1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.

1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.

1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.

1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) and products produced by or through the use of

genetic engineering are prohibited.

1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

(NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?

- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?

- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?

- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?

- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?

- Does the substance allow for an increase in the long-term viability of organic farm operations?

- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?

- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?

- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?

- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?

- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?

- Does use of the substance have a positive impact on biodiversity?

3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

Duty of Care

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.

- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.

- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

Duty of Loyalty

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In dispatching their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.

- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

Duty of Obedience

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990.
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual.

B. APPENDIX 2: FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years, or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.

- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.

- Designated Federal Officers must approve all meetings and agendas and attend meetings. The Advisory Committee Specialist is the NOSB's Designated Federal Officer.

- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:

    - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin.

    - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin.

    - Publish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" in which the NOSB and NOP can receive public comment. Notwithstanding the above, the NOP will publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin.

- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.

- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.

- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.

- Additional information may be found at the FACA homepage: www.gsa.gov/faca

National Organic Standards Board
Policy Development Subcommittee
Sunset Review Efficiency Discussion Document
Spring 2026

Summary:
At the Spring 2024 NOSB Meeting, the Policy Development Subcommittee (PDS) brought forth a discussion document and began to implement a process for a more efficient voting procedure for sunset substances. In this approach, the PDS proposed a group vote specifically for substances (1) that have widespread support for relisting and (2) where there is no new information suggesting that the products do not comply with National List criteria. At the Spring 2024 meeting, Board members indicated whether or not a particular substance would be eligible for a group vote.

Public comments related to this new procedure were mixed. Some stakeholders were supportive of reducing the time it took to vote on each substance and expressed a willingness to trial a new process that could reduce the time spent at meetings voting on each substance. Other stakeholders cautioned that any system that grouped substances into a single vote would reduce the transparency that is a hallmark of the National List review and approval process. Board members and public commenters also raised a number of procedural questions related to the mechanics of identifying which substances would be eligible for group voting and conditions that would result in a substance previously flagged for a group vote to be removed and voted on individually.

The PDS discussed the pros and cons of this sunset review efficiency process and decided that the potential time savings was not worth the potential confusion among Board members related to the voting procedure, and the potential for reduced transparency of the voting process among stakeholders. Instead, the PDS encourages Board members to present substances up for sunset review efficiently, focusing mostly on new information. NOSB will continue to vote individually on each substance up for sunset review.

Subcommittee Vote:
Motion to accept the discussion document on sunset review efficiency.
Motion by: Nate Lewis
Second by: Allison Johnson
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Chitosan
Spring 2026

Summary of Petition [December 2024 Petition]:

The petitioner is requesting that chitosan be classified as a nonsynthetic and added to the National List of Allowed and Prohibited Substances under 7 CFR 205.605(b) as a nonagricultural (nonorganic). The petition focuses on use of chitosan, derived from fungi, as a processing aid in winemaking, to improve clarification and filterability, prevent and treat volatile aromas, and boost microbial stability.

The petitioner requested its addition to the National List at § 205.605(b) so that chitosan may be used as a processing aid in organic wine production). Winemakers use chitosan for: clarification, filtration, stabilization and preservation, and enzyme and flavor enhancement.

The petitioner bases their request on chitosan's ability to achieve the following objectives:

- preventing microbial contamination and oxidation, thereby maintaining lower levels of sulfur dioxide
- eliminating spoilage microorganisms such as *Brettanomyces bruxellensis*, known for causing off-flavors
- removing oxidative precursors like catechins and inhibiting enzymes such as laccase that contribute to wine spoilage
- chelating pro-oxidant metals like copper and iron, thus reducing the potential for oxidation

Summary of Review:
The Handling Subcommittee finds chitosan, as petitioned, does not meet the OFPA criteria because sulfur dioxide is an already listed alternative.

Chitosan is currently used in nonorganic wine making. wine makers use chitosan derived from *Aspergillus niger* as a clarifying agent. The US Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau regulate the relevant legal uses of this substance (Draft 2026 TR). It is also referenced for allowed use in international organic programs such as the EU, UK, and Switzerland.

This petition's focus is on the use of fungi-derived chitosan as a nonsynthetic substance. The NOSB must consider the source, derivation methods, and end use. A previous petition focused on the crustacean extraction methods, which use harsh chemicals, and were previously recommended by NOSB to be synthetic and not allowed. While fungi sources naturally contain chitosan, commercial chitosan manufacturing methods still rely on chemical deacetylation of chitin. Thus, the material, as commercially produced, is synthetic according to the Decision Tree for Classification of Materials as Synthetic or Nonsynthetic (NOP 5033-1). The draft 2026 TR concludes that the fungi source is synthetic. There is potential for a version of this material to be classified as nonsynthetic in the future, if it is produced using enzymatic or other non-chemical methods to deacetylate the chitin to chitosan. At the end of the process, the synthetic materials used in the alkali deproteination and acid extraction are removed from the final product and have no technical or functional effect in the final product. However, after the extraction, chitin undergoes further chemical processing to become chitosan. The Subcommittee finds the commercial production of chitosan still relies on chemicals to produce the product and therefore, it is considered synthetic.

Category 1: Classification

1. Substance is for: ____x___ **Handling** _____ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or ___x____ **Non-Agricultural?**
   Describe reasoning for this decision using NOP 5033-2 as a guide:

   The substance is derived from a microorganism and not agriculture or livestock.

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __x__ **Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

   While fungi sources naturally contain chitosan, commercial chitosan manufacturing methods still rely on chemical deacetylation of chitin. After extraction, chitin undergoes further chemical processing to become chitosan. Thus, the material, as commercially produced, is synthetic according to the decision tree.

3. For **LIVESTOCK**: Reference to appropriate OFPA category
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   N/A

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   EPA has determined this ingredient to be of minimal risk. On January 9, 2023, the Environmental Protection Agency (EPA) added a substance commonly referred to as chitosan (also known by its chemical name: poly-D-glucosamine) (CAS No. 9012-76-4) to the list of active ingredients eligible for use in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In doing so, EPA is specifying that the listing also includes those chitosan salts that can be formed when chitosan is mixed with the acids that are listed as active or inert ingredients eligible for use in minimum risk pesticide products.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   In agricultural practice, chitosan acts as an induced resistance promoter characterized by its ability to stimulate internal mechanisms of treated plants to resist plant pathogens (US EPA, 2007). As an antimicrobial pesticide, chitosan employs antibacterial properties to protect fabrics from bacterial and fungal growth (US EPA, 2007). Antibacterial modes of action may include, but are not limited to, disruption of bacterial cell membranes or cell wall integrity, inhibition of respiration, interactions with bacterial DNA/RNA, and/or physical deposition (smothering) (review by Malerba and Cerana, 2016). No known adverse effects have been reported for humans and other non-target organisms following agricultural, biopharmaceutical, biomedical, cosmetic, textile, and food additive applications of products containing chitosan.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

   Chitosan is widely used in agricultural, biopharmaceutical, biomedical, cosmetic, textile, and food additive applications with no known reports of adverse effects to humans and the environment. Based on information obtained from studies submitted to the EPA in support of product registrations, and from the open technical literature, chitosan has been shown to have minimal acute and sub-chronic toxicity, is not a sensitizer or an allergen, and is not genotoxic, mutagenic, or carcinogenic. In addition to exposure to humans and the environment via intentional uses of chitosan-containing products, naturally occurring chitosan, as well as its sole natural source, chitin, are widespread in the environment in the form of shells of aquatic organisms (e.g., marine and freshwater crustaceans and molluscs), soil microorganisms, and insect exoskeletons. The apparent ubiquitous presence of chitosan-degrading bacteria in soils indicates that chitosan is readily biodegraded in soils and may be important in the biocycling of chitin and chitin derivatives (likely derived from soil fungi) in the environment. Chitosan applied as a minimum-risk pesticide likely would not persist in the environment due to ubiquitous presence of chitosan-degrading microorganisms.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

   Chitosan has minimal acute toxicity and is classified in Toxicity Category IV for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, acute eye irritation, and acute dermal irritation; it is not a skin sensitizer (Draft 2026 TR).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   No adverse effects are expected when non-target organisms are exposed to chitosan. Chitosan is produced naturally in several species of marine bacteria, fungi, and some insects and may serve as a protective mechanism against pathogen infection (Draft 2026 TR). Positive effects on plant growth and the suppression of plant pathogens in the soil rhizosphere and plant foliage have been reported by numerous authors (Draft 2026 TR).

6. Are there any adverse impacts on biodiversity? (§205.200)

   At the rates this substance is applied, no adverse impacts on biodiversity are expected. The environmental fate of chitosan (poly-D-glucosamine) has not been thoroughly investigated, although many soil types have been reported to contain chitosan-degrading bacteria. The apparent ubiquitous presence of chitosan-degrading bacteria in diverse soil types indicates that chitosan may be readily degraded in soils and may be important it the biocycling of chitin and chitin derivatives in the environment(Draft 2026 TR). Few studies were identified that assessed the rates of Chitosan biodegradation in soil.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The National List currently includes a number of fining agents, filter aids, antioxidants, and antimicrobials for use in wine: nonsynthetic bentonite, carrageenan, diatomaceous earth, enzymes, gums, yeast, kaolin, and perlite, and synthetic sulfur dioxide, activated carbon, ascorbic acid, and silicon dioxide (Draft 2026 TR).

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)].

   N/A

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

   Chitin, from which chitosan derives, is the second most abundant polysaccharide biosynthesized on earth, after cellulose (Roberts, 1992). Chitin is an important constituent of the exoskeleton in many shelled aquatic (e.g., crustacea) and land (e.g., molluscs, insects) organisms (Draft 2026 TR). In addition, it is the principal fibrillar polymer in the cell wall of certain fungi (Draft 2026 TR). Both chitin and chitosan occur naturally as structural components in the cell walls of fungal classes Basidiomycota, Ascomycota, Mucoromycota (formerly Zygomycota), and Deuteromycota (Draft 2026 TR). Chitosan is chemically extracted from naturally occurring organisms that contain chitin. *Aspergillus niger* is one fungal species that naturally produces chitosan in its cell walls.

   Most commercial production of chitosan relies on artificially deacetylating chitin from crustaceans in order to produce chitosan (Draft 2026 TR). Unlike with crustacean sources, chitosan derived from fungi avoids the need for the demineralization and decolorization steps. Chitosan is neutral pH (6-7) and presents several interesting functional properties such as antimicrobial activity, antioxidant activity, absorptivity, metal chelation ability, film- and coating-forming ability, flocculation, and biocompatibility (Draft 2026 TR).

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

   The environmental impact and disposal costs of processing waste have benefits and drawbacks. The benefits are that chitosan is more environmentally friendly and has lower disposal costs of effluents as compared to the traditional methods for disposing of shellfish waste. Utilizing the shellfish waste stream as a source of raw materials is upcycling the materials that would otherwise be the waste. The drawbacks are with potential risks of dispersal of pathogenic fungi when dealing with species not satisfying the generally regarded as safe (GRAS) requirements.

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

   In 2011, the FDA released GRAS Notice No. GRN 397 pertaining to the use of chitosan from the fungus *Aspergillus niger* (Draft 2026 TR). According to numerous sources cited in the draft 2026 TR, chitosan is nearly non-toxic to humans and most other animals, and its degradation products do not cause side effects in the body (Draft 2026 TR).

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

   The petition focuses on use of chitosan, derived from fungi, as a processing aid in winemaking, to improve clarification and filterability, prevent and treat volatile aromas, and boost microbial stability.

   The petitioner requested its addition to the National List at § 205.605(b) so that chitosan may be used as a processing aid in organic wine production. Winemakers use chitosan for clarification, filtration, stabilization and preservation, and enzyme and flavor enhancement.

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

   In 2011, the FDA released GRAS Notice No. GRN 397 pertaining to the use of chitosan from the fungus *Aspergillus niger* (US FDA, 2011). Chitosan currently used in wine making: Wine makers use chitosan derived from *Aspergillus niger* as a clarifying agent. The US Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau regulate the relevant legal uses of this substance (US FDA, 2023a). It is also referenced for allowed use in reciprocal Organic programs such as the EU, UK, and Switzerland.

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

   Not essential. Multiple materials currently included on the National List serve similar functions.

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   The Subcommittee finds that the substance as petitioned is synthetic and does not meet the OFPA criteria. This petition's focus is on the use of fungi derived chitosan. A previous petition focused on the crustacean extraction methods, which use harsh chemicals, and were previously ruled as not allowed. While fungi sources naturally contain chitosan, commercial chitosan manufacturing methods still rely on chemical deacetylation of chitin. Thus, the material, as commercially produced, is synthetic according to the decision tree. Potential for this to be nonsynthetic in the future using enzymatic or other non-chemical methods to deacetylate the chitin to chitosan. Synthetic chitosan is not essential to organic production, because materials already included on the National List can be used for the petitioned uses.

Category 5: Additional criteria for agricultural substances used in Handling (review of commercial unavailability of organic sources):

N/A. Chitosan is non-agricultural.

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?

5. Does the industry information about unavailability include (but is not limited to) the following?:
   Regions of production (including factors such as climate and number of regions);
   Product is readily available and supply is not a concern.
   a. Number of suppliers and amount produced.
   b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies.
   c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or none.
   d. Other issues which may present a challenge to a consistent supply?

6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?

  Chitosan extracted from chitin is in its pure chemical form and does not contain ancillary ingredients. However, the petitioner mentions that their product contains inactivated yeast, ascorbic acid (E 300) and lactic acid (E 270), all of which are on the National List at §205.605(a) or (b). Other commercial chitosan products used in wine processing might contain other ingredients (e.g., enzymes, colloidal silica) that also function in wine clarification, as described in *Combinations of the Substance*.

- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?

  Yes chitosan can be derived from an abundant natural resource. Chitosan is a relatively benign product and also has the advantage of taking a waste stream of seafood shells and converting them into a useful recycled product. Both chlorine and sodium hydroxide are energy-intensive, toxic chemicals used in the production of chitosan, and must be considered.

- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?

  Chitin, from which chitosan derives, is the second most abundant polysaccharide biosynthesized on earth, after cellulose (Roberts, 1992). Chitosan is chemically extracted from naturally occurring organisms that contain chitin. *Aspergillus niger* is one fungal species that naturally produces chitosan in its cell walls. Most commercial production of chitosan relies on artificially deacetylating chitin from crustaceans in order to produce chitosan (Shigemasa & Minami, 1996). Unlike with crustacean sources, chitosan derived from fungi avoids the need for the demineralization and decolorization steps.

- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?

  According to numerous sources cited in the draft 2026 TR, chitosan is nearly non-toxic to humans and most other animals, and its degradation products do not cause side effects in the body.

- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?

Chitosan is chemically extracted from naturally occurring organisms that contain chitin. *Aspergillus niger* is one fungal species that naturally produces chitosan in its cell walls. Fungal chitosan is usually produced by fermenting *Aspergillus niger* on standard culture. The 2020 Crops TR provides more information on chitosan extraction from crustacean sources. Compared with fungal chitosan, extraction of chitosan from crustaceans generally involves two additional steps: demineralization and decolorization.

- Does the substance allow for an increase in the long-term viability of organic farm operations?

  There is no history of using chitosan in USDA certified organic handling/processing. However, chitosan of fungal origin is approved as a clarifying agent in organic winemaking in the European Union and the UK since 2009 (International Organization of Vine and Wine, 2009). If chitosan could be utilized as a total replacement option for SO2 compounds then it would have clear need.

- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?

  None

- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?

  No, the petitioner is requesting a change in classification from synthetic to nonsynthetic and allowance for use at 205.605. A final rule, published December 10, 2007 (72 FR 69569), clarifies that chitosan is covered under "EPA List 4" listing at § 205.601(m).

- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?

  The US Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau regulate the relevant legal uses of this substance (Draft 2026 TR).

- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?

  Chitosan of fungal origin is approved as a clarifying agent in organic winemaking in the European Union and the UK (Draft 2026 TR).

- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?

  There is sufficient information to make a determination about compliance, as it has been reviewed multiple times. Documents used for this review include the 2020 Crops Technical Report, the October 2021 NOSB Subcommittee Proposal (plant disease control), the October 2021 NOSB Recommendation (plant disease control), and the December 2024 Petition requesting classification as a nonsynthetic substance.

- Does use of the substance have a positive impact on biodiversity?

  At the rates this substance is applied, no adverse impacts on biodiversity are expected.

Classification Motion:

Motion to classify chitosan as petitioned as synthetic
Motion by: Andrea Hatziyannis
Seconded by: Allison Johnson
Yes: 4 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add Chitosan as petitioned to the national list, § 205.605(b)
Motion by: Andrea Hatziyannis
Seconded by: Amanda Felder
Yes: 0 No: 4 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Sodium Bicarbonate Reclassification Proposal
Spring 2026

Introduction
The Handling Subcommittee requested the reclassification of sodium bicarbonate as a work agenda as a result of its review of the 2025 technical report (TR) during the sunset review process. Due to the age of the information regarding sodium bicarbonate's classification (from 1995 TAP) and the concerns raised during the previous sunset review regarding the substances manufacturing processes and classification, the Handling Subcommittee requested a new TR.

The Handling Subcommittee proposes to update the regulations to align with the types of sodium bicarbonate in use today.

Background
Sodium bicarbonate was added to the National List with the first publication of the National Organic Program (NOP) Final Rule (65 FR 80548, December 21, 2000). This substance had a Technical Advisory Panel Report (TAP) from 1995. The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review.

The 2025 TR explains the historical classification of sodium bicarbonate: During the 1995 NOSB meeting in Orlando, Florida, the NOSB voted to classify sodium bicarbonate as nonsynthetic. Prior to the Board's vote, a TAP report was conducted that briefly described the manufacturing process for sodium bicarbonate. Publicly available notes from the NOSB meeting do not contain any further details regarding the decision to classify sodium bicarbonate as nonsynthetic, or which forms are nonsynthetic. The classification recommended by the NOSB in 1995 was not based on the decision tree in Guidance NOP 5033-1: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, which was not published until 2016. The 1995 TAP review only discussed two manufacturing processes, neither of them being the direct method from nahcolite. Based on the NOSB recommendation and the listing of sodium bicarbonate on 7 CFR 205.605(a) as nonsynthetic, many certifiers and material review organizations consider sodium bicarbonate from trona ore as nonsynthetic, and sodium bicarbonate from the Solvay process as synthetic (2025 TR, lines 757-769).

However, in recent rounds of sunset review (after the publication of NOP 5033-1) stakeholders have questioned the classification.

Discussion
The 2025 TR explains the various manufacturing processes of sodium bicarbonate and the resulting synthetic or nonsynthetic classification, as well as which forms are primarily available for commercial uses.

1. **Sodium bicarbonate produced from sodium carbonate:** Food-grade sodium bicarbonate is primarily derived from the carbonation of a refined sodium carbonate precursor. There are two primary ways to produce sodium bicarbonate from sodium carbonate: the Solvay process or from trona ore.
    a. **Solvay process** (2025 TR, lines 783-789)
    The Solvay process utilizes ammonia, a synthetic reactant produced through the Haber-Bosch process. The Solvay process involves a displacement reaction between sodium

chloride and ammonia, which takes place in the presence of carbon dioxide, derived from calcium carbonate. This reaction facilitates the formation of sodium bicarbonate. Due to this, the material is synthetic because it is not manufactured from a natural source.

b. **Trona ore processing** (2025 TR, lines 791-813)
Sodium bicarbonate is manufactured through carbonation using two precursors (sodium carbonate and carbon dioxide).
    - The sodium carbonate precursor is produced by calcining (heating) sodium sesquicarbonate, which is mined. Sodium sesquicarbonate is a double salt of sodium carbonate and sodium bicarbonate. The calcination process decomposes sodium sesquicarbonate, ultimately releasing carbon dioxide and water. This converts the double salt into the single salt, sodium carbonate.
    - The carbon dioxide precursor may be derived from the calcination of lime, from carbon dioxide wells, from fermentation processes, from calcination of sodium sesquicarbonate, or from other sources.
    - Sodium carbonate is combined with carbon dioxide and water to produce sodium bicarbonate.

    According to the decision tree, a chemical change caused by heating a mineral results in a synthetic material. Furthermore, to create sodium bicarbonate, the material undergoes another chemical reaction to transform sodium carbonate into sodium bicarbonate via carbonation.

2. **Sodium bicarbonate extraction from nacholite deposits:** Nahcolite deposits of sodium bicarbonate are recovered through solution mining operations in the Green River area of Colorado. Hot, pressurized water is pumped into wells, and the saturated solution is cooled to precipitate sodium bicarbonate. This is the only common process to generate sodium bicarbonate directly from a mineral, without further chemical reactions (2025 TR, lines 547-551). According to evaluation question #1C in the 2025 TR, sodium bicarbonate extracted from nahcolite bed solution mining is nonsynthetic (2025 TR, lines 773-781). While sodium bicarbonate can be directly extracted from a mineral (nahcolite), this source is not as common as other sources (described above).

Due to the lack of clarity regarding the original listing and the fact that many certifiers believed sodium bicarbonate produced via trona ore to be nonsynthetic, it appears that much of the sodium bicarbonate in use today is actually synthetic.

To resolve this, two options were considered by the Subcommittee:
1. Keep the nonsynthetic listing only. This would significantly limit the allowed sodium bicarbonate, as any sodium bicarbonate produced from the processing or trona ore would be prohibited.
2. Add a listing for synthetic sodium bicarbonate produced via trona ore processing only. This would align with the status quo of certification decisions and prohibit synthetic sodium bicarbonate produced using the Solvay process.

The Subcommittee chose to move forward with the second option. This appears to align with the original intent of the listing (although it was inaccurate) and would not impact the market, whereas excluding sodium bicarbonate produced from the processing of trona due to its now known synthetic status could have significant market impact.

Summary of Proposal:

The Subcommittee proposes adding synthetic sodium bicarbonate to 7CFR 205.605(b).

Classification Motions:
Motion to classify sodium bicarbonate extracted from nahcolite deposits as nonsynthetic.
Motion by: Kyla Smith
Second by: Andrea Hatziyannis
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Motion to classify sodium bicarbonate produced from sodium carbonate (e.g. Solvay and trona ore) as synthetic.
Motion by: Kyla Smith
Second by: Amanda Felder
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

National List Motion
Motion to add synthetic "sodium bicarbonate – produced via trona ore processing only" to 7CFR 205.605(b).
Motion by: Kyla Smith
Second by: Andrea Hatziyannis
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Sunset 2028
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), & § 205.606
Spring 2026

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 coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances 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, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2026 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2026 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

Public comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic handling.

For Comments that Do Not Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:
If you provide comments that do not support a substance on § 205.605(a), § 205.605(b), and/or § 205.606, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments Addressing the Availability of Alternatives:
Comments may include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

For Comments on Nonorganic Agricultural Substances at Section § 205.606:
For nonorganic agricultural substances on section § 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e., is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. Comments received after that date may not be reviewed by the NOSB before the meeting.

§ 205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'':

- Agar-agar
- Animal enzymes
- Calcium sulfate-mined
- Carrageenan
- Glucono delta-lactone
- Tartaric acid

§ 205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’:

- Cellulose
- Chlorine materials
    - (i) Calcium hypochlorite
    - (ii) Chlorine dioxide
    - (iii) Hypochlorous acid—generated from electrolyzed water
    - (iv) Sodium hypochlorite
- Potassium hydroxide
- Potassium lactate
- Silicon dioxide
- Sodium lactate

Agar-agar

Reference: § 205.605(a)(2)
Technical Report: 1995 TAP; 2011 TR; 2025 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Agar-agar has been used as a food additive for over 350 years. Current uses in food include stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. Agar-agar can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. A useful characteristic of agar-agar is its ability to withstand high temperatures. Since agar-agar is practically tasteless and does not require the addition of cations to form gels, it doesn't interfere with taste profiles. Agar-agar can be used in foods in combination with other thickening or gelling agents. Agar-agar is classified as generally recognized as safe (GRAS) by the FDA.

Manufacture
Agar-agar is a mixture of polysaccharides derived from the cell walls of red algae (seaweed) that live in marine environments, mainly from the cultivated genus *Gracilaria*. The amount and composition of agar-agar produced is highly variable within and across individuals, species, locations, and time of year [2025 TR, lines 169-170]. Specific manufacturing processes are generally confidential.

Algae are cultivated on floating rafts, bottom cultivation or in tanks or ponds. Algae that washes ashore may also be gathered. Algae are harvested, washed, and dried by sun or in ovens.

Prior to extraction, the *Gracilaria* species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution); others may receive mild acidic pretreatments. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides that produce agar-agar with increased gel strength. Without this pretreatment, the gels extracted from *Gracilaria* species would be too weak for most commercial production [2025 TR, lines 138-142]. Other algal species (*Gelidium* and *Pterocladia*) have a more active natural process that results in higher gel strength and lower gelling temperatures, but these species are much more difficult to cultivate; demand for the agar-agar from these species is high for use in pharmacology and microbiology applications, and shortages have occurred [2025 TR, lines 146-151].

After pretreatment, the agar-agar is extracted with boiling or hot water, followed by filtration. Water is removed from the gel through a freeze-thaw process or by mechanical pressure. The gel is then dried with hot air and may be shredded or milled, resulting in a finished product of flakes, strips, or powder.

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

- **Agar** is permitted as a soil amendment for use in initial mushroom spawn production (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).

- **Agar** is permitted. See Table 6.3 Extraction solvents and precipitation aids (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Microorganisms are permitted. Microbial preparations may contain substrates derived from agricultural or biological substances such as milk, lactose, soy, **agar**, etc. May also contain permitted carriers (see Table 6.3 & 6.4 Carriers). Includes starter and dairy cultures and other preparations of microorganisms normally used in product processing (Table 6.4 - Ingredients not classified as food additives, CAN/CGSB-32.311-2020).

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

- **Agar** is permitted in products of plant origin, milk-based products, and meat products (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- **Agar** is permitted in food of plant origin, although exclusions of the GSFA still apply. **Agar** is permitted in food of animal origin, although exclusions of the GSFA still apply (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Agar** is permitted as an additive (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Agar-agar** is not explicitly mentioned in the regulations.

Ancillary Substances

According to EU regulations, gel strength may be standardized by the addition of dextrose and maltodextrin or sucrose. Various materials may be used in the production process, but these steps are all followed by washing [2025 TR, 485-488]. After filtering of the crude gel, researchers mention the possible use of bleach or amylase, or precipitation with isopropanol, to remove algal residue [2025 TR, lines 490-491].

Human Health and Environmental Issues

Industrial agar-agar production requires large quantities of both alkali materials for pretreatment and energy to sustain high temperatures for several hours [2025 TR, lines 295-296]. The typical process takes 2-4 hours for extraction, consumes energy and water (15-20 times the weight of dry algae used, not including washing or freeze-thawing), and generates waste [2025 TR, lines 296-300]. These materials are costly in terms of waste disposal and exposure to employees and the environment.

Discussion

In 2011, the Handling Subcommittee voted unanimously to add agar-agar to the § 205.605(b) list of allowed synthetics, while retaining the nonsynthetic listing at § 205.605(a). However, based on public comments, the Subcommittee ultimately determined that the classification determination should be made after the Guidance NOP 5033-1, Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, was finalized. That Guidance has been completed, and the 2025 TR concludes that the most widely used form of agar-agar – alkali-extracted – is synthetic [2025 TR, line 472].

Given that current uses likely include synthetic agar-agar, the Handling Subcommittee is considering recommending the addition of synthetic agar-agar to the National List, while retaining the nonsynthetic listing as well, to align the regulation with practice.

Questions to our Stakeholders

1. What form(s) (nonsynthetic or synthetic) of agar-agar are currently in use in organic products?
2. Is agar-agar commonly used in organic products?

Animal enzymes

Reference: § 205.605(a)(3) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Technical Report: 2000 TAP; 2011 TR; 2015 Limited Scope TR (ancillary substances in enzymes)

Petition(s): N/A

Past NOSB Actions: 11/2000 meeting minutes and vote; 11/2007 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation

Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)

Sunset Date: 05/29/2028

Subcommittee Review

Use

Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients [2011 TR, lines 140-142]. Animal enzymes, such as rennet, are used as a coagulant to curdle milk to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect.

Manufacture

Traditionally, the fourth stomach of calves or goat kids is dried, cleaned, and then sliced into pieces, before being stored in either whey or saltwater. Vinegar or wine can be added to lower the pH. After allowing the solution to sit for a few days, it is filtered repeatedly. A small amount of boric acid is added to the filtrate. In industrial production, the stomach is minced, and the pH adjusted by adding hydrochloric acid and sodium phosphate [2011 TR, lines 444-458].

International Acceptance

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

- Enzymes are permitted as soil amendments and as production aids. Derived from plants, **animals** or microorganisms through the action of microorganisms are permitted (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Enzymes are permitted. Derived from plants, **animals** or microorganisms. Examples include, but are not limited to, bromelain, **bovine liver catalase**, ficin, **animal lipase**, malt, **pancreatin**, **pepsin**, **trypsin**, proteases and carbohydrases. **Animal-derived enzymes** shall be free of Specified Risk Material (SRM). This annotation will be reviewed at the next revision of the standard (Table 5.2 - Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- The following sources of enzymes are permitted: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) **derived from animals**—shall be organic if commercially available: **rennet**; **catalase from bovine liver**; **animal lipase**; **pancreatin**; **pepsin**; and **trypsin**. Animal-

derived enzymes shall be free of Specified Risk Material (SRM); and c) egg white lysozyme (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

- The following sources of enzymes are permitted: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) **animal-derived**—shall be organic if commercially available: **rennet**; **catalase from bovine liver**; **animal lipase**; **pancreatin**; **pepsin**; and **trypsin**. **Animal-derived enzymes** shall be free of Specified Risk Material (SRM); c) egg white lysozyme (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).

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

- In the processing of food, the following products and substances may be used: (a) preparations of micro-organisms and **food enzymes** normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production (Processed food production rules, EC No. 2018/848).
- For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including **food enzymes** to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008 of the European Parliament and of the Council and, where applicable, in accordance with national provisions based on Union law (Food additives and processing aids, EC No. 2021/1165).
- **Enzymes** and micro-organisms are permitted silage additives, only authorised to ensure adequate fermentation (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).
- **Enzymes** and micro-organisms are permitted zootechnical additives (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).

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

- Specific criteria for additives and processing aids: a) binders, anti-caking agents, emulsifiers, stabilizers, thickeners, surfactants, coagulants: only natural sources are allowed; b) antioxidants: only natural sources are allowed; c) preservatives: only natural acids are allowed; d) colouring agents (including pigments), flavours and appetite stimulants: only natural sources are allowed; e) probiotics, **enzymes** and micro-organisms are allowed; f) antibiotics, coccidiostatics, medicinal substances, growth promoters or any other substance intended to stimulate growth or production shall not be used in animal feeding (Livestock and livestock products: Nutrition, CXG 32-1999).
- Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only: sea salt; coarse rock salt; yeasts; **enzymes**; whey; sugar; or sugar products such as molasses; honey; lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority (Livestock and livestock products: Nutrition, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Fodder preservatives such as the following may be used: a. bacteria, fungi and **enzymes**; b. natural products of food industry; c. plant based products; d. vitamins and minerals subject to 5.5.6. (Animal Nutrition, IFOAM NORMS 2014).
- Preparations of micro-organisms and **enzymes** commonly used in food processing may be used, with the exception of genetically engineered microorganisms and their products. Cultures that

are prepared or multiplied in-house shall comply with the requirements for the organic production of microorganisms (Ingredients, IFOAM NORMS 2014).

- Additives and processing aids from biological sources, such as fermentation cultures, **enzymes**, flavors, and gums must be derived from naturally occurring organisms by the use of biological, mechanical, and physical methods. Nonorganic forms are allowed in organic products only if there are no organic sources (Source and Manufacturing Process, IFOAM NORMS 2014).
- These may be used as ingredient or processing aids with approval from the control body: organic certified micro-organisms; preparations of micro-organisms; **enzymes and enzyme preparations** (Preparations of Micro-organisms and Enzymes for use in food processing, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Enzymes** are permitted (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Enzymes** are permitted (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Enzymes** are permitted (Table B.1 - Additives for alcohol beverages, JAS 1606 Organic Processed Foods).
- **Enzymes** are permitted (Table A.1 - Substances used in the preparation etc., JAS 1607 Organic Feed).
- Any feeds other than those (feeds) listed below must not be given **enzymes** or microorganisms (excluding those that have been produced using recombinant DNA technology) (Feeding, JAS 1608 Organic Livestock Products).

Ancillary Substances

Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients. In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation. Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients, which function as diluents, preservatives, stabilizers, antioxidants, etc. These additives must be generally recognized as safe (GRAS) or be FDA approved food additives for this use [2015 TR, lines 34-40].

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis. To control microbial contamination of enzyme preparations, preservatives are added [2015 TR, lines 54-59]. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations [2015 TR, lines 72-81].

Ancillary Substances by Food Additive Functional Class

Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide, calcium stearate, magnesium silicate/talc, magnesium sulfate.

Carriers and fillers	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate, calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, purity gum (starch), saccharose, sorbitol, soy flour, sunflower oil, trehalose, vegetable oil, microcrystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	Sodium benzoate, potassium sorbate, ascorbic acid, alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.
Stabilizers	Maltodextrin, betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers	Acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Human Health and Environmental Issues
Producing or using animal enzymes does not negatively impact biodiversity or the environment. Since only small quantities are used, and the enzymes break down naturally, their release poses no environmental threat.

Discussion
There are no direct substitutes for animal-derived enzymes; an enzyme must be replaced with another that performs the same function. For example, one replacement for animal-sourced rennet in cheese production is genetically engineered chymosin, though its use is not compatible with organic food standards because of excluded methods involved in its creation [2011 TR, lines 809-812]. The 2000 TAP report indicated that animal enzymes could potentially be sourced from organic livestock.

During the comment period for the 2021 Spring meeting, most participants supported keeping animal enzymes on the National List. Comments highlighted the lack of organic animal enzymes, difficulties in establishing a consistent organic source, and cost concerns. Many noted that alternatives are insufficient for making certain varieties of cheese. Only one opposing comment called for further research into the necessity of catalase, animal lipase, pancreatin, pepsin, and trypsin.

Questions to our Stakeholders
1. What is the feasibility of producing animal enzymes from organic livestock? What would be barriers?
2. Are there any concerns regarding source materials from non-organic sources?
3. What challenges do certifiers encounter when verifying the origin and compliance of animal-derived enzymes?
4. What is the environmental impact of animal-derived enzymes vs. microbial/fermentation-based alternatives?
5. Are all of the animal enzymes listed necessary and being used in organic production?

Calcium sulfate-mined

Reference: § 205.605(a)(8)
Technical Report: 1996 TAP; 2001 TAP
Petition(s): 2000
Past NOSB Actions: 09/1996 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

- Coagulate in tofu manufacturing. Calcium sulfate is essential for traditional, soy-based tofu.
- Yeast food and dough conditioner, water conditioner.
- Firming agent (in canned foods).
- Jelling ingredient.
- Baking powder.
- Anticaking agent.

Manufacture

Calcium sulfate is produced either by mining naturally occurring mineral deposits or as a byproduct of industrial processes. The listing restricts calcium sulfate to mined sources, and mined gypsum is the primary source. After crude gypsum is mined in open-cast quarrying or via deep mining, it is ground and separated. It is normally sold in pure form but may contain impurities of calcium carbonate and natural occurring silica. These impurities are typically present at low levels and are reduced through physical processing such as crushing, screening, washing, or drying, but the material is not chemically synthesized or purified. Synthetic calcium sulfate can form as a by-product from many different processes, including from emissions from fossil fuel power stations. The material is generally recognized as safe (GRAS) by the FDA.

International Acceptance

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

- Calcium is permitted with the following origin/usage conditions: calcium carbonate (calcitic limestone), calcium magnesium carbonate (dolomitic limestone), calcium silicate, and **calcium sulphate (gypsum), all from mined sources**. Other biological or mineral sources, such as shells from aquatic animals (for example, oyster shell flour), aragonite, eggshell meal and lime from sugar processing. Calcium chloride derived from naturally occurring brines and not chemically treated. Prohibited forms include slaked limestone (calcium hydroxide); quicklime (calcium oxide); **calcium sulphate produced using sulphuric acid and calcium products that have been used in controlled atmosphere storage** (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Calcium sulphate (gypsum)** is permitted as a soil amendment with the following origin/usage conditions: **from mined sources** are allowed; **calcium sulphate produced using sulphuric acid is prohibited**. To correct calcium and sulphur deficiencies and soil salinity problems (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Calcium sulphate (gypsum) from mined sources** is permitted; **calcium sulphate produced using sulphuric acid is prohibited** (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

- **Calcium sulphate (gypsum)** is permitted. Sulphates produced using sulphuric acid are prohibited. May be used: a) as a carrier for cakes and biscuits; b) for soybean products; and c) for bakers' yeast (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).

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

- **Calcium sulphate (gypsum)** is permitted in products of natural origin containing calcium sulphate at various degrees of hydration. Minimum content of nutrients (percentage per weight): 25% CaO; 35% SO_3. Calcium and sulphur expressed as total CaO + SO_3. Fineness of grind: at least 80% to pass through a sieve with a 2 mm mesh width; at least 99% to pass through a sieve with a 10 mm mesh width. From 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply (Annex II: Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- **Calcium sulphate** is permitted in products of plant origin as a carrier (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- **Calcium sulphate** is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- **Gypsum (calcium sulphate)** is permitted, only from natural sources/origin (Table 1 - Substances for use in soil fertilizing and conditioning, CXG 32-1999).
- **Calcium sulphate** is permitted in food of plant origin: soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10); cakes, cookies and pies (e.g. fruit-filled or custard type); yeast and like products; soybean protein products; fermented soybean products. **Calcium sulphate** is not permitted in food of animal origin (Table 3 - Ingredients of non-agricultural origin, CXG 32-1999).
- **Calcium sulphate** is permitted for plant products as a coagulation agent (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Calcium sulfate** is permitted as an additive for soybean products, confectionery, and in bakers' yeast (Appendix 4, Table 1: List of approved additives and processing/postharvest handling aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- In the cases where it is difficult to obtain the spawns specified in (a)-(c), spawns [can be] cultured by using the following cultivation substances: 1) yeast extract, 2) malt extract, 3) sugar, 4) glucose, 5) calcium carbonate, 6) **calcium sulfate** (Spawns, JAS 1605 Organic Products of Plant Origin).
- Gypsum (calcium sulfate) is permitted with the following criteria: natural substances or substances derived from natural sources which have not undergone any chemical treatment (Table A.1 - Fertilizers and soil improvement substances, JAS 1605 Organic Products of Plant Origin).
- **Calcium sulfate** is permitted with the following criteria: limited to the use as a coagulant, or in confectionery, prepared legumes/beans, or baker's yeast (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Calcium sulfate** is permitted (Table B.1 - Additives for alcohol beverages, JAS 1606 Organic Processed Foods).

Ancillary Substances

None reported in the 2001 TAP.

Human Health and Environmental Issues
Calcium sulfate may be obtained from natural sources, with mined gypsum being the primary natural source. Gypsum is one of the most widely used minerals worldwide, and the United States is the largest producer. Gypsum is mined across many regions of the United States and Canada, with a significant share of production concentrated in a small group of leading states. Most deposits occur as gypsum in the dihydrate form, although anhydrite also occurs naturally. The mining of calcium sulfate involves quarrying or blasting and the use of heavy equipment, generating gypsum dust in the process. This dust can affect air quality and can be a potential exposure hazard to humans and other animals. There are no other known negative effects of toxicity and/or persistence in the environment caused by production of calcium sulfate from these methods, if standard regulations for proper mining activities are followed.

Discussion
In organic handling and processing, calcium sulfate is utilized because it is naturally derived and minimally processed with a long history of safe use. Its necessity is limited to specific applications, such as traditional tofu production, where few alternatives provide equivalent functionality without compromising product quality or organic principles. In past sunset reviews, manufacturers and trade associations have emphasized its use in tofu production. It was also noted that calcium sulfate was used in the brewing industry to adjust the mineral content of water. One interest group asked that its use be limited to coagulation of bean curd, noting evidence was not available for its use in other food applications. During the last sunset review in 2021, the Board agreed that this material satisfies the OFPA evaluation criteria and unanimously supported the relisting of calcium sulfate.

Questions to our Stakeholders
1. Are there any alternative coagulants or processing aids that could replace calcium sulfate without compromising quality or organic principles?
2. Are there specific applications where calcium sulfate is essential versus optional?
3. How would limiting or restricting its use impact your production processes or product offerings?

Carrageenan

Reference: § 205.605(a)(9)
Technical Report: 1995 TAP; 2011 TR; 2016 Limited Scope TR; 2026 Limited Scope TR

Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987 – misspelled as 'carageenan'); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Carrageenan is a food additive used as an emulsifier, thickener, and gelling compound primarily in meat and dairy products. It is often used as a vegan alternative to animal-sourced gelatin. Carrageenan provides a 'mouthfeel' similar to that of fatty foods and thus may be used in low fat or dairy replacement products (Zhang et al., 2024a). Carrageenan is listed as an FDA-approved food additive at 21 CFR 172.620, and is allowed for use as an emulsifier, stabilizer or thickener in foods in the amount necessary to have the

intended effect. In Europe, carrageenan is not allowed in infant formula, while China restricts the amount allowed in baby formula (Zhang et al. 2024a).

Manufacture
Carrageenan is made through three common methods of production: alcohol process, gel process, and semi-refined process. In all processing methods, the finished carrageenan is produced through a fairly simple process of heating edible red algae in a hot alkali solution, typically using potassium hydroxide. The cellulose from the plant is then removed through centrifugation and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder for addition to foods.

The three main kinds of carrageenan (kappa, iota, and lambda carrageenan) are extracted from different seaweed species (or are extracted from seaweed at different life stages) and are distinguished chemically by the number and position of ester sulphates on the carbohydrate units in the molecules. This information is relevant, as the different types have different properties and uses in the food industry, but are not distinguished in food labelling:

- Kappa-carrageenan – forms strong gels in combination with potassium ions and is used primarily in dairy products.
- Iota-carrageenan – forms soft gels in the presence of calcium ions.
- Lambda-carrageenan – does not gel and is used to thicken dairy products.

Historically, the seaweed used to make carrageenan grew in small patches along the coastline and required a large amount of labor to harvest (Langford, 2024a). Larger scale farming of seaweed was unsuccessful until 1974, when a location in the South Philippines had all the necessary components to allow for seaweed farms to thrive. About a decade later seaweed farming also became viable in Indonesia (Langford, 2024a). An innovation in processing reduced the cost of processing carrageenan in the 1990s (Langford, 2024a). This allowed seaweed farming to emerge in other tropical regions, but 92 percent of the supply still comes from the Philippines and Indonesia (Langford, 2024b). In 2021, Indonesian seaweed (carrageenan) production totalled 7.1 metric tons (Langford, 2024b). Processing plants are located in China, Philippines, and Indonesia (Zhang et al., 2024a). China is the top country in terms of carrageenan processing, both domestically and through heavy investment in processing facilities in Indonesia (Zhang et al., 2024b).

In 2018, the carrageenan industry was valued at $500 million, with production equal to 60,000 metric tons in China, Indonesia, and Philippines (Taylor, 2019). The volume of carrageenan used in dairy products and processed meats remained relatively stable between 2009 and 2019, while the amount used for bakery, confectionary, and beverages increased by a sizeable amount (Zhang et al., 2024a). The market for carrageenan is expected to increase 3.8 percent in volume and 5.4 percent in value between 2023 and 2030 (Zhang et al., 2024a).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids. By exception, isopropyl alcohol may be used to derive carrageenan.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
The EEC allows carrageenan as an additive to organic dairy foods, and its use is prohibited in all baby formula.

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

Permitted, although exclusions and limitations as specified by the GSFA still apply.

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM allows carrageenan as a food additive with no annotations.

Japan Agricultural Standard (JAS) for Organic Production
Limited to use in dairy products.

Ancillary Substances
The 2026 limited-scope TR indicates that manufacturers may include the following ancillary materials in food-grade carrageenan [2026 TR lines 578-595]:

- sugars for standardization purposes (e.g., dextrose or maltodextrin)
- sodium, potassium, or calcium salts to obtain specific gelling or thickening characteristics
- emulsifiers carried over from drum-drying processes (e.g., xanthan gum)

Food-grade refined carrageenan produced by alcohol precipitation contains approximately 90% anhydrous carrageenan, 8% moisture, and 2% inorganic salts (mainly chlorides). Food-grade refined carrageenan manufactured by the gel-press method contains about 77% anhydrous carrageenan, 8% moisture, and up to 15% inorganic salts (mainly chlorides). Additionally, both food-grade refined and semi-refined carrageenan may not contain more than 0.1% of methanol, ethanol, or propane-2-ol, singly or in combination.

Environmental Issues and Human Health Concerns
Seawood farming, specifically for the seaweed raised for carrageenan, has several environmental issues. Seaweed farms can be a lucrative business for small scale aquaculture as the overhead is low, requiring at the most basic level nylon strings or netting in shallow coastal waters. The turnover to harvest is quite short, at only 6 weeks. The harvested product is shelf-stable and can be stored for a relatively long period of time (Langford, 2024b) However, increased demand for seaweed has resulted in the establishment of some farms that involve first destroying important nearshore habitats like mangrove swamps or eelgrass beds to provide growing environments. Drifting mats from the established farms can also smother other nearby habitats, such as coral reefs. For example, when seaweed farming was introduced to India, to promote aquaculture for carrageenan, the seaweed rapidly invaded and smothered coral reefs in a nearby marine reserve (Baglar, 2008). Some coastal communities have improved their economic condition, but for some the economic gains were short lived due to environmental collapse (Langford, 2024b).

Research into the ecological effects of seaweed farming indicates that the diversity of fish is reduced in and around the seaweed farms. Proximity to seaweed farming reduces the size and growth rates of sea grass beds. A proposed environmental mitigation strategy is to move seaweed farming to deeper, sandy-bottomed areas and ensure that the farms are a safe distance from vulnerable habitats like coral reefs (Kelly et al.,2020).

The impacts of seaweed aquaculture can be positive. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, remove impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some effects of climate change (Duart et al., 2017). In addition, it is a food source that requires no freshwater or chemical inputs, making it an attractive alternative to terrestrial-based crops. Lastly, seaweed farming can provide a viable alternative to fishing in areas where overfishing has depleted fish populations.

Current scientific evidence on the human health impacts of food-grade carrageenan remains mixed and, in several areas, limited. Research continues to differentiate food-grade carrageenan from *degraded carrageenan* (including poligeenan), which is not used in food and is known to cause gastrointestinal ulceration and cancer in animal models. Although some low-molecular-weight fractions can arise during extraction or through microbial fermentation, the extent and relevance of in-vivo degradation of food-grade carrageenan remain uncertain.

Digestive Fate. Studies using simulated digestive systems indicate that carrageenan largely resists digestion in the stomach and small intestine but may undergo microbial fermentation in the colon. Recent work suggests that gut bacteria—particularly species within *Bacteroides*—may degrade carrageenan and produce metabolites capable of influencing inflammatory responses. However, the physiological significance of these interactions in humans has not been fully established.

Toxicology. Available toxicological data do not identify safety concerns for carrageenan consumed at typical levels found in food. Carrageenan shows low acute toxicity in mammals, and only two isolated human allergic reactions have been reported. Reviews, including by McKim et al. (2019), have found no evidence that food-grade carrageenan is carcinogenic, genotoxic, or tumor-promoting. Intake estimates vary widely among populations, and the ADI for carrageenan remains "not specified" due to limited data on exposure and long-term effects.

Impurities. Food-grade carrageenan may contain low levels of naturally occurring or process-related impurities such as formaldehyde or semi-carbazide. Regulatory evaluations, including the European Food Safety Authority (EFSA's), conclude that these impurities occur at levels far below those associated with health risks and do not pose a concern for consumers.

Inflammation and Ulceration. Evidence regarding carrageenan's role in intestinal inflammation is conflicting. In vitro studies suggest that carrageenan can contribute to inflammatory signaling under certain conditions, especially when inflammation is already present. Limited human data—including a small trial in ulcerative colitis patients—suggest that individuals with pre-existing inflammatory bowel disease may be more susceptible to adverse effects. Additional research indicates that inflammatory outcomes may depend on interactions between carrageenan, gut microbiota, and the integrity of the epithelial barrier.

Metabolic Effects. Findings related to metabolic outcomes are inconsistent. Some studies in animals and humans suggest that carrageenan may negatively affect glucose tolerance or insulin signaling, while others show potential lipid-lowering benefits or no adverse metabolic effect. Large-scale epidemiological data from France indicate a statistical association between carrageenan intake and increased risk of type 2 diabetes, though causal pathways remain unclear and limitations of self-reported dietary data apply.

Antiviral and Antibacterial Properties. Several studies demonstrate that specific forms of carrageenan—particularly iota-carrageenan—exhibit antiviral and antibacterial activity. Iota-carrageenan nasal sprays have shown clinical benefit in reducing common cold symptoms, and in vitro studies indicate potential inhibition of pathogens such as herpes simplex virus and *Chlamydia* species. These therapeutic findings remain separate from food uses.

Discussion

The relationship between carrageenan and the National Organic Standards Board (NOSB) has been marked by decades of evolving deliberation, reflecting shifting scientific perspectives, regulatory interpretations, and consumer expectations within organic food production. Notably the following:

At its 1995 meeting, the NOSB classified carrageenan as nonsynthetic, based on a TAP report outlining its manufacturing process. The decision was made without guidance from NOP 5033-1, which was published in 2016, and there was no clarification on which forms were considered nonsynthetic. Carrageenan is listed as nonsynthetic under 7 CFR 205.605(a), so certifiers generally treat it as such.

In 2012, the NOSB Handling Subcommittee suggested moving carrageenan to § 205.605(b) due to updated manufacturing information, recommending a review after new classification guidance from NOP. The full Board later proposed relisting carrageenan at § 205.605(a) with specific CAS numbers allowed and prohibiting use in infant formula; this recommendation was not implemented.

In 2016, the NOSB recommended removing carrageenan from § 205.605(a), but NOP did not act on these proposals noting that public comments suggested carrageenan remained necessary due to a lack of fully natural substitutes.

In 2021, NOSB voted against removing carrageenan from the list due to reaffirmed necessity.

Another point that should be taken up is the classification of carrageenan as a non-synthetic given Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016a) [2026 TR lines 486-562]. While it appears that all or virtually all carrageenan on the market is synthetically produced via alkaline extraction, stakeholder feedback on the feasibility of other extraction methods that avoid solvents would assist in further guiding this determination.

Some stakeholders in the past have questioned whether carrageenan remains truly necessary in organic processed foods, noting that while certain manufacturers consider it functionally useful, it is unclear whether its roles—such as gelling, stabilizing, or texturizing—lack feasible organic-compliant alternatives in all current applications.

Questions to our Stakeholders

1. Which organic products and uses currently rely on carrageenan?
2. What type of carrageenan (semi-refined / refined) and forms (kappa-, iota-, or lambda-) are being used in organic products?
3. Are carrageenan alternatives available to replace all uses?
4. Are there feasible methods to produce carrageenan as a non-synthetic (according to NOP 5033-1)?
5. Are there any concerns about ancillary ingredients used with carrageenan?
6. What restrictions or annotations might be appropriate for carrageenan? What new science on the safety or human health effects has emerged?

References:

Bagla, P. (2008) Seaweed invader elicits angst in India. Science. 320:1271.

Bixler, HJ (2017) The carrageenan controversy. Journal of Applied Phycology, 29**:**2201–2207.

Duarte CM., Wu J, Xiao X, Bruhn A, Krause-Jensen D (2017) Can seaweed farming play a role in climate change mitigation and adaptation? Frontiers in Marine Science 4.

Kelly EL, Cannon AL, Smith, JE (2020) Environmental impacts and implications of tropical carrageenophyte seaweed farming. Conservation Biology 34(2): 326-337.

Langford, Z. 2024a. Preface. *Globalisation and livelihood transformations in the Indonesian seaweed industry*. Taylor & Francis. Oxon and New York.

Langford, Z. 2024b. Introduction. *Globalisation and livelihood transformations in the Indonesian seaweed industry*. Taylor & Francis. Oxon and New York.

Taylor, A. 2019. Seaweed farming for food and fuels. Chemical and Engineering News, 97(34).

Tobacman JK, Bhattacharyya S, Borthakur A, Dudeja PK. (2008) The carrageenan diet: not recommended. Science 321(5892):1040-1041.

Zhang, J., Langford, Z. and Waldron, S., 2024a. The global carrageenan industry. In *Globalisation and livelihood transformations in the Indonesian Seaweed industry* (pp. 23-50). Routledge.

Zhang, J., Waldron, S., Langford, Z., Julianto, B. and Komarek, A.M., 2024b. China's growing influence in the global carrageenan industry and implications for Indonesia. *Journal of Applied Phycology*, *36*(2), pp.639-660.

Glucono delta-lactone

Reference: § 205.605(a)(14) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.
Technical Report: 2002 TAP; 2016 TR
Petition(s): 2002
Past NOSB Actions: 09/2002 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly silken tofu, and is generally thought to be the only material that can produce the physical and sensory components favored in that product. In tofu production, GDL serves as a coagulant. GDL can also be used as a curing or pickling agent, leavening agent, pH control agent and sequestrant. It is also used in feta cheese in place of lactic acid bacteria to reduce pH. Less tangy than citric acid, GDL slowly undergoes hydrolysis in water and converts to gluconic acid to produce a tangy flavor in food applications. GDL is generally recognized as safe (GRAS) by the FDA [2016 TR, lines 587-590, 597-599].

Manufacture
GDL is produced by crystallization from an aqueous solution of gluconic acid. There are a variety of ways gluconic acid can be produced. The most common method to produce gluconic acid is called the Blom process, where gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium

hydroxide or calcium carbonate is added to the fermentation process to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via fermentation and acid-base reactions [2016 TR, lines 500-525]. Other processes to make GDL involve oxidation of D-glucose with bromine water (which is not allowed by the National List annotation) and the use of purified enzymes [2016 TR, lines 281-282].

International Acceptance

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

- **Glucono delta lactone** is permitted with the following origin/usage conditions: production by the oxidation of D-glucose with bromine water is prohibited (Table 6.3 - Ingredients classified as food additives, CAN/CGSB-32.311-2020).

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

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

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

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Glucono delta-lactone** is not explicitly mentioned in the regulations.

Ancillary Substances

GDL is >99% pure and has no ancillary substances present. GDL is often sold in formulation with other additives specifically designed for the application. These substances should be reviewed separately as they are not ancillary substances.

The 2016 technical report (TR) states that there are many chemical methods of gluconic acid synthesis other than bromine water. It also states that some enzymes used in the production of GDL may be genetically engineered. Standard of purity for GDL is listed in the Food Chemicals Codex. It must be >99% pure. It can contain up to 4mg/kg of lead. Standards for other heavy metals are not listed. Up to 0.5% glucose contaminant is allowed. No reports of GDL contamination were found on the Internet or in CAB or Pub Med databases as of September 29, 2015 [2016 TR, lines 283-284, 646-649].

Human Health and Environmental Issues

The Handling Subcommittee was unable to document any environmental or human health issues associated with the production or consumption of GDL. Some sources have indicated it may cause minor bladder discomfort and/or back pain.

The 2016 technical report examined human health and environmental impacts of GDL use and production but found low to no risk. The TR did raise the question of classification, given the substance is produced via fermentation and acid-base reactions similar to the production of citric acid, which is also listed as nonsynthetic at § 205.605(a). The TR also raised concerns about the potential for GMO enzymes used in the production of GDL via the oxidation with enzymes production method (not the most common form of production).

Discussion

The original 2002 petition and primary use of GDL is for the coagulation of tofu. Other coagulants for tofu include magnesium chloride, calcium chloride, calcium sulfate, and magnesium sulfate [2016 TR, lines 256-257]. Acids such as citric or lactic acid can be used as well. Each of these substances produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu; sulfate salts produce soft tofu and GDL produces silken tofu. Citric and lactic acids produce acidified tofu that is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

For the 2021 sunset review, the Handling Subcommittee requested public comments regarding the use of GDL in organic processed foods other than tofu production. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic product. Further, the Handling Subcommittee asked if alternative tofu coagulants such as calcium and sulfate salt would be sufficient to produce all forms of tofu if GDL were removed from the National List. In response, companies commented that alternatives on the National List result in distinctly different and firmer tofu and that GDL is critical for silken, jelly-like tofu. Several tofu manufacturers commented in favor of retaining GDL. Lastly, the Subcommittee asked stakeholders whether GDL produced from enzymes should be prohibited or further restricted due to concerns about GMOs, an issue that is referenced in the 2002 TAP and noted as an issue for ongoing monitoring. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the Board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means; however, no information was presented on the commercial viability of this approach.

NOSB Review

At the Spring 2021 NOSB meeting, the Subcommittee received limited commentary from stakeholders about GDL. However, one commenter did indicate that the misalignment between the current annotation – which prohibits GDL made from bromine water and ensures only nonsynthetic GDL is used in organic – and the 2016 TR, which suggests GDL can be made from a variety of different chemical means, leaves the listing exposed to synthetic GDL production and some excluded methods. That comment suggests a clarification of the annotation may be needed.

The Handling Subcommittee heard from several certifiers about somewhat limited use of the material among their members. Although use was limited, support for relisting was clear. One non-profit stakeholder shared a concern flagged by the Subcommittee about potential negative impacts from mining for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only. Another stakeholder suggested GDL is nonessential, though several certifiers reported that a number of their members and clients are currently using GDL. Public comments at the last sunset review supported continued listing of GDL on the National List. Some public comments called for further review on the synthesis of gluconic acid to ensure only non-synthetic sources, potentially leading to further clarification of the annotation.

At this time, this material satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports the relisting of glucono delta-lactone.

Questions to our Stakeholders

1. How widespread is the use of GDL in organic applications?
2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?

4. Is the lack of international acceptance significant?
5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Tartaric acid

Reference: § 205.605(a)(28) Tartaric acid - made from grape wine.
Technical Report: 2011 TR
Petition(s): 2011 Petition to remove from § 205.605(b) - made from malic acid
Past NOSB Actions: NOSB meeting review 11/1995; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Tartaric acid naturally occurs in many plants, especially grapes, bananas, and tamarinds. It can also be produced synthetically from maleic acid, but the synthetic version was removed from the National List in 2013. Tartaric acid can be used to create several different salts, including tartar emetic (antimony potassium tartrate), cream of tartar (potassium hydrogen tartrate), and Rochelle salt (potassium sodium tartrate). The primary uses of tartaric acid are associated with its salts [2011 TR, lines 53-56].

Tartaric acid and its salts have a wide variety of uses. These include use as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. It has been used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks [2011 TR, lines 58-63].

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to rise without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties. Cream of tartar is used to make cake frosting and candies [2011 TR, lines 69-74].

Although tartaric acid is isolated from wines, it may also be used in winemaking to alter acidity. For non-grape wines, it may be added to increase acidity or to help prevent degradation of the flavor from unwanted microorganisms [2011 TR, lines 76-83].

Tartaric acid and its salts (i.e., potassium acid tartrate, sodium potassium tartrate acid) are classified by FDA as generally recognized as safe (GRAS).

Manufacture
The 2011 TR states that tartaric acid is an unwanted component present at the end of the winemaking process, and with the addition of calcium hydroxide and potassium hydroxide, it can be precipitated out as

a calcium or potassium tartrate salt [2011 TR, lines 151-155]. The salts can then be purified to tartaric acid. The TR details the most prevalent processes for production of tartaric acid [2011 TR, lines 221-234]:

> The nonsynthetic form of tartaric acid is isolated from the undesirable wastes created during the winemaking process. These unwanted materials include grape pomace, grape stalks, grape seeds, and vine, which naturally contain a significant amount of tartaric acid. An excess of tartaric acid is generally unwanted in winemaking because it creates a sour and undesirable taste. The available excess tartaric acid is precipitated using potassium hydroxide or calcium hydroxide in order to create a wine with the desired taste. Then the resulting waste mixture is evaporated. This process produces a powder containing calcium or potassium tartrate and additional substances including polyphenols and tannins. The powder is then sold to facilities that purify tartaric acid. The process for extracting tartaric acid from waste materials is similar to the processing of excess tartaric acid, in that potassium hydroxide is added to the waste mixture. Activated carbon is also added to remove unwanted pigmentation. The potassium tartrate is precipitated by adding saturated pure tartaric acid solution and then the precipitate is redissolved with acidic water at 70°C. Potassium and sulfate ions must be removed from the remaining solution, so cation exchanges are performed followed by evaporation. The solution is then crystallized at 4°C.

International Acceptance

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

- Tartaric acid from lees is permitted for beverages (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Tartaric acid from lees is permitted for beverages (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

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

- Tartaric acid (L(+)-) is permitted in products of plant origin and mead (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).
- Tartaric acid (L(+)-) is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- Tartaric acid is permitted in food of plant origin, although exclusions of the GSFA still apply. Tartaric acid is not permitted in food of animal origin (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Tartaric acid is permitted as an additive and a processing and post-harvest handling aid only for wine (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- L-Tartaric acid is limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

- L-Tartaric acid is permitted (Table B.1 – Additives for alcoholic beverages, JAS for Organic Processed Foods).

Ancillary Substances
None identified.

Human Health and Environmental Issues
If appropriate use patterns and disposal recommendations are followed, it is unlikely that tartaric acid would cause harm to the environment. The biodegradability of tartaric acid is 95% after 3 days and the substance is considered readily biodegradable. No bioaccumulation is to be expected [2011 TR, lines 390-391].

Discussion
Tartaric acid is a critical component in several areas of food handling. While baking powder can be replaced with baking soda, cream of tartar must be added to maintain the baking powder properties. While tartaric acid is made from grapes, it is also an important component in winemaking and there are no organic alternatives. Other natural components of grapes, such as malic acid, can be used to alter the acidity of wine and possess preservative characteristics, but they often impart a different taste than tartaric acid [2011 TR, lines 438-440].

Public comments submitted for the previous sunset review raised the possibility of increasing the supply of organic tartaric acid. However, in order for tartaric acid to be labeled "organic," sulfur dioxide could not be used in the winemaking process prior to extraction of the tartrate salts – i.e., it would have to be a byproduct of wine that will be labeled "organic" or the relevant byproducts would need to be separated from the wine made from organic grapes prior to addition of sulfur dioxide. Production of wine labeled "organic" remains low, relative to wine labeled "made with organic grapes" that has sulfur dioxide added, and it is not clear whether removal of the tartrate salts prior to use of sulfur dioxide is a viable pathway for production. Accordingly, it is unclear whether there is capacity for significant production of organic tartaric acid.

For pH adjustment, citric acid and malic acid can be used; however, they impart certain flavors to the product. If a grape flavor is needed, tartaric acid would be the first choice.

Due to low impacts on human health and the environment and the advantageous qualities that tartaric acid lends to baked goods, wines, and other products, tartaric acid is a good candidate for relisting.

Questions to our Stakeholders
1. Is organic tartaric acid available in significant quantities?
2. Can tartrate salts be removed from wine made from organic grapes prior to addition of sulfur dioxide?
3. Are there other barriers to production of organic tartaric acid that could be lowered?

Cellulose

Reference: § 205.605(b)(11) Cellulose (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.
Technical Report: 2001 TAP; 2016 TR
Petition(s): 2001

Past NOSB Actions: 10/2001 meeting minutes and vote; 11/2007 recommendation; 05/2012 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: National List amended 11/03/2003 (68 FR 62215); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Annotation change effective 12/27/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028
Subcommittee Review

Use
In the powdered form, cellulose is used as a processing aid for filtration of juices and an anti-caking agent ingredient for use in shredded cheese. Regenerated cellulose casings are used for peelable/non-edible hot dog and sausage casings. Some of these uses in organic handling have been around since before the enacting of OFPA, with cellulose allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture
Cellulose is available in several different forms, each with varying functional qualities used for multiple purposes in organic handling. There are two specific forms of cellulose currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing.

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth [2016 TR, lines 55-56]. Most commercially available cellulose (powdered) is produced from wood pulp or other plant sources, e.g., corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc. The plant material goes through a delignification process that results in a chemically changed synthetic substance. The original process for making regenerated cellulose casing, the viscose method, dates to the 1890's and converts cellulose fibers into regenerated fibers and films. With some minor changes to the process, it is still in use today. Cellulose is considered Generally Regarded as Safe GRAS under 21 CFR 121.101 [2016 TR, line 320].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- For collagen casings, collagen shall be derived from animal sources. If derived from cattle, collagen shall be guaranteed free of Specified Risk Material (SRM). Other ingredients (such as, but not limited to cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture that remain in the collagen casing when it is used shall respect the requirement provided in 1.4 a) of CAN/CGSB-32.310. Permitted for poultry sausage (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Cellulose is permitted as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings. The TCF (Totally Chlorine Free) method of bleaching is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- Cellulose is permitted in gelatine (Authorized food additives and processing aids, EC No. 2021/1165).
- Cellulose is permitted in products of plant origin and gelatine (Processing aids and other products, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
- Cellulose is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Cellulose is permitted as a processing and post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Powdered cellulose is limited to the use as a filter aid in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

The 2016 TR referenced three sources of commercially available cellulose that do not include any ancillary substances [2016 TR, line 133], yet suggested that the inclusion of ancillary substances potentially increased functional efficacy. The 2016 TR provided additional information about the use of ancillary substances [2016 TR, lines 131-154]. Some examples are polymers and co-polymers that improve absorption, increase or decrease viscosity, and increase yield. Food grade filtering systems composed mainly of cellulose may also include various polymers or substances like fiberglass for ease of handling, or to increase throughput. Enzymes may improve the shelf life of grated cheeses that use cellulose as an anti-caking agent, although cellulose without additives is commercially available and clearly identified. Sausage casings, including those made from regenerated cellulose, may be lubricated with vegetable, animal or mineral oil in the shirring process. Synthetic sausage casings may be formulated with mineral oil, propylene glycol and lecithin. Regenerated cellulose sausage casings are commercially available without additives.

Ancillary items were discussed at the 2016 meeting in St. Louis, where the NOSB decided that a proposal on ancillary items was needed. The subcommittee prepared a January 3, 2017 proposal titled *Ancillary Substances Permitted in Cellulose,* which listed 6 functional classes of ancillary substances for cellulose: shirring aid, humectant, coating, coating with Ph control, peeling aid, and synthetic binder. The proposal states that any ancillary items in these classes would not need to be reviewed, while a new functional class of ancillary substances would need to be reviewed. At the 2017 Spring meeting, in Denver the proposal was sent back to subcommittee because it contained mistakes (e.g. vinyl chloride was listed as an ancillary substance). At the Fall 2017 meeting, the Handling subcommittee chair reported that work would not continue on this topic, and that it would be better to work on ancillary substances in cellulose after the NOP finishes their review of ancillary substances. At the previous sunset review, ancillary substances were not discussed. The 2024 Research Priorities of the NOSB included the following statement (page 157): *Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.*

Human Health and Environmental Issues

During previous reviews, public comment, as well as the 2016 TR, raised concerns regarding the use of wood pulp as a source for cellulose and the environmental impact that logging of primary forests and replacement with monoculture plantations may have. Concerns were also raised about environmental problems caused by waste cellulose generated from food processing. The 2016 TR states that conversion of cellulosic food wastes, as well as cellulose waste from filtration aids and/or spent casings, into useful products is the subject of research. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs, and governmental regulations [2016 TR, lines 396-401].

Discussion

Most of the discussion pertained to the text of the previous sunset review, where the ancillary substances were listed in a table by functional class. After a lengthy discussion, the subcommittee members agreed

that the categorization was not included in the TR, leading us to track down the history of the ancillary substance use in cellulose. The question remains whether cellulose requires ancillary substances.

Questions to our Stakeholders

1. For which products, if any, is cellulose currently essential for organic handling?
2. Which ancillary substances are used with cellulose, for the three allowable uses in handling (filtration, anti-caking, and regenerative casings)?
3. Is it still necessary to allow cellulose with ancillary substances, given that versions with no ancillaries are available?

Chlorine materials – Calcium hypochlorite

Reference: § 205.605(b)(12)(i) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

Calcium hypochlorite

Technical Report: 2006 TR (Chlorine materials- Handling); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Calcium hypochlorite is an Environmental Protection Agency (EPA)-registered pesticide (OPP Nos. 014701). Calcium hypochlorite 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 allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2) [2006 TR, lines 77-79].

Calcium hypochlorite is an "indirect" food additive approved by Food and Drug Administration (FDA). Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the

label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hypochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 117-122].

Manufacture
Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuum dried [2006 TR, lines 151-152].

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

- The following chlorine compounds are permitted: a) **calcium hypochlorite**; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) **calcium hypochlorite**; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.

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

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Calcium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Calcium hypochlorite** is not explicitly mentioned in the regulations.

Ancillary Substances
Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues
Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in a 2006, 2011, and 2025 Technical Reports (TR) (referenced above).

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 under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS 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.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized “by specific use or application” with clear identification of the hazards to humans and the environment (NOC 2020). Further, “Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021).” Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders
1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Chlorine dioxide

Reference: § 205.605(b)(12)(ii) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(ii) Chlorine dioxide

Technical Report: 2006 TR (Chlorine materials); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
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 [2006 TR, lines 66-67]. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases [2011 TR, lines 149-150].

Manufacture
To form chlorine dioxide, sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid is reacted with methanol (CH_3OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate [2011 TR, lines 206-210].

International Acceptance

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

- Teat dips and udder wash are permitted. Substances, such as alcohol, iodine, hydrogen peroxide, **chlorine dioxide** and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations. Chlorhexidine can be used as a post-milking teat dip if alternative germicidal agents and physical barriers have lost their effectiveness (Table 5.3 - Health care products and production aids, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted: a) calcium hypochlorite; b) **chlorine dioxide**; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) **chlorine dioxide**; c) hypochlorous acid generated via electrolyzed water; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

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

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Chlorine dioxide** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Chlorine dioxide** is not explicitly mentioned in the regulations.

Ancillary Substances

Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above).

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 under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS 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.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders

1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: § 205.605(b)(12)(iii) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iii) Hypochlorous acid - generated from electrolyzed water.

Technical Report: 2006 TR (Chlorine materials - Handling); 2011 TR - Crops; 2015 TR; 2025 TR (pending post)
Petition(s): 2015
Past NOSB Actions: 2016 NOSB Recommendation to add; 10/2021 recommendation

Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Hypochlorous acid 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 allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SWDA) (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 118-122].

Manufacture
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 hypochlorite 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. [2006 TR lines 48-68].

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) **hypochlorous acid generated via electrolyzed water**; d) sodium hypochlorite. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade

cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) **hypochlorous acid generated via electrolyzed water**; d) sodium hypochlorite (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- **Hypochlorous acid** is not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
- **Hypochlorous acid** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms
- **Hypochlorous acid** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- Any substances other than **hypochlorous acid water** and sodium hypochlorite, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- Sodium hypochlorite is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of **hypochlorous acid water** produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Hypochlorous acid water** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Ancillary Substances
Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues
Hypochlorous acid, generated from electrolyzed water, is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at § 205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above.).

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

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 under the Food

Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS 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.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders

1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Chlorine materials – Sodium hypochlorite

Reference: § 205.605(b)(12)(iv) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iv) Sodium hypochlorite

Technical Report: 2006 TR (Chlorine materials); 2011 TR - Crops; 2025 TR (pending post)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset review; 10/2021 recommendation
Recent Regulatory Background: Added to National List 02/20/2001 (65 FR 80547); Amendment to annotation effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Sodium hypochlorite is an EPA-registered pesticide (OPP No 014703). Sodium hypochlorite 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 allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

Sodium hypochlorite is an "indirect" food additive approved by FDA. Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). These hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops [2006 TR, lines 93-99].

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosphosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function [2006 TR, lines 117-122].

Manufacture
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 (Na_2CO_3) [2006 TR, lines 156-159].

International Acceptance

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

- The following chlorine compounds are permitted: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) **sodium hypochlorite**. Shall not exceed maximum levels for safe drinking water. Chlorine compounds may be used: a) for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage or transport units—application to crops or fields is permitted (Table 7.3 - Food-grade

cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).
- The following chlorine compounds are permitted up to maximum label rates: a) calcium hypochlorite; b) chlorine dioxide; c) hypochlorous acid generated via electrolyzed water; d) **sodium hypochlorite** (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

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

- **Sodium hypochlorite** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Sodium hypochlorite** is permitted with the following limitation: an intervening event or action must occur to eliminate risks of contamination (Appendix 4, Table 2: Indicative list of equipment cleansers and equipment disinfectants, IFOAM NORMS 2014).
- **Sodium hypochlorite (e.g. as liquid bleach)** is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Any substances other than hypochlorous acid water and **sodium hypochlorite**, both of which are specified in Table D.1, should not be used for the seeds specified in 5.6.1 (Seeds used in cultivation facilities of sprout, JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite sodium chloride** is permitted with the following criteria: limited to those obtained by electrolyzing the salt solution (limited to those using salt containing no less than 99% sodium chloride) (Table D.1 - Substances for preparation etc., JAS 1605 Organic Products of Plant Origin).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use in processed products of plant origin (limited to the use of hypochlorous acid water produced by electrolyzing salt water (limited to the use of salt containing 99% or more sodium chloride)), or the use for disinfecting the intestines of livestock animals for processed meat products, or cleaning of eggs (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).
- **Sodium hypochlorite** is permitted with the following criteria: limited to the use only for the purpose of disinfecting meat in the process of dismantling or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS 1608 Organic Livestock Products).

Ancillary Substances

Other substances are sometimes added to chlorine materials in order to stabilize the formula.

Human Health and Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict

adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in the 2006, 2011, and 2025 Technical Reports (TR) (referenced above.).

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 under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS 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.

Public comment during the last sunset review and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS may recommend a work agenda item to advance these suggestions.

Questions to our Stakeholders
1. What alternatives are being used to chlorine materials?
2. Are all chlorine materials needed for handling purposes?
3. What ancillary substances are being used in chlorine materials?
4. Are clarifications of uses sufficiently clear in NOP 5026?
    a. Active ingredients vs all ingredients
    b. Differing review policies
    c. Where a sanitizer is used and reviewed. Direct contact versus non-food contact

Potassium hydroxide

Reference: § 205.605(b)(26) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.
Technical Report: 2001 TAP; 2016 TR
Petition(s): 2001 petition; 2011 petition to amend annotation
Past NOSB Actions: 10/1995 meeting minutes and vote; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to the National list 12/21/2000 (65 FR 80548); National List amended 11/03/2003 (68 FR 62215); National List amended 05/28/2013 (78 FR 31815); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base, and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent [2016 TR, lines 22-23].

Potassium hydroxide in poultry chill water increases the shelf life of broilers and other meat birds by killing various spoilage organisms, particularly when used in combination with lauric acid. To a limited extent, potassium hydroxide will also act as a preservative in the curing of certain foods, such as olives [2016 TR, lines 278-281].

Potassium hydroxide is also used in the lye peeling of fruits and vegetables. The annotation permits this use exclusively for peeling peaches. Peaches peeled for canning or pickling typically use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution - about 10% - and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and citric acid is used to neutralize the pH of the fruit [2016 TR, lines 88-92].

For certain grains and legumes, potassium hydroxide is used to remove tannins that interfere with nutrient uptake. For example, it increases the solubility of proteins in soybeans. It can also be used as a solvent to determine protein quality and total soluble protein in assays. Potassium hydroxide can be used as a substitute for the traditional calcium hydroxide (lime water) used to remove the pericarp of corn, a process known as nixtamalization - part of the process to make masa from corn. Furthermore, the removal of the pericarp or bran from corn, sorghum, and other grains increases the nutritional quality and digestibility of those grains [2016 TR, lines 296-306].

Manufacture

The 2016 technical report (TR) notes that the FDA specifies that food grade potassium hydroxide (KOH) is made by the electrolysis of potassium chloride (KCl) and water in the presence of a porous diaphragm [21 CFR 184.1631(a)]. Potassium chloride, also known as muriate of potash, is a naturally occurring mineral, with the main global source being Canada. Most U.S. production occurs in New Mexico and Utah. Potassium chloride is put into aqueous solution and is electrolyzed by various processes. Diaphragm cells will produce a liquor that contains 10-15% by weight of KOH and about 10% KCl. Most of the KCl crystallizes by evaporation and subsequent cooling during concentration. The concentrated KOH is about a 50% solution with about 0.6% KCl. Potassium hydroxide is regarded by the chemical industry as a by-product of the process for producing hydrochloric acid [2016 TR, lines 203-217].

International Acceptance

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

- Aquatic plant products may be extracted by using the following substances in order of preference: a) substances in Table 4.2 Extractants; b) **potassium hydroxide**; c) sodium hydroxide provided the amount of solvent used does not exceed the amount necessary for extraction. The operator shall provide an affidavit from the manufacturer that proves the need to use sodium hydroxide. Sodium benzoate and potassium sorbate may be used as preservatives for water-extracted aquatic plant products. All other preservatives are prohibited unless listed in Table 4.2 (Column 1 or 2) with the exception that Formulants used in crop production aids are prohibited (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).

- Humates, humic acid and fulvic acid are permitted if mined; produced through microbial activity; extracted by physical processes; or with: a) Table 4.2 Extractants; or b) **potassium hydroxide**—**potassium hydroxide** levels used in the extraction process shall not exceed the amount required for extraction. Levels (mg/kg) of arsenic, cadmium, chromium, lead and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilising Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- Plant extracts, oils and preparations are permitted as production aids with the following origin/usage conditions: permitted extractants include fats and oils (such as cocoa butter, lanolin and animal fats); alcohols; water; or substances listed on Table 4.2 (Column 2) other than Formulants used in crop production aids. Extraction with other solvents is prohibited except with, in order of preference: a) **potassium hydroxide**; or b) sodium hydroxide; provided the amount of solvent used does not exceed the amount necessary for extraction. The operator shall provide an affidavit from the manufacturer that proves the need to use sodium hydroxide. For control of pests (e.g., diseases, weeds and insects). Clove oil is permitted for sprout inhibition in potatoes (Table 4.2 - Substances for crop production, CAN/CGSB-32.311-2020).
- **Potassium hydroxide (caustic potash)** is permitted for pH adjustment. Prohibited for use in lye peeling of fruits and vegetables (Table 6.5 - Processing aids, CAN/CGSB-32.311-2020).
- **Potassium hydroxide (caustic potash)** is permitted (Table 7.4 - Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

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

- **Caustic potash** is permitted (Annex IV: Authorised products for cleaning and disinfection, EC No. 2021/1165).

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

- **Potassium hydroxide** is permitted for pH adjustment for sugar processing (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Seaweed and seaweed products are permitted with the following conditions for use: as far as obtained by (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or **potassium hydroxide** solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation (Appendix 2: Fertilizers and soil conditioners, IFOAM NORMS 2014).
- Algal preparations are permitted with the following conditions for use: as far as obtained by (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or **potassium hydroxide** solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation (Appendix 3: Crop protectants and growth regulators, IFOAM NORMS 2014).
- Caustic potash (**potassium hydroxide**) is permitted (Appendix 5: Substances for pest and disease control and disinfection in livestock housing and equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Potassium hydroxide** is permitted with the following criteria: limited to the use as a pH control agent in the processing of sugar (Table A.1 - Additives for organic processed foods excluding organic alcohol beverages, JAS 1606 Organic Processed Foods).

- Sodium hydroxide and **potassium hydroxide** are permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS 1608 Organic Livestock Products).

Ancillary Substances
The TR did not identify any ancillary substances.

Human Health and Environmental Issues
The amount of fresh water used in the lye peeling process and the release of effluent that increases biological oxygen demand are two key environmental concerns about the lye peeling process. The release of potassium hydroxide in untreated or improperly treated wastewater will raise the pH and potassium levels of the body of water receiving it. Soap manufacturing can also threaten environmental health in the immediate vicinity of the soap manufacturing facility, as nutrient loading of potassium may result in algal blooms and eutrophication [2016 TR, lines 341-344, 353-355].

Human health toxicity mainly involves the risk of ingestion of concentrated potassium hydroxide. Ingestion of lye inevitably leads to esophagus damage, with over 90% of the cases also involving stomach damage [2016 TR, lines 376-377].

Discussion
In 1995, the NOSB approved the addition of potassium hydroxide to § 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read —prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process. The 2001 TAP review for that expansion noted that the stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances. The 2001 TAP review also noted that the environmental effects that had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step. Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Subcommittee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercial processing methods used for peaches, the NOSB favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Alternatives to potassium hydroxide include naturally occurring alkali substances such as sodium carbonate and sodium bicarbonate. The drawbacks of these natural materials are that they are less soluble than potassium hydroxide and they may not be effective in raising the pH. For fruit peeling, mechanical, steam, or hand peeling is an alternative. As noted above, while potassium hydroxide was not initially allowed for

peeling in organic processing, subsequent petitions and NOSB decisions allowed for its limited use for the peeling of peaches.

Questions to our Stakeholders

1. For which organic products or processes do you currently use potassium hydroxide, and what functional role does it serve?
2. Are heat or mechanical methods not sufficient for peach peeling? Are there alternatives?

Potassium lactate

Reference: § 205.605(b)(27) Potassium lactate - for use as an antimicrobial agent and pH regulator only.
Technical Report: 2015 TR
Petition(s): 2004; 2014 NOP memo to NOSB
Past NOSB Actions: 04/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Potassium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as generally recognized as safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas [2015 TR, lines 209-211].

Manufacture
Potassium lactate is generally produced from natural (fermented) lactic acid, which is then reacted with potassium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch [2015 TR, lines 102-103, 115-116].

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

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

- **Potassium lactate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Potassium lactate** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Potassium lactate** is not explicitly mentioned in the regulations.

Ancillary Substances
None reported in the 2015 TR.

Human Health and Environmental Issues
There does not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, the necessary precursor of potassium lactate. However, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment [2015 TR, lines 772-773].

Discussion
Many stakeholders view this listing as "enormously complicated," saying that it is the procedural history that is complicated and not the material itself. Potassium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the National List was based on the fact that both of the materials used to produce potassium lactate (lactic acid and potassium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Potassium lactate was added to the National List effective January 28, 2019. In past sunset reviews, the Handling Subcommittee found significant merit to keep potassium lactate on the National List at § 205.605(b) with the annotation: for use as an antimicrobial agent and pH regulator only.

In previous rounds of public comments, a majority of commenters were in support of relisting potassium lactate. A review of the use tables supplied by several associations indicate that potassium lactate is a widely used material. Some stakeholders asked why both potassium and sodium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as low sodium meat alternatives, that require potassium lactate specifically.

Questions to our Stakeholders
1. Are there any new technologies or ingredients that could replace the lactates?
2. What applications are Potassium and Sodium Lactate used in conjunction?

Silicon dioxide

Reference: § 205.605(b)(29) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.
Technical Report: 1996 TAP; 2010 TR, 2025 TR
Petition(s): 2010 petition to remove
Past NOSB Actions: 09/1996 minutes and vote; 11/2005 recommendation; 12/2011 recommendation; 11/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL 12/21/2000 (65 FR 80548); National list amended 05/28/2013 (effective 11/03/2013) (78 FR 31815); Sunset renewal notice effective 05/29/2018 (83 FR 14347); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Synthetic amorphous silica (SAS), the most common form of the chemical compound silicon dioxide used commercially, is used as a food additive for various functions including as:

- a flow agent in syrups, oligodextrines, fruit snacks and cheese powders
- an anticaking agent in foods, specifically spice blends and organic seed pellets
- a stabilizer in beer production (filtered out of the beer prior to final processing)
- an adsorbent in tableted foods
- a carrier
- a defoaming agent

Silicon dioxide is also available in the form of crystalline silica. The crystalline silica form is not used in food manufacturing.

Additionally diatomaceous earth (DE) is a nonsynthetic form silicon dioxide. DE has its own listing on the National List at § 205.605(a)(10). Its use is limited as a filtering aid only.

Manufacture
SAS can be manufactured by two main pathways.

1. Thermal process: The thermal process forms silicon dioxide through high-temperature fusion yielding pyrogenic silica, commonly known as fumed silica.
2. Wet process. The wet process forms silicon dioxide through silicic acid polymerization yielding precipitated silica, silica gel or colloidal silica.

The 2025 technical report (TR) provides an extensive explanation of both processes [2025 TR, lines 728-950]. Both the thermal and wet manufacturing processes result in a synthetic substance according to the decision tree [2025 TR, lines 979-997].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Silicon dioxide (silica) is allowed with no restrictions on sources or uses except for maple syrup production, at CAN/CGSB-32.311 Permitted Substances List Table 6.3-Ingredients classified as food additives, and Table 6.5-Processing Aids. CAN/CGSB-32.310 7.2.12.6 allows silica powder in organic maple syrup production only for simple filtration with a filter press to remove suspended solids.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Silicon dioxide (E551) is permitted as outlined in Annex V, Section A1, which covers food additives, including carriers. It can be used in cocoa, herbs, spices in dried powdered form, flavorings, and propolis. However, there are specific conditions and limits for cocoa; it is only allowed for use in automated dispensing machines.
Annex V, Section A2 pertains to processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It also permits “silicon dioxide gel or colloidal solution,” albeit with a restriction on plant origin.

Furthermore, Annex V, Part D, concerning authorized products and substances for the production and conservation of organic grapevine products in the wine sector, allows “silicon dioxide gel or colloidal solution.”

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

Silicon dioxide (amorphous) is included as INS No. 551 and is listed under CODEX guidelines specifically in Annex 2, Table 3.1. This table lists additives permitted for use under specified conditions in certain organic food categories or individual food items. Amorphous silicon dioxide is allowed in “herbs, spices, seasonings, and condiments,” such as seasonings for instant noodles. However, it is not permitted in foods of animal origin under these guidelines. Additionally, silicon dioxide is permitted in the form of a gel or colloidal solution, as outlined in Table 4 of the CODEX guidelines. This table details processing aids that may be used in the preparation of products of agricultural origin, as specified in Section 3 of the guidelines, but their use is limited to plant products only.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Silicon dioxide (amorphous) is included as INS 551 and is listed under IFOAM guidelines Appendix 4–Table 1: Approved additives and processing/post-harvest handling aids. It is allowed without limitation.

Japan Agricultural Standard (JAS) for Organic Production

Silicon dioxide (INS Number 551) is permitted as outlined in Annex A, Table A.1, for additives in organic processed foods, excluding organic alcoholic beverages. Its use is limited to processed products derived from plant sources, where it can be utilized as a gel or colloidal solution.

Additionally, these standards allow silicon dioxide as listed in Appendix B, Table B.1, for additives in organic alcoholic beverages, with no specific annotations regarding its use.

Korea: Republic of Korea (ROK) Korean Organic Act

We were unable to access the specific ROK standards that detail the allowance of silicon dioxide in organic food handling.

Switzerland: Federal Office for Agriculture (FOAG), Switzerland Organic Ordinances, Organic Farming Ordinance (SR 910.18), EAER Ordinance on Organic Farming (SR 910.181), FOAG Ordinance on Organic Farming (SR 910.184)

Silicon dioxide (E551) is permitted in the form of a gel or colloidal solution, as outlined in Annex 3, Section A, which lists authorized food additives, including carriers. According to the specific restrictions set forth in these standards, silicon dioxide is allowed for products of plant origin, specifically dried powdered herbs, spices, and flavorings. For animal-origin products, it is only permitted for flavorings.

Additionally, silicon dioxide in gel or colloidal solutions is permitted in Annex 3, Section B, which covers directly used technical aids and other products that may be used to process organically produced agricultural ingredients, only for plant-origin products. Lastly, in Annex 7, Part B, which discusses feed additives for animals, colloidal silicon dioxide is also allowed as a binder and/or release agent, with no special conditions or restrictions.

Taiwan: Organic Agriculture Regulations

Silicon dioxide is permitted without specific conditions in Chapter 2, entitled "Substances Allowed for Production, Processing, Packaging, Distribution, and Sale," as shown in Table 3, which lists food additives permitted for use.

United Kingdom (Great Britain): Organic Products Regulations (2009), Retained Council Regulations (EC) (834/2007, 889/2008, and 1235/2008)

Silicon dioxide (E551) is permitted as detailed in Annex VIII, Section A, which pertains to food additives, including carriers. Specifically, it can be used for dried powdered herbs, spices, flavorings, and propolis. This standard also allows silicon dioxide to be included in preparations of foodstuffs derived from both plant and animal origins.

Additionally, Annex VIII, Section B covers processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It permits the use of silicon dioxide gel or colloidal solution solely in preparations of foodstuffs from plant origins without any specific conditions or restrictions.

Ancillary Substances
According to the 2016 NOSB Ancillary Substances Procedure, ancillary substances are intentionally added. The 2025 TR indicates that precipitated silica and silica gel may contain small amounts of sodium sulfate as an impurity. Since sodium sulfate appears to be residual from the acid-base reaction in the wet process and is not added intentionally, it appears that this does not meet the definition[2025 TR, Lines 1077-1083]

According to the 2025 TR, colloidal silica does contain stabilizing agents like aluminum oxide for the purpose of keeping SAS suspended in solution for up to six months. Certifiers should review stabilizing agents according to their ancillary substances policies[2025 TR, Lines 1085-1091].)

Human Health and Environmental Issues
Human Health
SAS toxicity is dependent on whether it is produced via wet processes (silica gel, precipitated silica, and colloidal silica) or thermal processes (fumed silica).

According to the 2025 TR, many recent studies have assessed the toxicity of food-grade SAS, including fumed silica and hydrated silica (such as precipitated silica, silica gel, and colloidal silica) and have not found conclusive evidence that SAS produces toxicity or harmful effects on human health when used as a food additive. Recent studies evaluating the oral toxicity of food-grade SAS in living animals have not shown adverse toxicological evidence. All studies published before 2022 indicate that oral exposure to SAS is safe.

Additionally, the 2025 TR notes recent concerns being raised by stakeholders in the food industry about the potential hazards and risks associated with SAS nanoparticles and their toxicity. The TR discusses several research studies that have been conducted. The following suggestions or results noted in the TR seem to indicate little to no impact on human health:

- SAS nanoparticles may not persist in living organisms after consumption because the material tends to form aggregates and agglomerates, or, in the case of colloidal silica, quickly polymerize.
- SAS nanoparticles may not be able to cross the mucus layer of the intestine.
- SAS nanoparticles were not internalized by the intestinal cells.
- Digested SAS nanoparticles did not induce any toxic effect on the intestinal barrier model.
- Overall absorption rates for SAS nanoparticles are relatively low and accumulation of these nanoparticles in tissue diminishes over time[2025 TR, Lines 1384-1404].

The TR did note one study that showed bioaccumulation of SAS particles in tissues—including the liver, placenta, and umbilical cord—can occur[2025 TR, Lines 1397-1399]. Also, there were some studies that discussed some specific toxicities. However, these studies are not all that relevant; in one case they used different forms of silicon dioxide (not SAS – which is used in food manufacturing) and in another case, the SAS particles were introduced intravenously (not ingested).

Lastly, the 2025 TR stated that inhalation of crystalline silica can cause silicosis. However, as stated earlier, crystalline silica form is not used in food manufacturing. The TR also noted that SAS exposure showed no evidence of adverse pulmonary effects, such as fibrosis of the lungs or any other permanent respiratory ailments.

Environmental

The 2025 TR states that while it is possible for SAS to negatively affect aquatic organisms, it is unlikely to have negative effects on the environment or biodiversity at the concentrations used in food processing [2025 TR, Lines 1178-1179].)

The SAS manufacturing processes (both thermal and wet), however, does pose some environmental concerns specifically regarding the precursors (silicon tetrachloride and sodium silicate). Silica sand, obtained through mining can lead to deforestation, biodiversity loss, soil erosion and acid drainage. However, the TR does state that most of the extracted sand is not used for SAS production but rather for hydraulic fracturing or well packing. [2025 TR, Lines 1276-1686].

Additionally, silicon tetrachloride production uses chlorine and carbon black. Chlorine contributes significantly to the environmental impact of fumed silica production due to the energy needed to obtain it via electrolysis and the aquatic implications of the chemicals used during its manufacture Carbon black is sometimes derived from petrochemical sources, significantly impacting the environment on multiple levels. [2025 TR, Lines, 1292-1300].

Lastly, sodium silicate uses large amounts of energy.

Discussion

Silicon dioxide was petitioned for removal in 2010 by RIBUS, the manufacturer of a commercially produced rice-based certified organic alternative to silicon dioxide. Data was presented in the petition claiming that a reformulation of the rice-based alternative could be substituted for silicon dioxide at a nearly 1:1 ratio. The Handling Subcommittee felt the data was limited, not published from a third-party source, and did not conclusively demonstrate its applicability in all products and processes; however, they wished to acknowledge the availability of a natural alternative. An annotation was proposed resulting in its current listing, which requires the use of organic rice hulls when commercially available.

In its last sunset review in 2021, public comments indicated that organic rice hulls are *not* a viable alternative for all current uses of silicon dioxide such as when used as:

- An anticaking agent in organic powders, including organic cheese powders, and spice and seasoning blends, where it was noted that rice hulls absorb excess moisture and clump. Additionally, it was noted that in order to achieve the desired technical effect, rice hulls must be used at a rate of 15-50% compared to 2% silicon dioxide to achieve the same effect.
- In organic dry flavors in which rice hulls have not adequately or evenly disbursed flavor actives and have taken up moisture. Additionally, increased rates render the flavor unsuitable for its intended use of flavoring.
- A flow agent for rice syrup solids.
- A clarifier in the production of beer.

Most stakeholders were in favor of relisting based on essentiality and seemed comfortable with the current annotation. However, there were a few comments that suggested NOSB should review the current annotation against the original annotation passed by the Board to ensure the intent of the original annotation is accurately conveyed.

The Handling Subcommittee reviewed the history regarding the annotation change. On the cover sheet that accompanied the Board's recommendation in 2011, the following was stated:

> "Motion to amend the annotation of the following substance: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetics allowed—Silicon

dioxide—providing sufficient evidence showing non-synthetic alternatives are not commercially available for a specific product/process is presented.

Correction made by NOP on 4/12/12: The motion as stated in the meeting transcript is: “Move to change the annotation of Silicon Dioxide on § 205.605 nonagricultural substances be synthetics allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.”

The cover sheet noted the original motion that was presented in the meeting packet. However, the Board did not vote on that motion. Rather, during the Fall 2011 meeting an alternative motion was drafted and voted on. This is the motion listed above as the correction made by NOP on 4/12/12.

The annotation was modified during the rulemaking process. NOP proposed to modify as follows: “permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available” to specify the specific alternative substance (e.g. organic rice hulls) the Board was considering at that time so that certifying agents can consistently verify that organic handlers are in compliance with the regulations as well as reduce the burden on organic handlers since they would not be required to demonstrate that all nonsynthetic alternatives to synthetic silicon dioxide were considered prior to its use.

There was also one commenter that suggested the Board limit the use of organic rice hulls when commercially available for products labels as “organic” and not for products labeled as “made with organic.” This would more align with the yeast annotation. The Handling Subcommittee is seeking feedback on this idea.

The 2025 TR did evaluate alternatives to silicon dioxide. The TR explained that the silicon dioxide most commonly used in food handling cannot be obtained from nonsynthetic sources. As previously noted, the most common form used is SAS. The synthetic nature is right in the name of this substance. Natural forms, such as crystalline form or diatomaceous earth (a type of amorphous silica) are unsuitable for food applications[2025 TR, Lines 1487-1500]. The TR goes on to state that a single material that serves as a substitute for SAS in all applications was not able to be identified. Table 4 in the [2025 TR, line 1574] provides nonagricultural, nonsynthetic alternatives to silicon dioxide. The TR also notes some organic agricultural materials such as oat, barley and pelt hulls, rice and corn flours, and starches that could potentially be used for certain functionalities. As with the nonagricultural, nonsynthetic alternatives there is not one item that will work for all use cases, and these also are likely to have increased application rates similar to rice hulls, which would limit their viability[2025 TR, Lines 1637-1643].

Lastly, there has been some concern regarding whether silicon dioxide is an engineered nanomaterial. The TR authors state they were unable to classify SAS according to the definitions outlined in NOP Policy Memo 15-2 (i.e., “engineered nanomaterial”), based on the available analytical measurement data, as measurement estimates are limited in accuracy. The TR references one study whereby the researchers indicate that they do not understand SAS to be intentionally engineered under 100 nm for functional purposes. The TR references another study that states that particles between 1-100 nm are likely included in commercial products. However, in this second reference there isn’t any indication that these are engineered nanomaterials, only that they are nano-sized[2025 TR Lines 1007-1069].

In reviewing the historical record (previous TRs and recommendations), there is no reference to “nanotechnology” or “nanomaterials.” In the 2010 TR there is reference to the “submicron particle size” having unique physical and chemical properties[2010 TR, Lines 40-41]. Another place in the 2010 TR states that the most outstanding characteristics of amorphous silica, particularly synthetic amorphous silica, are their small particle size and high specific surface area, which determine their numerous applications [2010

TR, Lines 58-59]. It appears that previous Boards have recognized the small particle size and have not flagged these as engineered nanomaterials, which are prohibited from inclusion on the National List per NOP Policy Memo 15-2. The Handling Subcommittee is seeking feedback on this topic.

Questions to our Stakeholders

1. What is your understanding of the current listing of silicon dioxide in regards to engineered nanomaterials? Does the current listing allow silicon dioxide as an engineered nanomaterial since the substance is synthetic and their prohibition is not specified in the annotation? Or are they prohibited? Explain your rationale.
2. Should the Subcommittee consider annotating to:
    a. Only allowed synthetic amorphous silica (SAS)?
    b. Only require the use of organic rice hulls when commercially available for products labeled "organic" and not for products labeled as "made with organic?"
3. The 2025 TR lists several alternatives (both nonagricultural, nonsynthetic and organic agricultural). Do you have experience in using any of these alternatives to silicon dioxide? If so, please explain the alternative used and specific function.

Sodium lactate

Reference: § 205.605(b)(33) Sodium lactate - for use as an antimicrobial agent and pH regulator only.
Technical Report: 2015
Petition(s): 2004; 2014 NOP memo to NOSB
Past NOSB Actions: 04/2016 recommendation; 10/2021 recommendation
Recent Regulatory Background: Added to NL effective 01/28/2019 (83 FR 66559); Sunset renewal notice effective 04/14/2023 (88 FR 22893)
Sunset Date: 05/29/2028

Subcommittee Review

Use
Sodium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as generally recognized as safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas [2015 TR, lines 203-204].

Manufacture
Sodium lactate is generally produced from natural (fermented) lactic acid, which is then reacted with sodium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch [2015 TR, lines 102-103, 115-116].

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

- **Sodium lactate** is not explicitly mentioned in the regulations.

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

- **Sodium lactate** is permitted in products of plant origin, milk-based products, and meat products (Annex V: Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed, EC No. 2021/1165).

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

- **Sodium lactate** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM) Norms

- **Sodium lactate** is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- **Sodium lactate** is not explicitly mentioned in the regulations.

Ancillary Substances

None reported in the 2015 TR.

Human Health and Environmental Issues

There does not appear to be any human health concerns associated with sodium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid; however, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment [2015 TR, lines 772-773].

Discussion

Many stakeholders view this listing as "enormously complicated," saying that it is the procedural history that is complicated and not the material itself. Sodium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the National List was based on the fact that both of the materials used to produce sodium lactate (lactic acid and sodium hydroxide) were already approved on the National List. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process. Sodium lactate was added to the National List effective January 28, 2019. In past sunset reviews, the Handling Subcommittee found significant merit to keep sodium lactate on the NL at § 205.605(b) with the annotation: for use as an antimicrobial agent and pH regulator only.

In previous rounds of public comments, a majority of comments were supportive of relisting sodium lactate. A review of the use tables supplied by several associations indicate that sodium lactate is a widely used material. Some stakeholders asked why both sodium and potassium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as low sodium meat alternatives, that require potassium lactate specifically.

Questions to our Stakeholders

1. Are there any new technologies or ingredients that could replace the lactates?
2. What applications are potassium and sodium lactate used in conjunction with?