Sunset 2027
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
Spring 2025

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 2025 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 §205.601 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:

Vitamin D3
Aquatic plant extracts
Lignin sulfonate
Fatty alcohols (C6, C8, C10, and/or C12)
Sodium silicate
EPA List 4 Inerts
Paper

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

Potassium 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) Potassium hypochlorite—for use in water for irrigation purposes
Technical Report: 2011 TR (chlorine materials); 2025 Limited Scope TR
Petition: 2019 Request to add potassium chlorite; 2019 Addendum
Past NOSB Actions: 10/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 03/23/2022 (87 FR 16371)
Sunset Date: 04/22/2027

Subcommittee Review

Use
Potassium hypochlorite is a chlorine material listed for pre-harvest use at 7 CFR 205.601(a)(2)(iv) as a synthetic substance for use in organic crop production. It is listed for use in the treatment of irrigation water with the requirement that residual chlorine levels of water in direct contact with crops or water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. A limited scope technical report (TR) was done in 2024 to provide pertinent information specifically on potassium hypochlorite for the Board's review of the material. This is because prior to the 2024 TR, potassium hypochlorite was assessed based on information in a 2011 TR on chlorine/bleach materials. That TR only covered specific information on sodium hypochlorite, calcium hypochlorite, and chlorine dioxide.

Manufacture
Potassium hypochlorite is a powerful oxidizing agent produced by the reaction of chlorine with a solution of potassium hydroxide (2024 TR, lines 64-67):
$Cl_2 + 2\ KOH \rightarrow KCl + KClO + H_2O$

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

- Potassium hypochlorite is not explicitly mentioned in the regulations.

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

- Potassium hypochlorite is not explicitly mentioned in the regulations.

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

- Potassium hypochlorite is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Potassium hypochlorite is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Potassium hypochlorite is not explicitly mentioned in the regulations.

Toxicity, Mode of Action of Substance and Persistence in Environment.
The antimicrobial mode of action of chlorine stems from both oxidation and chlorination (2024 TR, lines 234-235).

Mixing potassium hypochlorite with water generates highly reactive hypochlorous acid (HOCl), which is the active ingredient in hypochlorites. Hypochlorous acid exerts it effects by forming superoxide radicals that cause oxidative injury and cell death (2024 TR, lines 236-237). As pH increases, the proportion of HOCl can partially dissociate into hypochlorite ion (OCl^-) at physiological (neutral) pH levels. Hypochlorous acid and its conjugate base, OCl^-, are potent oxidizing agents under physiological conditions (2024 TR, lines 237-240).

According to the 2024 TR, hypochlorous acid (HOCl), which predominates at pH solutions below 7.5, is 20 to 30 times as effective a sanitizer as the hypochlorite ion (favored by pH above 7.5) (2024 TR, lines 235-240, 242-243). The strong oxidizing power of the neutral HOCl species enables it to penetrate pathogen cell walls and membranes; entry is followed by removal of electrons from those membranes (2024 TR, lines 243-245). Hypochlorous acid contributes to the unfolding of proteins through oxidation and the aggregation of essential proteins in bacteria. This protein unfolding is like heat-induced denaturation which causes proteins to irreversibly clump together in a mass that impairs their natural functioning (2024 TR, lines 245-248).

In developing the 2024 TR, even though no specific information on degradation of potassium hypochlorite was found (2024 TR, line 304), it was assumed to be comparable to that of sodium hypochlorite due to the similarity in their chemistry and uses. A major difference between the hypochlorites is the replacement of sodium with potassium in potassium hypochlorite, thereby reducing the salinization of soils associated with sodium hypochlorite. The half-life of aqueous chlorine (an equilibrium mixture of hypochlorite and its conjugate hypochlorous acid) is affected by solution concentration, pH, temperature, light exposure, wind, and presence of organic materials. As the concentration and temperature drop, the material becomes more stable (2024 TR, lines 306-309). Chlorine is converted between different chemical forms by natural processes in a global biogeochemical cycle. Chlorine is released from and returned to rock; added and removed from organic molecules; volatilized and degraded by sunlight; and oxidized and reduced both biotically and abiotically, with important implications for life on Earth at each step (2024 TR, lines 299-309).

Environmental Contamination
As stated previously, potassium hypochlorite is produced by the reaction of chlorine with a solution of potassium hydroxide (2024 TR, lines 64-67). Environmental contamination potential is heavily dependent on the source of chlorine used in the production of potassium hypochlorite. The three primary electrolytic

processes used in chlorine production are (a) the diaphragm cell process (b) the mercury cell process and (c) the membrane cell process (2024 TR, lines 368-370). The diaphragm cell process relies on the use of asbestos and was responsible for 75% of the US production in 2000 (2024 TR, lines 372-373). The mercury cell process results in mercury emissions and is thus being phased out by European manufactures (2024 TR, lines 375-377). The membrane cell process employs a modification of the diaphragm cell method. It is superior to the other two methods in its energy efficiency and lack of harmful chemicals and is used to produce more than 90% of chlorine in Japan (2024 TR, lines 384-388).

Application of potassium hypochlorite according to the NOP regulations is unlikely to result in levels that are harmful to human and environmental health. The regulations allow application rates that are consistent with drinking water standards for humans, which are 1-2 ppm and a maximum of free chlorine of 4 ppm (2024 TR, lines 537-539).

Even though the initial application rate can be much higher, the maximum residual disinfectant level under the Safe Drinking Water Act for chlorine materials is 4 mg chlorine/L water (NOP, 2024). At the maximum residual disinfectant level, potassium hypochlorite remaining in water that is discharged to fields or the environment is unlikely to have any detrimental interactions with other substances used in organic crop or livestock production or handling (2024 TR, lines 129-133). At higher concentrations, potassium hypochlorite may react explosively with finely divided carbon. Potassium hypochlorite solution produces highly toxic chlorine gas fumes upon heating or contact with acids. It may form highly explosive NCl_3 on contact with urea (2024 TR, lines 133-136).

Most natural water contains some amount of inorganic nitrogen in the form of ammonia (NH_3) emitted from decaying organic vegetation. In addition, some water treatment plants add ammonia to the water before chlorination is performed, a process called chlorine–ammonia disinfection or chloramination (2024 TR, lines 139-142).

When chlorine (including hypochlorite and other forms) is added to water, the chlorine reacts with the water to form hypochlorous acid. When the water in this reaction contains ammonia, the hypochlorous acid then combines with ammonia to form chloramines (nitrogen and chlorine compounds) (2024 TR, lines 144-147).

Inorganic chloramines are degraded by ammonia-oxidizing prokaryotes (archaea and bacteria) and nitrate oxidizing bacteria. While inorganic chloramines decay with time, organic chloramines both decay and continue to form, leading to a higher proportion of organic chloramines compared to inorganic chloramines in the total chlorine. Organic chloramines can form from the reaction of dissolved organic carbon or dissolved organic nitrogen with inorganic chloramines or free chlorine. Organic chloramines are less effective disinfectants than inorganic chloramines. The drop in effective chlorine disinfectant residuals creates a favorable environment for nitrifying microorganisms to metabolize ammonia and proliferate. This accelerates the nitrification process, which further depletes disinfectant residuals and causes biological and chemical deterioration of water quality (2024 TR, lines 185-194).

Even though no information was found on potassium hypochlorite specifically, the EPA in 2012 made the following conclusion in its registration review of hypochlorites of calcium and sodium. “All environmental fate and ecological effects data requirements for sodium and calcium hypochlorite have been satisfied since the Registration Standard was issued in 1986. Upon reevaluating these data, EPA has concluded that the currently registered uses of the hypochlorites will not result in unreasonable adverse effects to the environment” (2024 TR, lines 517-520).

Effect of Substance on Biological and Chemical Interactions in the Agroecosystem

The application rate of 1-2 ppm, not to exceed free chlorine of 4 ppm, is consistent with drinking water standards for human beings. Use at this level in irrigation water is unlikely to have adverse biological and chemical interactions in the agroecosystem (2024 TR, lines 538-539). The fact that high concentrations of sodium are toxic to plants, destroy soil structure, and create growth conditions that are detrimental to plants make potassium hypochlorite a better option relative to sodium hypochlorite (2024 TR, lines 526-529). When applied as a disinfectant, chlorine is unstable and it easily gets converted to chloride (Cl^-) ions. The Cl^- ion is stable in soil environments and can move within and between ecosystems (2024 TR, lines 347-348).

Tens of species across all phyla can convert chloride to organic compounds (2024 TR, line 349). Studies on the effects of low concentration of chlorine on soil-wheat microbiome systems found no significant lasting effects on soil microbial community diversity and composition in the root zone or in bulk soil. Even though metabolic functions of the microbial community in the rootzone were slightly affected by continuous chlorine treatment, researchers observed recovery to the original status (2024 TR, lines 451-454). Exposure of selected invertebrates to short-chain chlorinated paraffins (64% chlorine) revealed differences in sensitivity to chlorine. In the study involving species of earthworms, white worms, springtails, and nematodes, researchers found that springtails were the most sensitive (2024 TR, lines 463-465). A separate laboratory study involving selected fish species found differences in the toxicity of hypochlorite ion, hypochlorous acid, monochloroamine, and dichloroamine to emerald shiners, channel catfish, and rainbow trout. Hypochlorous acid was the most toxic, followed by dichloroamine. Monochloroamines and hypochlorite ions recorded between a third to a quarter of the toxicity of hypochlorous acid and dichloroamines. Emerald shiners were found to be most sensitive to the four forms of chlorine. The researchers concluded that fish species, total residual chlorine, and duration of exposure are principal factors that impact the effect of chlorine on fish (2024 TR, lines 470-485). In general, fish avoid elevated levels of chlorine when they detect the source point. Elevated temperature magnifies the toxic effects of chlorine on fish. Chlorine levels that are not high enough to elicit avoidance behavior in fish may cause high mortality at elevated temperatures (2024 TR, lines 489-492). Acute toxicity tests on other freshwater organisms (including insects, crustaceans, bivalves, and aquatic plants) revealed that mayfly nymphs and the water flea (crustacean) were the most sensitive; fish were the least sensitive. The researchers, however, described their acute toxicity data as conservative because of the use of flow-through systems that prolong exposure in ways that do not mimic field conditions (2024 TR, lines 499-510).

Effect on Human Health

The NOP regulations allow potassium hypochlorite application rates that are consistent with drinking water standards for humans, which is 1-2 ppm, and not to exceed free chlorine of 4 ppm. According to the EPA, these levels are unlikely to be harmful to human health or the environment (2024 TR, lines 537-539). The TR developers did not find any specific reports on the effect of potassium hypochlorite on human health (2024 TR, lines 549-550). It is a powerful oxidizing agent that produces highly toxic fumes of chlorine gas upon heating or contact with acids (2024 TR, lines 549-550). The TR authors did not find any reports on the effect of potassium hypochlorite on human health, specifically. Sodium hypochlorite was included in the search for human health effects because of its similarity to potassium hypochlorite in chemical characteristics and uses (2024 TR, lines 549-550). Chlorine, the active ingredient in hypochlorites (2024 TR, line 550) reacts with natural organic matter to produce a variety of toxic disinfection by-products. The removal of natural organic matter present in water via physical/chemical treatment processes helps to avoid such harmful reactions; treatment processes include enhanced coagulation and activated charcoal filtration (2024 TR, lines 556-558).

Hypochlorites pose human health and environmental concerns under some circumstances (2024 TR, line 560). Ingestion of hypochlorites may be dangerous to human health. Human exposure to high concentrations of hypochlorites may result in a wide range of reactions and damage, including, irritation or damage to the skin, eyes, and the respiratory tract, kidney damage, diarrhea, vomiting, inflammation, burns, perforation, stricture, and death (2024 TR, lines 568-578). A review of medical studies on the health effects of sodium hypochlorite led to the conclusion that health impacts resulting from long-term occupational or environmental exposure to low sodium hypochlorite concentrations were rare. Ingestion of large volumes of bleach can result in severe health problems including death (2024 TR, lines 587-588). Apart from the fact that ingestion is disallowed and inconsistent with label instructions, occupational and environmental exposure to the substance do not approach such levels.

Alternatives/Compatibility
Hypochlorites of sodium and calcium can be used for the same purposes as the potassium hypochlorite. The absence of sodium and the fact that potassium is a plant nutrient make potassium hypochlorite a better option relative to sodium hypochlorite. Overall, potassium hypochlorite is compatible with the principles and practice of sustainable agriculture.

Questions to our Stakeholders

1. Is the substance used in concentrations that do not exceed the maximum limits spelled out in the Safe Drinking Water Act?
2. Is there interest in introducing an annotation to ensure that only potassium hypochlorite produced using environmentally friendly chlorine production methods is allowed for use in organic production in the United States?
3. Are there effective alternatives?

Soap based algicide/demossers

Reference: 205.601(a)(7) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
Technical Report(s): 1996 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: Actions: 09/1996 NOSB recommendation; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Synthetic soap salts are approved as algicides/demossers and are permitted to control algae and mosses in and around production areas including walkways, greenhouse surfaces, and irrigation systems.

Manufacture
Various preparatory methods depend on the desired soap salt composition for a particular herbicide/algicide formulation.

Potassium salts of fatty acids are produced through a process known as saponification, whereby aqueous potassium hydroxide is added to fatty acids found in animal fats and plant oils. Sources of potassium soap salts are prepared through hydrolysis of triglycerides using water under high pressure and temperature. A carbonate or hydroxide salt of an alkali metal (potassium or sodium) traps the free fatty acid into a soap salt. Commonly used fats (triglycerides) include coconut, sunflower, palm, tallow, and olive oil. Soaps are mixtures of fatty acid salts with various carbon chain lengths and generally do not consist exclusively of one soap salt compound (2015 TR, lines 254-265).

International acceptance

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

- Soap-based algicide (demossers) are 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

- Soap-based algicide/demossers are not explicitly mentioned in the regulations.

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

- Potassium soap (soft soap) is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Soft soap is permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).
- Potassium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Sodium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Potassium and sodium soap 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 soap (soft soap) is permitted (Table B.1 - Chemical agents, JAS for Organic Feed).
- Soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Invert soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Ampholytic soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted; not permitted for use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).

- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Environmental issues and human health

Environment:
When released into the environment, soap salts essentially behave as the carboxylate anions of fatty acids. In general, potassium and ammonium salts of fatty acids decompose rapidly and do not accumulate or persist in the environment. Biodegradation is expected to be an important fate process, and field tests show half-lives of less than one day for these salts (2015 TR, lines 479-482).

EPA/FDA:
U.S. EPA has waived all generic mammalian toxicity data requirements for potassium and ammonium soap salts due to the lack of effects at high doses in the available toxicity literature.

The FDA generally recognizes potassium salts of fatty acids as safe (GRAS) (2015 TR, lines 355-357). Studies have also shown that soap salts are practically non-toxic to honeybees (2015 TR, lines 367-368).

Discussion:
2015: The Crops Subcommittee voted to delist soap-based algicides/detergents in 2015 because they thought it was no longer used in organic crop production and keeping it on the National List was unnecessary. However, public comments indicated that some producers were still using these materials. Based on public comments, they were not removed.

2020: Public comments in 2020 supported continuing to list these products and indicated that they are still being used in organic farming. Public comments noted that there was a lack of viable alternatives.

Questions to our Stakeholders
None

Ammonium carbonate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate —for use as bait in insect traps only, no direct contact with crop or soil.
Technical Report: 1995 TAP (Ammonium bicarbonate and ammonium carbonate); 2025 TR (Handling)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use

Ammonium carbonate is used in small quantities as an attractant in traps. In some cases, ammonium carbonate is used alone, and in others, as a mixture with yeast to enhance its chemical attraction to insects. It is used for the control of flies that are problematic in fruit and nut production. This material compliments other natural alternatives such as the release of natural predators and parasitoids and manure management.

Manufacture

Ammonium carbonate manufactured by the reaction of ammonia sourced from the synthetic Haber-Bosch process, with carbon dioxide sourced from industrial processes like power generation, cement manufacturing, or fossil fuel processing (2024 Handling TR, lines 100-102).

International Acceptance

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

- Ammonium carbonate is permitted as an attractant in insect traps (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as an attractant in insect traps (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

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

- Ammonium carbonates are permitted in products of plant origin (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 (GL 32-1999)

- Ammonium carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- **Ammonium carbonates** are permitted as additives only for cereal products, confectionery, cakes, and biscuits (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Ammonium carbonate is permitted; limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).
- Ammonium carbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Human Health and Environmental Issues

Ammonium carbonate is labeled as an irritant. The intended use in crop production is as a bait that would not come in contact with plants or soil. A small amount of ammonium carbonate is used alone or in a mixture with yeast. The ambient temperature during use would result in ammonium carbonate volatilizing, releasing ammonia and carbon dioxide as gases. Given the small amount of ammonium carbonate used, the impact of its volatilization would be small. We were unable to find reports of non-target effects on other insect species; such information would aid in our review of this material.

Discussion
The main alternatives are manure management and enhancement of predators and parasitoids, but its use to trap adult flies complements the use of other methods that control egg-laying and immature stages. Previous boards supported the relisting of this material.

Questions to our Stakeholders
1. Is there new research determining the effects of ammonium carbonate bait on non-targeted insect species?

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).
Technical Report: 1994 TAP; 2020 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Insecticidal soaps are used for control of soft bodied insects and hard bodied insects in the larval stage on organic crops.

Manufacture
A reaction of an alkali, such as sodium or potassium hydroxide, on natural fatty acids (from both animal and plant sources) is used to prepare insecticidal soaps. The fats, such as laurate, myristate, oleate, and ricinoleate, are further processed to create a blend of selected fatty-acid chain lengths. The cation for soap molecules is determined by the base used in its production. Potassium soaps are derived from treating fatty acids with potassium hydroxide, while ammonium soaps are produced by saponification with ammonium hydroxide (2020 TR, lines 58-65).

International acceptance
Summary:
1. European Economic Community (EEC) lists potassium soaps as an insecticide with applications "from traditional us in organic farming."
2. Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).
3. Canadian General Standards Board Permitted Substances List includes ammonium soaps as a permitted substance.
4. IFOAM lists potassium soaps as an equipment cleanser and equipment disinfectant.

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

- Soaps (including insecticidal soaps) are permitted and shall consist of fatty acids derived from animal or vegetable oils (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

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

- Insecticidal soaps are not explicitly mentioned in the regulations.

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

- Potassium soap (soft soap) is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Soft soap is permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).
- Potassium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Sodium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Potassium and sodium soap 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 soap (soft soap) is permitted (Table B.1 - Chemical agents, JAS for Organic Feed).
- Soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Invert soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Ampholytic soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted; not permitted for use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Environmental issues and human health
The toxicological profile of the substances differ based on the environment in which they are located.

Impact:
Insecticidal soaps are widely regarded as having low toxicity to terrestrial organisms like mammals and avian animals (2020 TR, lines 341-343). Potassium salts are highly toxic to aquatic invertebrates and slightly

toxic to cold and warm water fish species. Due to this potential toxicity to aquatic environments, insecticidal soap product labels stipulate that the products are not intended for application to aquatic systems, including ponds and streams (2020 TR, lines 347-351). Recent studies (2018) have shown insecticidal soaps to be non-toxic to desirable insects such as ladybugs and the coccinellid beetle (2020 TR, lines 412-413).

Environmental:
Insecticidal soaps are rapidly biodegradable in the environment, and the half-life is estimated to be less than one day (2020 TR, lines 421-422). Microbial organisms rapidly degrade fatty acids in soils (2020 TR, lines 322-323). A recent technical review (2020) reports that "there is little to suggest that insecticidal soaps pose a threat to the environment when used as approved." The report goes on to state that because of the low toxicity, even if it is used improperly, environmental impact would be minimal (2020 TR, lines 430-434).

EPA/FDA:
EPA has given these insecticides the lowest Toxicity Category IV (indicating the lowest level of toxicity) (2020 TR, lines 343-344). Potassium salts of fatty acids used on food and feed crops have been exempted from the requirement of a tolerance (or maximum residue limit) for all raw agricultural commodities since 1982 (2020 TR, lines 267-271). They are also generally recognized as safe (GRAS) by the FDA.

Discussion
Alternatives include cultural pest control methods, oils, botanicals, or biological controls (depending on species). Various essential oils and pyrethrum have been used. However, horticultural oils and pyrethrum are easily degraded under common conditions like UV radiation. Moreover, differences in the mode of action and the targets (hard-bodied vs. soft-bodied) of essential oils and pyrethrum make them poor substitutes (2020 TR, lines 475-478).

2015: In the previous Sunset review in 2015, there was overwhelming support for the continued listing of this material. Public comments stated that this material remains a necessary tool in organic crop production and has increased in use due to the growth of organic production. Public comment stated that most organic certifying bodies allow these oils to be used worldwide.

2020: The 2020 public comments for this product, again, showed overwhelming support for the continued listing of insecticidal soaps and that they were also in wide use.

Questions to our Stakeholders
None

Sucrose octanoate esters

Reference: 205.601(e) - As insecticides (including acaricides or mite control) (10) Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)—in accordance with approved labeling.
Technical Report: 2005 TR; 2025 Limited Scope TR
Petition(s): 2004 Sucrose Octanoate Esters; Amendment #1; Amendment #2
Past NOSB Actions: 08/2005 NOSB recommendation for addition to NL; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 - recommendation to remove
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420); Sunset renewal notice published 02/28/2022 (87 FR 10930)
Sunset Date: 03/15/2027

Subcommittee Review

Sucrose octanoate esters (SOEs) belong to the organic chemical family, sucrose fatty acid esters (SFAEs) (2005 TR, lines 23-24). SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals (2005 TR, lines 27-28). SOEs, marketed as biopesticides, are synthetic analogs of the naturally occurring sugar ester isolates of *Nicotiana* plant species (2024 TR, lines 57-58) that mimic the pest control properties of the natural forms of the compound in wild tobacco and other plants in the *Nicotiana* genus. *gossei* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant (2005 TR, lines 35-38).

Use

Sucrose octanoate esters are listed at §205.601(e) in organic crop production as insecticides (including acaricides or mite control) in accordance with approved labeling (2024 TR, lines 32-33). Producers use SOEs to control soft-bodied pest organisms including mites, aphids, and whiteflies (2024 TR, line 56). The EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops, and for *Sciarid* fly control in mushroom-growing media.

Manufacture

Commercial synthesis of SOEs involves the use of materials such as alcohols, several catalysts, solvents, and sucrose octanoate acid (2024 TR, lines 60-62). Steps in the production include (1) Esterification of fatty acids, (2) Neutralization and separation of catalyst, (3) Second esterification with sugar, (4) Vacuum distillation and emulsification, (5) Separation of emulsified product, and (6) Purification and recovery of sugar ester product (2024 TR, lines 66, 140, 154, 178, 183, and 188). The raw materials are derived from various sources: octanoic acid from both synthetic and nonsynthetic sources, alcohol (methanol or alcohol) from synthetic and nonsynthetic sources, and sucrose that is usually obtained from nonsynthetic sources (2024 TR, lines 197-200). The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids.

International Acceptance

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

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

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

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

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

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

International Federation of Organic Agriculture Movements (IFOAM)

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

Japan Agricultural Standard (JAS) for Organic Production

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

Human Health and Environmental Issues

Effect on the Environment:

The chemical structure of SOEs, consisting of sucrose and octanoic acid, renders the material readily biodegradable (2024 TR, line 215). Naturally occurring microorganisms in soil and water can break down these compounds. The compound biodegrades within approximately five days at temperatures ranging from 68°F to 80°F in both aerobic and anaerobic conditions. Typical degradation products are carbon dioxide and water, both of which are harmless. In addition to the fact that these degradation products are harmless, some are incorporated as microbial biomass (2024 TR, lines 216-220).

Impact on Non-Target Organisms

The EPA's evaluation report on the potential impact of SOEs on non-target insects and other organisms, such as fish, stated that the use of the compound had minimal potential for exposure and toxicity to these organisms as well as soil and water (2024 TR, lines 223-225). According to the EPA, the fact that the mode of action of the compound is via physical effects as opposed to biochemical toxicity gives the compound a minimal toxicity profile. The petitioned substance primarily targets soft-bodied insects by physically disrupting the lipid layer of their cuticle, thereby causing dehydration and death. Insects with thicker and/or more robust exoskeletons are not affected by the petitioned substance (2024 TR, lines 231-233).

The physical mode of action enables the compound to target soft-bodied insects without producing general toxic metabolites, thereby decreasing the likelihood of adverse effects on mammals and birds (2024 TR, lines 225-229). Soft-bodied organisms targeted include mites and insects such as thrips, aphids, and whiteflies. The fact that SOEs do not exert their pesticidal effects via a biochemical pathway common to all insects renders it selective, resulting in minimal effects on non-target organisms such as pollinators (e.g., bees), predators (ladybugs), earthworms, and other soil organisms (2024 TR, lines 233-236). Some non-synthetic pesticides are known to have adverse effects on beneficial organisms such as predators and parasitoids. An assessment of the effect of SOEs on multiple beneficial insects from different insect orders in citrus ecosystems revealed a high survival rate of ladybeetles (Coccinellidae), lacewings (Chrysopidae), and parasitoids of red scale insects (Anthocoridae) even when exposed to 8,000 ppm (i.e., parts per million), which represents twice the recommended field application rate (2024 TR, lines 238-242). Soil organisms and non-target insects may be exposed to SOEs during and after applications until the compounds biodegrade in ~5 days. Direct and specific detrimental effects from SOEs on soil organisms have not been studied extensively. Available literature does not show detrimental physiological effects of SOEs on soil organisms, soil microbiome, or non-target insects (2024 TR, lines 257-260). Current literature states that SOEs have low toxicity and biodegrade rapidly. When SOEs are applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOEs is expected (2005 TR, lines 201-202).

Effect on Human Health

SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified (2005 TR, lines 303-304). An ocular risk exists but it is unlikely if the product is used according to the label (2005 TR, lines 309-311).

Comparison with natural (Nonsynthetic alternatives

In the absence of research studies that compare SOEs to nonsynthetic alternatives, the 2024 TR covered the performance and characteristics of nonsynthetic pesticides including neem extract, Pyrethrins, *Bacillus thuringiensis* (Bt), Spinosad, miscellaneous botanicals such as essential oils derived from thyme and eucalyptus, garlic extracts, and biological control agents. Even though neem extracts were reported to be effective against listed insect pests, cases of neem oil poisoning in humans were reported (2024 TR, lines 299-300). Pyrethrins can harm beneficial insects such as bees and aquatic organisms if used improperly (2024 TR, lines 312-314). *Bacillus thuringiensis* affects a broader range of organisms than SOEs (2024 TR, line 332). There are reports of non-targeted adverse effects on several groups of insects that are closely related or have an affinity to targeted insects (2024 TR, lines 337-339). At regular field application rates, Bt has been reported to impair the growth and developmental time of non-target true flies such as *Drosophila melanogaster* (common fruit fly) larvae (2024 TR, lines 341-344). There are also reports of insect pest resistance to Bt products (2024 TR, line 352). Spinosad breaks down quickly in the environment and is considered safe for humans and most beneficial insects. It can, however, be toxic to bees if applied directly to flowering plants. Spinosad application has also been demonstrated to have adverse effects on genes associated with energy production in honeybees (2024 TR, lines 367-368).

Rationale for Previous NOSB Recommendation
Despite the apparent low use of sucrose octanoate ester, the Crops Subcommittee voted in 2018 to relist it. Additional information obtained afterwards and prior to the 2018 Fall NOSB meeting, however, led the full NOSB to recommend removing this material from §205.601(e) of the National List. The current information at the time indicated that there were no EPA-registered pesticides containing sucrose octanoate esters. This meant that the material could not legally be used as an insecticide. Based on this information, sucrose octanoate esters were deemed to have failed the essentiality test for use in organic production. A majority of the Board voted to remove SOEs from the National List, but a minority were in favor of relisting it in anticipation of the availability of EPA-registered SOE-formulations in the future. The minority sought to avoid removing any tools from the organic producer's toolbox.

Subcommittee Discussion
During the February 4, 2025 Subcommittee call, a Board member said he was aware of one product that uses SOEs. He, however, described the product as expensive.

Questions to our Stakeholders
1. Are there EPA-registered products formulated using SOEs?
2. Is there current information on the need and use of SOE formulations in crop production?
3. Is there a need to keep SOEs in the crops toolbox to be rotated with other products?

Vitamin D3

Reference: 205.601(g) - as rodenticides.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Vitamin D3 (cholecalciferol) is used to fortify food and aids in the growth and maintenance of bones. It is typically found in milk and cereals (2011 TR, lines 45-47). Forms of vitamin D are also found in margarine and infant formula. In this listing, vitamin D3 is used as a synthetic rodenticide in gel and pellet baits.

Vitamin D3 kills gophers, mice, rats, and other rodents by causing an excessive, highly elevated level of calcium, which results in hypercalcemia and mineralization of major organs (including kidney failure), leading to death (2011 TR, lines 55-57).

Manufacture
The commercial manufacture of vitamin D3 utilizes cholesterol obtained by organic solvent extraction of animal skins (pig, sheep, or cow) and extensive purification. Typically, cholesterol is extracted from the lanolin of sheep wool and converted to 7-dehyrdocholesterol after a process of chemical synthesis that involves eighteen steps. The crystalline 7-dehyrdocholesterol is then dissolved in an organic solvent and irradiated with UV light. This process causes a photochemical transformation of 7-dehyrdocholesterol into cholecalciferol, which is similar to the natural process that occurs in the skin of humans. It is then purified and crystallized further before being formulated for use. Details of the manufacturing process are subject to several patents and are not publicly available (2011 TR, lines 179-187).

Since the formulations contain 0.075% cholecalciferol, with the remainder being "inerts," much of it will be attractive food to rodents.

International Acceptance
Summary:

1. The Canadian General Standards Board Permitted Substances List has this annotation on vitamin D3 (cholecalciferol) "if used outdoors and inside greenhouses for rodent control when methods described in 5.6.1 of CAN/CGSB-32.310 have failed. Prohibited inside on-farm food processing and food storage facilities."
2. CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999), has an allowance for rodenticides with this caveat "Products for pest control in livestock buildings and installations. Need recognized by certification body or authority."
3. The European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 states rodenticides are only to be used in traps.
4. The Japan Agricultural Standard (JAS) for Organic Production. Not mentioned for Crop applications.
5. The International Federation of Organic Agriculture Movements (IFOAM) do not list this product, nor have any specific requirements for rodenticides.

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

- Cholecalciferol (vitamin D3) is permitted if used outdoors and inside greenhouses for rodent control when methods described in 5.6.1 of CAN/CGSB-32.310 have failed. Prohibited inside on-farm food processing and food storage facilities (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Biological and mineral sources of all vitamins are permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Pre-mixes (concentrated mixture of minerals and vitamins) are permitted. From organic sources if commercially available. All ingredients in pre-mixes shall be essential for animal nutrition, and listed in Table 5.2. Non-GE fillers, for example rice hulls, may be non-organic (Table 5.2 – Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- Vitamins are permitted for enrichment or fortification. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of CAN/CGSB-32.311 are permitted (Table 5.2 – Feed, feed additives and feed supplements, 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).
- Vitamins and mineral nutrients shall be used if legally required (e.g., fluid milk, white flour, infant formula, meal replacement, etc.) (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Cholecalciferol (vitamin D3) is prohibited inside organic food processing and food storage facilities (Table 8.2 – Facility pest management substances, 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 of natural origin are permitted, 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).
- Minerals (trace elements included), vitamins, amino acids and micronutrients, provided that their use in food for normal consumption is "directly legally required," in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added (Detailed requirements for the production of processed food, EC No. 2018/848).
- Vitamins and provitamins are permitted if derived from agricultural products. If not available from agricultural products, they may be derived synthetically. Only those identical to vitamins derived from agricultural products may be used for monogastric animals and aquaculture animals. Only vitamins A, D, and E identical to vitamins derived from agricultural products may be used for ruminants (Nutritional Additives, EC No. 2021/1165).

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

- Minerals (including trace elements), vitamins, essential fatty and amino acids, and other nitrogen compounds are permitted only if their use is legally required in the food products in which they are incorporated (Ingredients of Non-Agricultural Origin, CXG 32-1999).
- 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 (Specific criteria for feedstuffs and nutritional elements, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- 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 (Animal Production, IFOAM NORMS 2014).
- Organic processing only uses minerals (including trace elements), vitamins, essential fatty amino acids, and other isolated nutrients when their use is legally required or strongly recommended in the food products in which they are incorporated (Processing and Handling, IFOAM NORMS 2014).
- Animals may be fed vitamins, trace elements, and supplements from natural sources. Synthetic vitamins, minerals, and supplements may be used when natural sources are not available in sufficient quantity and quality (Animal Nutrition, IFOAM NORMS 2014).
- Fodder preservatives such as the following may be used: a) bacteria, fungi and enzymes; b) natural products of food industry; c) plant-based products; and d) vitamins and minerals subject to 5.5.6.

Synthetic chemical fodder preservatives such as acetic, formic, and propionic acid are permitted in severe weather conditions (Animal Nutrition, IFOAM NORMS 2014).

- Minerals (including trace elements), vitamins, and similar isolated ingredients shall not be used unless their use is legally required or where severe dietary or nutritional deficiency can be demonstrated in the market to which the particular batch of product is destined (Processing and Handling, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Feeding: Such natural substances or feeds derived from natural substances (that have not undergone chemical treatment), which are intended for vitamin or mineral supplementation (Criteria for Raising and Production methods, JAS for Organic Livestock Products).
- Health Management: 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 (Criteria for Raising and Production methods, JAS for Organic Livestock Products).

Environmental Issues

Aquatic Life/Animals: According to the TR, vitamin D3 is not expected to mobilize in soil, and its bioconcentration in aquatic life is expected to be very low (2011 TR, lines 238-239). Since the Environmental Protection Agency restricts its use to bait stations, the risk of accidental poisonings of non-target species has been addressed. Vitamin D3 is of low toxicity in birds, unlike the more widely used anti-coagulant rodent baits not approved for organic production (2011 TR, line 323). Most stakeholders report anecdotal findings that vitamin D3 has low toxicity to birds and to other non-target species, particularly as compared to other rodenticides.

Environment: Because of its insolubility in water, its use is unlikely to cause contamination to ground or surface waters (2011 TR, lines 260-261).

Subcommittee Review

Alternatives/Non-Target: Since birds of prey can greatly control rodents on the farm, vitamin D3 is preferred due to its very low risk to bird populations. Birds have a much lower body weight and consuming just one or two rodents that have consumed an anticoagulant bait could harm the bird’s health or cause death. Using a rodenticide that does not harm the predator population is an ecosystem-friendly approach to controlling rodent populations.

While non-target mammals could consume ill rodents that consumed vitamin D3, it would take many of these rodents to cause harm to the food chain. Notably, one non-profit stakeholder organization has suggested, via public comment, that vitamin D3 can lead to a painful death in rodents and could be replaced with other substances.

There are system-based methods that can be used to control rodent populations, such as improving structures to prevent their entry and keeping food/water and harborage to a minimum. However, there are times when toxic bait is necessary to lessen the rodent population so that other system-based approaches can take over.

2020: At the April 2020 NOSB public meeting, a range of stakeholders provided public comment on vitamin D3 as a rodenticide. With almost no exception, the community expressed support for the material’s continued listing for permitted use in organic production. Most of the comments addressed the issue of non-target species toxicity.

Use: Vitamin D3 continues to be widely used by many organic stakeholders as a rodenticide, particularly in situations where environmental factors and built structures create conditions conducive to rodent infestations. Some have criticized its efficacy, but nearly no grower or certifier expressed opposition to its continued listing as an essential substance for the organic toolkit.

Questions to our Stakeholders
None

Aquatic plant extracts

Reference: 205.601(j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount is limited to that amount necessary for extraction.
Technical Report: 2006 TR; 2016 TR; 2025 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Plant extracts are composed of chemicals naturally found in aquatic plants (2006 TR, line 19), namely marine plants (also called seaweed). Aquatic plant extracts are used as foliar fertilizers or as soil conditioners. They also are used in combinations as a foliar/soil feed or transplant solution and seed treatment. The material is absorbed into the plant and acts as a growth promoter (2006 TR, lines 63-66). Aquatic plants contain proteins, lipids, sugars, amino acids, nutrients, vitamins, plant hormones, and other biochemicals (2006 TR, lines 26-27). Aquatic plants contain a wide range of naturally occurring plant nutrients and trace minerals essential to plant growth, health, and productivity (2006 TR, lines 41-42). Cytokinins, a class of plant hormones present in aquatic plant extracts, have been reported to have beneficial effects on crops, including increases in number or size of fruits or seed heads, synchronization of flowering within a field, and delayed decay of mature plants (2006 TR, lines 46-48).

Manufacture
Seaweeds are classified into three broad groups based on pigmentation: *Phaeophyceae* (brown), *Rhodophyceae* (red), and *Chlorophyceae* (green) (2016 TR, lines 103-104), and all three classes are used in aquatic plant extracts. Seaweeds are also called macro-algae, distinguishing them from micro-algae (*Cyanophyceae*) which are microscopic in size and often unicellular (2016 TR, lines 108-110). Seaweeds used in aquatic plant extracts are macro-algae.

Seaweed extract is produced from fresh, live plants that are processed into a soluble powder or liquid and may be stabilized with synthetic acids and fortified with other ingredients. An alkali extraction process is used to "digest" the plants and derive both micronutrients and naturally occurring plant hormones. This process also transforms the plants into a soluble, easily transported form. The majority of manufacturers use potassium hydroxide as the primary reagent in the alkali extraction process. Other alkali reagents used by some manufacturers include sodium hydroxide, calcium hydroxide, and sodium carbonate (2006 TR, lines 181-189).

For this sunset review, the Crops Subcommittee (CS) requested a limited scope technical report (TR) to evaluate the use of synthetic alkali substances in the manufacture of aquatic plant extracts and whether additional restrictions on the use of these extraction substances is necessary. The TR revealed that the typical pH range among OMRI-listed products was 8-11 (2024 TR, lines 186-187). It also indicated that there is no set of industry specific considerations when determining what amount of alkali is necessary for extraction (2024 TR, lines 193-194) because extraction of aquatic plants is not necessarily focused on obtaining a singular substance from the algae, but rather a complex set of biologically active molecules (2024 TR, lines 198-203).

The current annotation for aquatic plant extracts is intended to prevent the practice of using extractants for their nutrient content. Currently, certifiers are requiring an attestation from the manufacturer explaining their rationale for including synthetic alkali extractants and how it meets the annotation restrictions. Another compliance verification method is a calculation method used for products extracted with potassium hydroxide. In this method, aquatic plant extracts are considered fortified by potassium hydroxide (and therefore prohibited) when the ratio of aquatic plant material to potassium hydroxide exceeds 3.20:1 (2024 TR, lines 257-288).

International Acceptance

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

- **Algae** is permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- **Aquatic plants and aquatic plant products** are permitted, and may be extracted using these substances in the following order: a) substances in Table 4.2 Extractants; b) potassium hydroxide; and c) sodium hydroxide provided the amount of solvent used does not exceed the amount necessary for extraction (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Growth regulators for plants are permitted. Plant hormones, such as gibberellic acid, indoleacetic acid and cytokinins, derived from terrestrial or **aquatic plants** or produced by microorganisms (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Plant by-products and plants are permitted. Includes plant preparations of **aquatic** or terrestrial plants or parts of plants, such as cover crops, green manures, crop wastes, hay, leaves and straw. Parts of plants used as soil amendments and foliar feeds are permitted. Wastes from crops that have been treated or produced with prohibited substances are permitted as compost feedstocks (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- **Seaweed and seaweed products** are permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

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

- **Algae and algae products** are permitted when directly obtained by (i) physical processes including dehydration, freezing and grinding, (ii) **extraction with water or aqueous acid and/or alkaline solution**, and (iii) fermentation, only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848 (Authorised fertilisers, soil conditioners, and nutrients, EC No. 2021/1165).

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

- Seaweed, seaweed meal, **seaweed extracts**, sea salts, and salty water are permitted, with the condition that their need is recognized by the certification body or authority, and they are not chemically treated (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).
- **Extract from Chlorella** is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Organic aquatic plants are grown and harvested sustainably without adverse impacts on natural areas. Aquatic plant production shall comply with the relevant requirements of chapters 2 and 4. Harvest of aquatic plants shall not disrupt the ecosystem or degrade the collection area or the surrounding aquatic and terrestrial environment (Aquatic Plants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Chlorella extract liquid** is permitted (Table B.1 - Agricultural chemicals, JAS for Organic Products of Plant Origin).
- Substances derived from plant, livestock, **marine** products which were used in food or textile industries are permitted: Natural substances or substances derived from natural sources which have not undergone any chemical treatment (excluding extraction of oils with organic solvents) (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues

Aquatic plant extracts are biodegradable and are likely to have a low impact on crops (2006 TR, lines 242-243). They are not expected to cause toxicity to plants, soil organisms, or higher animals (2006 TR, lines 151-152). There are no known human health hazards (2006 TR, line 320). The potential for over-harvesting of kelp/seaweed fields for production of aquatic plant extracts was identified as a possible environmental concern in the 1995 TAP review, but it offered no additional information.

The 2016 TR and 2016, 2017, and subsequent public comments raised concerns about the potential for negative environmental impacts on marine ecosystems from seaweed harvesting. Some examples noted in the 2016 TR were specific to species used in organic crop fertility inputs and aquatic plant extracts. For example, in mechanical harvesting in Iceland, as with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (2016 TR, lines 892-896). In Nova Scotia, commercial yields of rockweed are maintained. There still isn't sufficient information or analysis from industry or third-party research proving that their harvest rate is not detrimental to the habitat value that rockweed provides to associated plants and animals. Estimated recovery times based on percentages removed vary between publications (2016 TR, lines 597-600).

Additionally:

There is one species of red algae and two species of brown algae growing along the coasts of the United States that have gained attention as ecologically threatened in recent years. They are, respectively, Irish moss (*Chondrus crispus*), rockweed (*Ascophyllum nodosum*), and giant kelp (*Macrocystis pyrifera*). These plants are economically important and drive several seaweed industries including cosmetic products, nutraceuticals, fertilizers and hydrocolloids. Fertilizer applications are similar to farmyard manure, but may also include extracts and foliar applications (2016 TR, lines 522-527)

Kelp and rockweed are foundational species forming large expansive marine habitats supporting a diverse range of wildlife including other algal species, marine animals and many species of protozoans and bacteria. Without a good accounting of all of the species present, it is hard to predict the effects of harvesting rockweed and kelp on each ecological niche. Thus, it has been important to recognize that sustainable seaweed production perceived as reproducible harvest capacity may not guarantee the sustained subsistence of each resident species. Although not part of any agricultural waste stream, extracts from wild-harvested kelp and rockweed are allowed for use in organic production as soil amendments (§205.601(j)(1)) (2016 TR, lines 528-535).

Even within the 2016 TR, differences of opinion about the environmental impacts of harvesting were noted within the scientific community. For example, one study addressing the major components of the resident fish community in the rocky intertidal zone after rockweed harvest found no evidence linking rockweed harvest to changes in the ichthyoplankton component or the juvenile and adult fish of that community. In a summarized review of selected work, a researcher at the University of Maine also concluded that the effect of 17% rockweed harvest on some species including seabirds was negligible (2016 TR, lines 326-331).

The TR goes on to explain that rockweed has an important role as habitat, as food, and as a nutrient source supporting a community of organisms that inhabit its "forests." Any cutting of rockweed can produce an effect on the supported eco-communities. Furthermore, many aspects of this ecosystem have not been elucidated, encouraging more precaution as the brown algae "forestry" industry grows into the future (2016 TR, lines 356-60).

Discussion
Previous Boards have exhaustively focused on the impacts of seaweed harvesting on marine ecosystems and proposed regulations to address these concerns. NOP has declined to implement these recommendations. We are now focusing on the current annotation restriction and whether there is any update needed for this group of substances. We hope to receive information from manufacturers regarding the oversight of their products and the risk of fortifying aquatic plant extracts with potassium derived from the extractant rather than the aquatic plants themselves.

Questions to our Stakeholders
1. Should NOSB consider an annotation change to aquatic plant extracts to ensure that extractants are not used for their nutrient content? If yes, please provide suggestions for annotation changes and rationale.

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.
Technical Report: 1995 TAP; 2011 TR; 2020 TR (lignins)
Petition(s): 2014 Petition to remove as floating agent
Past NOSB Actions: 10/1995 NOSB Minutes and vote; 04/2006 Sunset Rec; 04/2011 NOSB Rec to amend, 04/2011 NOSB Sunset Rec; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Lignin sulfonate acts as a dust suppressant due to its large size and high affinity for binding with polar and nonpolar compounds. Small dust particles of fertilizers adsorb to lignin sulfonate to form a larger, heavier complex which reduces dust (2011 TR, lines 143-145). Products with less dust are easier to handle and are applied more efficiently and accurately. Similarly, lignin sulfonate acts as a chelating agent by binding with smaller, charged micronutrient ions such as boron, manganese, and iron, and are slowly released into the soil in a bioavailable form (2020 TR, lines 146-148).

Prior to 2015, lignin sulfonate could be used as a floating agent in postharvest handling for pears. However, it was petitioned for removal at § 205.601(l)(1) in 2014 and voted off the list by the Board in Fall 2015. There were no comments supporting its listing, indicating a lack of essentiality of this synthetic material as a floating agent.

Manufacture
Lignin sulfonates are produced from the process of sulfite chemical pulping. Sulfite pulping involves cooking softwood chips under pressure in sulfur dioxide-containing cooking liquors. When the cooking process is complete, sulfonated lignin is collected as a liquid by-product in the spent liquor (2020 TR, lines 520-524), while the pulp is used for paper production. Lignin sulfonates may also be obtained from the Kraft pulping process, which is similar to sulfite pulping, but involves treating the wood at high temperatures and pressure in a water solution containing sodium sulfide and sodium hydroxide (2020 TR, Table 4).

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

- Lignin and lignin sulphonates (lignosulphonates) are permitted as chelating agent(s), as formulant ingredient(s) and as dust suppressant(s) (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

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

- Lignin sulfonate is not explicitly mentioned in the regulations.

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

- Lignin sulfonate is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Lignin sulfonate is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Granulating agents and anticaking agent for fertilizers are permitted: Natural substances or substances derived from natural sources which have not undergone any chemical treatment. However, if granulating substance and anticaking agent for fertilizers are impossible to be produced by only using the relevant substances, lignin sulfonates may be used (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues
Sodium lignosulfonate is relatively low in toxicity based on results of tests in laboratory animals. However, high doses have been found to cause adverse health effects in laboratory animals. Rats that were given drinking water containing purified sodium lignosulfonate at a 10 g/100 ml concentration for 16 weeks had skin lesions, decreased weight gain, and increased white cell counts (2011 TR, lines 300-305).

Lignin sulfonates are soluble in water, so it is possible for dissolved lignosulfonates to enter waterways through direct contamination or soil runoff (2011 TR, lines 332-333). Also, as they break down in water, they consume dissolved oxygen in water due to their high BOD, which affect aquatic organisms through decreased available oxygen (2011 TR, lines 334-336). In a previous TAP Report (1995) the issue of potential dioxin contamination was addressed as a potential contaminant from the process of pulping paper. Dioxin is created during the bleaching process of paper production and the lignosulfonates are removed from the pulp before the bleaching process making it unlikely that they would be generated (2011 TR, lines 339-346).

The 2020 TR did not uncover any reports of environmental harm resulting from the use of lignins (2020 TR, lines 688-689). The lignin component typically comprises 10 percent or less of a fertilizer formulation and is applied at rates of approximately 50–200 pounds of lignin sulfonate per acre (2020 TR, lines 237-240).

Discussion
Dust suppressants are essential to reduce dust inhalation, air pollution, and surface water contamination from organic fertilizers and soil amendments during handling and application. Previous Boards have supported the relisting of this material, stating its essentiality to organic crop production. Opposing commenters stated that lignin sulfonate is not necessary since organic production methods increase organic matter in the soil and provide naturally occurring chelates and alternative dust suppressants are available.

Questions to our Stakeholders

1. Are lignin sulfonates still used as chelating agents or dust suppressants?

Fatty alcohols (C6, C8, C10, and/or C12)

Reference: §205.601(k) As plant growth regulators (2) Fatty alcohols (C6, C8, C10, and/or C12) - for sucker control in organic tobacco production.
Technical Report: 2016 TR (C8, C10)
Petition: 2015 to add at §205.601 for use as a pesticide (sucker control) (C8C10); 2017 petition addendum; 2018 to add at §205.601 for use as a pesticide (sucker control) (C6C8C10C12)
Past NOSB Actions: 11/2017 recommendation to not add; 10/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 04/22/2022 (87 FR 16371)
Sunset Date: 04/22/2027

Subcommittee Review

Use
Currently, EPA's registration for this material is limited to use on tobacco. Fatty alcohols (octanol and decanol) are used to chemically remove flower buds and suckers from tobacco plants. Removal of the flower tops and the suckers encourages the growth of larger leaves. The use of fatty alcohols is an alternative to two laborious hand operations in tobacco production (2016 TR, lines 64-66). A course spray of 5% decanol or a combination of decanol and octanol applied before bud formation inhibits the formation of the bud. Fatty alcohol dripping down the stem of the plant inhibits sucker formation (2016 TR, lines 68-70). Topping and suckering are the most time-consuming tasks associated with growing organic tobacco and may be necessary every week for 10 weeks. It can take one person per acre per day to do the job (2016 TR, lines 498-499). Yields are also increased with the use of this treatment (2016 TR, line 70).

Manufacture

The present world capacity of plant derived- and petroleum derived-fatty alcohols is greater than two million metric tons/year. Much of this production goes in to making detergents or plastics. Petroleum derived fatty alcohols production is estimated to be just 23% of total global capacity, whereas plant derived fatty alcohols production is currently 77% of total global capacity. In the USA the bulk of fatty alcohols is of petrochemical origin, whereas in Europe more than 60% of the total volume is made from natural fats and oils (2016 TR, lines 219-224).

The Lurgi process has been in commercial use since 2004. In the Lurgi process fatty acids are first converted to wax esters and then hydrogenated over a fixed bed reactor. This differs from the Davy process since there is no conversion to methyl esters and fatty alcohols come directly from wax esters. The Davy Process is used primarily for detergent alcohols with greater than 12 carbons; however, it can also be used for the production of plasticizer alcohols containing between 6 and 12 carbons. The Davy process provides an improved process for production of fatty alcohols by hydrogenation of lower alkyl esters, particularly methyl esters of fatty acids derived from natural triglycerides under conditions that minimize formation of byproduct alkanes and ethers followed by refining of the resulting ester containing product. Many production plants throughout the world have been licensed to produce fatty alcohols using the Davy process (2016 TR, lines 194-203).

Fatty alcohols are also produced synthetically from petroleum. Alkylaluminum derivatives are produced by adding hydrogen and ethylene to an aluminum slurry. Alkylaluminum reacts with ethylene to increase carbon chain length. Higher trialkylaluminum species produced by reacting ethylene with alkylaluminums under pressure at about 120°C can be further reacted with ethylene at higher temperatures to give straight chain alcohols with up to 22 carbons (alfene process). Reaction of the higher trialkylaluminums with air and sulfuric acid yields higher n-alcohols: alfol process. The choice of catalyst and reaction conditions significantly affect the process. For fatty alcohol production, it is difficult to practice an esterification on a continuous basis, thus it is convenient to adopt batch processing (2016 TR, lines 204-212).

Because fatty alcohols have important industrial uses as medicines, cosmetics, skin care products, detergents, fuels and plasticizers in addition to their role in tobacco production, extensive research to develop fermentation systems producing fatty alcohols has been undertaken over the past few years with the intention of industrial production in the near future. Naturally found strains of bacteria including *Escherichia coli*, *Salmonella spp*., *Klebsiella spp*., and *Enterobacter spp*. are known to excrete 1-octanol, 1-decanol, and 1-dodecanol. Several *E. coli* strains being examined for commercial scale production of 1-octanol and 1-decanol respectively produced as much as 508 and 740 nanograms/milliliter of culture (2016 TR, lines 230-237).

Mutations introduced into *Escherichia coli* strains have resulted in a number of commercially viable fermentation approaches to produce n-alcohols (2016 TR, lines 239-240). Mutated *E. coli* strains that produce upwards of 6.33 grams of fatty alcohol per liter of culture support future alternative industrial fermentation methods for the production of fatty alcohols (2016 TR, lines 246-248).

International Acceptance

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

- Alcohol, organic sources are 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

- Fatty alcohols are not explicitly mentioned in the regulations.

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

- Fatty alcohols are not explicitly mentioned in the regulations.

[International Federation of Organic Agriculture Movements (IFOAM)]

- Fatty alcohols are not explicitly mentioned in the regulations.

[Japan Agricultural Standard (JAS) for Organic Production]

- Alcohol is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).

Human Health and Environmental Issues

Alcohols with chain lengths up to C18 including hexanol, octanol, decanol, dodecanol, tetradecanol, hexadecanol, and octadecanol are readily biodegradable within ten days (2016 TR, lines 251-252). The fatty alcohols are susceptible to atmospheric degradation by hydroxyl radicals, with half-lives ranging between approximately 10-30 hours. Longer chain lengths have shorter estimated half-lives within this range. Fatty alcohols are used in the manufacture of surfactants for detergents and personal care products. These products are mostly disposed of down the drain at a rate of about 185,000 metric tons per year. Most use is as laundry detergent totaling about 532,000 metric tons per year (2016 TR, lines 258-263). By comparison, the contribution of fatty alcohols to the environment from tobacco topping and suckering is very small (2016 TR, lines 264-265).

Fatty alcohols all have the same mode of ecotoxicological action. In addition, they are all rapidly biodegradable especially at environmentally relevant concentrations (2016 TR, lines 315-317). 1-hexanol and 1-octanol present a hazard for the environment (acute toxicity to fish, daphnids and algae in the range 1-100 mg/l). However, both of these substances are readily biodegradable. 1-decanol and 1-undecanol present a greater hazard for the environment (high acute toxicity to fish, daphnids and algae, in the range 0.1-1 mg/l, and/or high chronic toxicity). The substances in this subgroup biodegrade rapidly and environmental monitoring data from seven countries indicates exposures to the environment is anticipated to be low (2016 TR, lines 320-326).

Available toxicity data indicate that aliphatic alcohols are “practically non-toxic” to honeybees (acute contact LD50 > 25 µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time (2016 TR, lines 327-329).

Toxicity data for the aliphatic alcohols consisting of acute toxicity, irritation, and sensitization studies, developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study were evaluated for the Environmental Protection Agency (EPA) human health risk determination (2016 TR, lines 389-391).

Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human health risks of concern for aliphatic alcohols. Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols was not found necessary (2016 TR, lines 397-402).

1-Decanol, which is a component of all the tobacco sucker control products in this case, is an acute Toxicity Category I eye irritant; therefore, products with agricultural uses must require a 48 hour REI and the following personal protective equipment (PPE) for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear (2016 TR, lines 404-409).

Discussion
In the previous review, the Board received numerous comments noting the essentiality of this material to organic tobacco growers. Numerous tobacco growers noted that without this material, they would be unable to produce organic tobacco and would most likely drop their organic certification, including the certification for crops they use in rotation with tobacco.

The TR refers to hand application of soybean or mineral oil as an alternative practice to remove suckers in tobacco. The question arises as to whether approved organic "burn down" herbicides could also be used for this purpose.

The Crops Subcommittee is well aware of the negative impacts on human health of tobacco use. However, tobacco is a legal crop and a crop eligible for organic certification. Like any other material reviewed for use on organic crops, the Subcommittee is limiting our review to whether the material meets the criteria necessary for adding it to the National List as a crop production aid.

Since fatty alcohols occur naturally throughout the plant world, break down readily after use, help to prevent worker exposure to tobacco poisoning, and reduce insect problems, they are compatible with a system of sustainable agriculture.

Questions to our Stakeholders
1. Are approved organic herbicides, such as those made with organic acids, effective to de-sucker tobacco?

Sodium silicate

Reference: 205.601(l) As floating agents in postharvest handling. Sodium silicate—for tree fruit and fiber processing.
Technical Report: 1996 TAP; 2011 TR; 2025 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Sodium silicate, also known as "water glass," has had a range of uses that include fiber processing, fire prevention, adhesives, egg preservation, and as an anti-corrosion agent (2011 TR, lines 39-44). For organic production, it may be used to modify water density in the water tanks that remove fruit from picking bins at the start of the packing process. This is especially important for pear packing lines since pears are denser than water and will sink to the bottom of the water tank. Adding sodium silicate to the water increases the density of the water, thus causing the pears to float and making them easier to remove from the dump tank and onto the packing line (2011 TR, lines 416-417).

The 2011 technical report (TR) notes that there are a number of uses of sodium silicate for fiber processing, but it did not specifically identify organic uses in fiber processing. For fiber processing in general, sodium silicate may be used as a peroxide buffer for processing cotton and jute. It also has uses as a bleaching agent, detergent for fiber cleaning, degumming of jute fibers, and in combination with various other bleaching and processing compounds.

Additionally, the TR notes that sodium silicate is exempt from the requirement of a tolerance when it is used as an inert ingredient in pre- and post-harvest agricultural products (40 CFR 180.910).

Manufacture
Solid glass is usually produced in a rotary kiln or tank furnace by fusing quartz sand with potash or soda at temperatures ranging from 1,100 to 1,330 degrees C. Sodium silicate, which makes up the majority of soluble silicates produced, is converted from solid glass to a liquid solution at 100 degrees C. The concentrations of sodium silicate in water can be varied according to particular processing needs (2011 TR, lines 176-180).

The 2011 TR notes that the production processes for lump glass and sodium silicate require high temperatures and sometimes high pressures to change silicon dioxide and soda or potash to soluble silicates. These processes do not occur in nature and, thus, this material was deemed to be synthetic (2011 TR, lines 189-193).

Early in 2025, the Crops Subcommittee (CS) received an updated, limited scope TR for this substance. The TR notes that “[s]odium silicate is not extracted from naturally occurring plants, animals, or minerals. It is produced by reacting the minerals silicon dioxide with sodium carbonate or sodium sulfate…[a]lternatively, sodium silicate is produced by reacting silicon dioxide and the synthetic chemical sodium hydroxide” (2025 TR, lines 101-103).

The 2025 TR goes on to update information from the EPA in 2022 which indicates that “most sodium silicates in the United States are produced with the furnace method, using silicon dioxide and sodium carbonate as precursors. Authors of an older source state that when sodium carbonate is not available, sodium sulfate can be used as a precursor” (2025 TR, lines 113-115).

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

- Silicon, silica and silicates: Sodium and potassium silicates are permitted only for crop protection (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Sodium silicate is permitted in detergents (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 silicate is not explicitly mentioned in the regulations.

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

- Mineral powders (stone meal, silicates) are permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).
- Sodium silicate is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

[*International Federation of Organic Agriculture Movements (IFOAM)*]

- Silicates (e.g. sodium silicates, quartz) are permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).

[Japan Agricultural Standard (JAS) for Organic Production]

- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table B.1 - Chemical agents, JAS for Organic Feed).
- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Sodium silicate is permitted, except for the use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues

As noted in the 2011 TR, sodium silicates are quickly diluted and depolymerize in the environment. These processes yield molecular forms that are indistinguishable from natural, dissolved silica in naturally occurring water (2011 TR, lines 220-221). Other testing has shown these silicates to be generally non-toxic, except for contact exposure to very high concentrations of the material which can cause dermatitis or, if ingested, vomiting and diarrhea. Additionally, the 2011 TR concluded that, based on its normal use patterns, sodium silicate is unlikely to contaminate soil or adversely affect soil organisms (2011 TR, lines 317-318). Sodium silicate has been characterized as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration. The U.S. Environmental Protection Agency has determined it is exempt from the requirement of a tolerance when used as an inert ingredient in pre- and post-harvest products (2011 TR, lines 76-81).

While normal uses of sodium silicate are unlikely to cause environmental damage, large scale spills of sodium silicate could have some environmental effects, either by altering the pH of the spill area or affecting the balance of nitrogen and phosphorous in the spill area (2011 TR, lines 320-322 and 327-329).

The 2025 TR attempted to build on previous information in order to update potential human health concerns for this substance. Unfortunately, the TR notes that "[l]ittle information exists on the effects on human health from exposure to sodium silicate in fruit packhouses. Packhouse workers might be exposed to sodium silicate on their skin or eyes" (2025 TR, lines 273-274). The TR also noted that research was unable to "find information related to residues of sodium silicate solutions on fruits as a result of petitioned use" (2025 TR, lines 309-310).

Discussion

Previous reviews of this substance generated few public comments. Commenters indicated that the substance is primarily used by small pear packers to float pears out of a water dump tank and into packaging lines. Larger pear packers use mechanical means to accomplish this, but for smaller packers, the equipment is prohibitively expensive. One commenter in a previous review did not view this material as compatible with organic systems of agriculture.

Previous Boards relisted sodium silicate, citing the benefit to small producers in the organic industry, does not contribute to environmental degradation during normal usage, is Generally-Recognized as Safe (GRAS) by the U.S. Food and Drug Administration, and the U.S. Environmental Protection Agency has determined it is exempt from the requirement of tolerance when used as an inert ingredient in pre- and post-harvest products (2011 TR, lines 76-81).

The 2025 TR provides an update on alternatives to the use of sodium silicate as floatation agents. The TR proposes sodium carbonate, potassium carbonate, calcium chloride, or naturally occurring sodium sulfate as floating agents allowed for use in post-harvest handling of tree fruit. The TR is able to provide some information about alternative substances and practices.

A study on alternative substances "found that fruit treatment with calcium chloride, potassium carbonate, sodium carbonate, or sodium sulfate resulted in no damage to the fruits when the process was done at either temperature range. They also reported that injury was moderate to severe when using potassium phosphate or calcium chloride for 45- or 60-minute durations" (2025 TR, lines 390-393).

The 2025 TR notes that "advances in pear genetics and processing techniques have reduced the need for floating agents" which led to the "removal of lignin sulfonate as an approved organic floating agent in 2017" (2025 TR, lines 404-406). The TR indicates that sodium silicate and previously mentioned alternatives allowed for use as floating agents are only used in "immersion water dumps, fruit unloading systems that do not rely on this method would make using sodium silicate unnecessary. Switching to a soft-landing, dry-drop system could be an alternative" (2025 TR, lines 408-410). The TR goes on to suggest foam coated belts and padded picking containers might be viable alternatives to water immersion methods that require floating agents.

The Subcommittee discussed the post-harvest handling dynamics for apple and pear producers, indicating that pears sink, and floating agents could be necessary as processing will have a step that involves moisture. A member observed that Dry-Pack is progressing, but pears will get exposed to moisture at some point in post-harvest handling where a floating agent is necessary and helpful to send fruit in right directions based on size, color, etc. This type of infrastructure also allows apples and pears to be processed in the same facility A member questioned the relationship of floating agents to sanitizing materials like chlorine, reflecting that the 2025 TR indicates that sodium silicate prevents the rapid decomposition of chlorine materials.

Questions to our Stakeholders

1. Is sodium silicate still an essential tool as a floating agent for small tree fruit producers?
2. Are the alternative methods and substances indicated in the updated TR being used by organic producers?
3. The limited TR indicates that sodium silicate prevents the rapid decomposition of chlorine materials. Does its use as a flotation agent in pear processing have impacts on the efficacy and longevity of chlorine materials that may be used for food safety reasons in pear packing?

EPA List 4 Inerts

Reference: 205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 – Inerts of Minimal Concern.

Technical Report: 2015 Limited Scope TR: Nonylphenol ethoxylates (NPEs)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2010 recommendation; 10/2010 NOSB sunset recommendation; 10/ 2012 NOSB recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

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

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

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

International Acceptance

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

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as **List 4A or 4B** by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2 (Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as **List 4A, 4B** or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Formulants 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).

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

- The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that

Regulation: (a) safeners, synergists, and co-formulants as components of plant protection products; (b) adjuvants that are to be mixed with plant protection products (General production rules, EC No. 2018/848).

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

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

- Inerts are not explicitly mentioned in the regulations.

<u>International Federation of Organic Agriculture Movements (IFOAM)</u>

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

<u>Japan Agricultural Standard (JAS) for Organic Production</u>

- Inerts are not explicitly mentioned in the regulations.

Human Health and Environmental Issues
As noted below, some of the materials listed on EPA List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of materials listed as to environmental issues is not possible without technical reviews of each material.

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

Presently, § 205.601(m) of the National List references EPA List 4 – Inerts of Minimal Concern as acceptable in organically approved pesticide formulations. List 4, however, is outdated and no longer maintained by EPA. The list of inerts that is referenced for review of products for organic certification was last updated in August 2004 (https://www.epa.gov/pesticide-registration/epas-national-organic-program-guidance) and may include materials that some stakeholders believe are inappropriate for organic agriculture. For example, nonylphenol ethoxylates (NPEs) are included on List 4. These materials are endocrine disruptors, may adversely impact fauna and flora, and have been identified by the California Department of Toxic Substances Control's Safer Consumer Products Program as a likely high priority chemical that should be formally phased out https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf. If evaluated on an individual basis, NPEs would likely not meet OFPA criteria for acceptability.

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

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

National List Motion, approved by NOSB in Fall 2024 (shown with changes from current language)**:**

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

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

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

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

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

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

OR

Motion to amend 205.601(m)

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

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

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

Motion to amend 205.603(e)

(e) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:
~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances

The Crops Subcommittee expects an improved listing to be implemented by the NOP in the next two years, replacing the reference to List 4. In the meantime, in order to maintain continuity in pesticide formulations used by organic farmers, we recommend that List 4 Inerts be relisted in this review at 205.601(m) on the National list.

Questions to our Stakeholders

1. Do stakeholders agree that List 4 Inerts should be relisted until they are replaced with a new listing via the rulemaking process currently underway?

Paper

Reference: §205.601 205.601 (p) Production Aids: (2) Paper-based crop planting aids as defined in § 205.2. Virgin or recycled paper without glossy paper or colored inks.
Technical Report: 1995 TAP (Newspaper, recycled paper); 2006 TR (Newspaper, recycled paper); 2017 TR (Newspaper, recycled paper); 2019 TR (Paper-based crop planting aids)
Petition: 2018 petition to add for use as a production aid (paper-based crop planting aids); 2018 petition addendum
Past NOSB Actions: 04/2021 recommendation to add
Recent Regulatory Background: Added to National List effective 11/14/2022 (87 FR 68021)
Sunset Date: 12/14/2027

Subcommittee Review

Use
A paper-based crop production and planting aid is defined at § 205.2 as "a material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in § 205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g., laboratory test using ASTM D6866 or composition review by qualified personnel)."

Paper pots are either single or in chains to allow for "mechanical" transplanting, either with a hand driven machine or with a tractor implement. The paper pots decompose into the soil and lessen transplant shock since the roots are not exposed to the air before transplanting like plants being removed from plastic pots. The use of paper pots can contribute to less use of plastic in the produce industry. Growers can also use soil blocks, which are compressed soil without any container, to grow transplants.

Other paper crop production aids include cloches (a temporary covering used to protect newly transplanted plants), seed tape (where individual seed is spaced correctly on a paper tape, which lessens the need for thinning), and collars to prevent cutworm damage to plants at the soil line. There could be other uses of paper currently used as crop production aids, or there may be other uses developed over time. The composition of the paper allowed in paper pots and other planting aids, as well as the adhesives approved, would meet the manufacturer needs of these other paper planting aids.

Most of the paper used as a crop planting aid is functionally identical to newspaper and recycled paper, and so the inclusion of paper production and planting aids such as paper pots on the National List was evaluated in the context of information about newspaper and recycled paper. While the current listing of newspaper and recycled paper – like the addition of paper production and planting aids -- has been found to have no detrimental interactions with other materials in organic agriculture, there has been sustained concern about the full composition of these products and the potential impact they could have on soils and composts supporting organic cropping systems.

Manufacture

Paper can be made from various plant sources including wood, trees, straw, hemp, bamboo, reeds, kenaf, sisal, jute, sugarcane bagasse, sunflower stalks as well as recycled sources of pulp (2017 TR, lines 67-68 and 80). Cellulose sources are typically mechanically ground and then chemically "cooked" using an alkali or sulfite process (2017 TR, lines 380-382). Newspaper and recycled papers can also have a variety of inks, although colored ink and glossy paper are not allowed as compost feedstocks or mulch under the organic rule. The paper used as a planting aid could include the typical adhesives and ink residues found in newspaper and recycled paper.

International Acceptance

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

- Biodegradable planting containers (for example, pots or cell packs) may be left to decompose in the field if all ingredients are listed in Table 4.2 (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

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

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

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

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Physical control: To control pest and disease by using light, heat, sound, etc. by using mulch derived from wastepaper (limited to those to which no chemically synthesized substances are added in the manufacturing process) or plastic mulch (limited to those, that are to be removed after use), or by manual or mechanical means (Terms and definitions, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues
Paper, depending on the percentage of cellulose and type of synthetic fibers/materials used, is biodegradable and has no negative effects on human health. The 2019 TR did not find any evidence of harmful effects to human health.

No toxicity or negative mode of action has been found in the breakdown of paper (cellulose) in the environment. No colored inks or glossy paper would be allowed for paper as a crop planting aid, similar to paper as it is currently annotated as a compost feedstock and/or mulch. The 2019 TR found many of the adhesives and synthetic fibers biodegraded with no negative impacts. There were some that were not as environmentally neutral as others, but all were also present in newspaper.

There could be contaminants released into the environment during the manufacture of paper, and environmental degradation caused by harvest of cellulose, but no more than newspaper or recycled paper, which historically have been approved for use in organic agriculture. A difference between this paper and the previously approved newspaper is that we are not restricting it to the use of only recycled paper products. The annotation allows virgin stocks of cellulose to be used in the paper used as a planting aid in organic agriculture. There are negative environmental impacts from harvesting trees to make paper such as road building, soil erosion, degraded water quality, and loss of habitat, but there are forestry best management practices that can mitigate some of these negative effects. Furthermore, there are non-tree cellulose sources that could be utilized in the future. The synthetic fibers that could be used in paper are manufactured in a wide range of production systems. These were not specifically addressed in the 2019 TR.

Paper that does contain high percentages of synthetic fibers that do not biodegrade readily could leave residues that would be harmful to terrestrial, avian, and aquatic wildlife if consumed. This potential and difficult-to-trace synthetic content could also have an impact on the total biodegradability of paper production and planting aids and the soil that harbors them. This content is also notable for its potential persistence in compost that could be used on organic farms (reference: Fall 2024 Compost Proposal, Crops Subcommittee).

In paper pots, use of synthetic pesticides embedded in the pots could also have adverse impacts on biodiversity, but only organically allowable nutrients would be allowed in the paper used as a planting aid and there is a restriction on the types of materials allowed in the 40% non-cellulose-based portion of the planting aids. The percentage of adhesives in the paper pots is very small. There could be an issue with paper used as a planting aid containing large percentages of synthetic fibers that would not biodegrade readily.

Discussion
NOP guidance 5034-1 "Materials for Organic Crop Production" excludes virgin paper from the "newspaper or other recycled paper" allowance for mulch or compost feedstocks. The guidance states: *"Includes newspaper and other recycled paper such as cardboard, without glossy or colored inks. Does not include paper that is not recycled (i.e., virgin paper)."*

The July 2019 Technical Review of Paper Pots and Containers, detailing the specific possible synthetic and natural fibers as well as synthetic adhesives found in paper pots currently commercially available, provided more clarity for the NOSB.

Historically, the Crops Subcommittee has viewed paper pots, used as a crop production aid, as another use of paper beyond compost feedstocks and mulch, which are allowed under the NOP regulations. However, to facilitate due diligence, the Crops Subcommittee requested a Technical Review (TR) to help identify the adhesives and synthetic fibers used in paper pots and identify if there are any that would not be present in the already allowed paper used in compost and mulch. Pots, compost, and mulch all degrade into the soil, and the Subcommittee believes if the fibers and adhesives are allowed in the other listings for paper, then their use in pots should be allowed as well.

When discussing the possible allowance for paper used as a planting aid, the Subcommittee also considered the fact that currently there is an allowance for "newspaper or other recycled paper" as weed control or as compost feedstocks and there are very few differences between the currently allowed paper and the paper as a planting aid under review, with the exception of paper pots that have a very high percentage of non-cellulose synthetic fibers. Requiring 60% cellulose fiber prevents the planting aids from being completely made of biobased, non-degradable plastics, and yet allows current products on the market. It is the hope that this percentage can increase over time. Requiring 80% biobased content prevents the use of planting aids made primarily from petroleum sources and allows the products currently on the market. Again, it is hoped that this percentage can be increased over time and that future Boards will be able to modify this annotation to reflect manufacturing technological advances that incorporate more natural materials and additional cellulose and biobased content. These future reviews should also encompass the biodegradability of both fibers and adhesives. Such reviews have most recently occurred in the context of work by the Crops Subcommittee to clarify parameters for organic compost.

The latest iteration of the Crops Subcommittee has had robust discussions about the implications of the paper pots listing in its first sunset review. Members have asserted the need to understand more fully whether paper pots are having broader negative impacts than believed at the time of approval. One issue that was raised related to the fact that many small producers were strongly in support of the original paper pots listing, which elicited at least two questions: (1) whether larger producers have identified benefits to paper pots since listing and are using it in larger operations, thus creating more concern about possible contaminants from the non-cellulose components of paper pots; and (2) whether paper pots – in keeping with OFPA – are indeed a necessity in small cropping systems. On the latter point, members have noted that the issue of necessity is often posed to larger producers in the context of listed materials they rely on, and so if paper pots are essential to small producers, they should also provide regular justification within the sunset cycle.

Questions to our Stakeholders

1. Are our stakeholders aware of materials of concern (like phthalates or PFAS) that could be appearing in paper planting and production aids like paper pots?
2. Is there soil contamination concerns unique to paper pots because of the potential to use paper pots multiple times in concentrated areas over the course of a single growing season?
3. Are the restrictions on paper pot composition applicable to the paper feedstock issues that have been raised in the context of compost?

Arsenic

Reference: 205.602(b)
Technical Report: None
Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Arsenic and its compounds, especially arsenic trioxide, are used in the production of pesticide-treated wood products, herbicides, and insecticides. These applications are declining due to the toxicity of arsenic and its compounds.

Arsenic is sometimes alloyed with lead to form a harder, more durable metal. Some areas of use include car batteries and bullets. Until recently, arsenic was commonly used in glassmaking. However, due to pressure from the EPA and environmentalists, most glass manufacturers have slowed down or stopped using arsenic.

Manufacture
Arsenic is a naturally occurring element in the environment that can enter the food supply through soil, water, or air. Arsenic levels in the environment are generally low, but can vary depending on the natural geological makeup of local areas.

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

- Arsenic is not explicitly mentioned in the regulations.
- Health Canada continues to monitor the concentrations of various chemicals, including arsenic, in foods through its ongoing Total Diet Study surveys and also conducts targeted surveys of arsenic in specific foods (Canadian Total Diet Study, Trace Elements 1993-2018). Health Canada will also continue to evaluate the potential human health risks associated with dietary arsenic exposure. Additionally, the Canadian Food Inspection Agency carries out monitoring and surveillance work for arsenic in foods, including those commonly consumed by infants and children.

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

- Arsenic 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)

- Arsenic is not explicitly mentioned in the regulations.
- In 2017 CODEX adopted a code of practice for the prevention and reduction of arsenic contamination in rice. The Codex provides national or relevant food control authorities, producers, manufacturers and other relevant bodies with guidance to prevent and reduce arsenic contamination in rice as source directed measures and agricultural measures. The Codex also includes guidance on monitoring and risk communication (CXC 77-2017: Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Arsenic is not explicitly mentioned in the regulations.
- Natural non-renewable resources—such as mined minerals—require a description of the deposit or occurrence in nature. Non-renewable resources are generally restricted or limited in their use. They

may be used as a supplement to renewable biological resources, provided they are extracted by physical and mechanical means, and are not rendered synthetic by chemical reaction. Inputs with high levels of natural environmental contaminants, such as heavy metals, radioactive isotopes, and salinity, may be prohibited or further restricted (Crop and Livestock Criteria: Source and Manufacturing, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Arsenic is not explicitly mentioned in the regulations.

Environmental Issues and Human Health Concerns
Contamination from mining, fracking, coal-fired power plants, arsenic-treated lumber, and arsenic-containing pesticides contribute to increased levels of arsenic in certain locations. As a naturally occurring element, it is not possible to remove arsenic entirely from the environment or food supply. The FDA, therefore, seeks to limit consumer exposure to arsenic to the greatest extent feasible.

The FDA tests arsenic levels in foods as part of a comprehensive approach to monitoring toxic elements and nutrients. The agency prioritizes monitoring inorganic arsenic levels in foods more likely to be eaten by infants and toddlers. These foods are a greater potential source of dietary inorganic arsenic exposure for infants and young children than for adults, because:

- they are commonly consumed by infants and young children;
- infants and children's dietary patterns are often less varied than those of adults, and
- infants and children consume more food relative to their body weight than do adults.

The FDA tests for toxic elements through:

- the Total Diet Study;
- the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program; and
- sampling assignments. Sampling assignments may be conducted in response to reports of elevated arsenic levels in certain foods or to focus on a specific food, food additive, or specific food group (such as foods commonly eaten by infants and toddlers).

A December 7, 2022, document issued by the World Health Organization (WHO) titled: "Arsenic" has seven sub tiles: 1) Key Factors; 2) Overview; 3) Sources of Exposure; 4) Health Effects; 5) Magnitude of Problem; 6) Prevention and Control and 7) WHO Response.

The third bullet point under Key Facts reads: "Contaminated water used for drinking, food preparation and irrigation of food crops poses the greatest threat to public health from arsenic." The fourth bullet point reads: "Long term exposure to arsenic from drinking-water and food can cause cancer and skin lesions. It has also been associated with cardiovascular disease and diabetes. In utero and early childhood exposure has been linked to negative impacts on cognitive development and increased deaths in young adults."

The first sentence under Health Effects reads: "Inorganic arsenic is a confirmed carcinogen and is the most significant chemical contaminant in drinking-water globally."

Discussion
Arsenic was discussed at subcommittee on 03 December, 2024 and added additional information under Environmental Issues and Human Health Concerns from a December, 2022 World Health Organization (WHO) document titled: "Arsenic."

Questions to our Stakeholders
None

Strychnine

Reference: 205.602(i)
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

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

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

Strychnine has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity with oral and ocular effects; inhalation toxicity is also presumed to be high.

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

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

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- Strychnine is not explicitly mentioned in the regulations.

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

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

International Federation of Organic Agriculture Movements (IFOAM)

- Strychnine is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Strychnine is not explicitly mentioned in the regulations.

Environmental Issues

According to the EPA, acute toxicity to birds is assumed to be very high. Subacute dietary data indicate that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds who may be subject to repeated or continuous exposure from spills.

Mammalian studies indicate that strychnine is highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occur within one hour. Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicates that strychnine is moderately toxic to aquatic invertebrates.

Discussion

There was very little discussion during subcommittee meetings. Previous boards have voted unanimously to keep this material listed as a prohibited substance.

Questions to our Stakeholders

None