Sunset 2022
Meeting 1 - Request for Public Comment
Crops Substances
April 2020

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 are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2020 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2020 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov by April 3, 2020 as explained in the meeting notice published in the Federal Register.

These 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 found to be: (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 focus on providing 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. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments
Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances under Review:
If you provide comments in support of an allowance of a substance on the National List, 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 Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

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

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

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 producers or handlers 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 through April 3, 2020 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2022
Meeting 1 - Request for Public Comment
Crops Substances
April 2020

Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.

Soap-based algicide/demossers
Ammonium carbonate
Soaps, insecticidal
Vitamin D3
Aquatic plant extracts
Lignin sulfonate(j)4
Sodium silicate
EPA List 4 - Inerts of Minimal Concern

205.602 Prohibited nonsynthetic substances
Arsenic
Strychnine

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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
As an approved algicide/demossers, synthetic soap salts are permitted for the control of algae and mosses in and around production areas, including walkways, greenhouse surfaces and irrigation systems.

Manufacture:
A variety of preparatory methods are employed depending 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 plants 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 oil, sunflower oil, palm oil, tallow, and olive oil. Soaps are mixtures of fatty acid salts having a variety of carbon chain lengths and generally do not consist exclusively of one soap salt compound.

International acceptance:
The Canadian General Standards Board, the European Union, Codex Alimentarius Commission, the Japanese Ministry of Agriculture, Forestry and Fisheries, and the International Federation of Organic Agriculture Movements (IFOAM) all allow soap-based compounds for the purposes listed for this product.

Environmental issues and human health:
Soap salts essentially behave as the carboxylate anions of fatty acids when released into the environment. 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 at less than one day for these salts. US 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. Potassium salts of fatty acids are generally recognized as safe (GRAS) by the FDA. Also, studies have shown that soap salts are practically non-toxic to honeybees.

Discussion:
The Crops Subcommittee voted to delist soap-based algicide/demossers in 2017 because it was thought that they were no longer used in organic crop production and it was not necessary to keep them on the National List. However, public comments indicated that these materials are still being used by some

producers. Based on public comment they were not removed.

Additional information or questions requested by Subcommittee:
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
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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Use for use as bait in insect traps, not intended for direct contact with the crop or soil. 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 marketed specifically for fly control. 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. While ammonium carbonate is used as a fly bait, we were able to find little published literature on the effects of the bait on other insect species. Natural alternatives include natural attractants. Other alternative materials are other ammonia-releasing chemicals. Practices that would make its use unnecessary include a good organic environment and enhancement of predators and parasitoids.

Manufacture:
Ammonium carbonate is produced by combining carbon dioxide and aqueous ammonia. Ammonia is volatile and toxic and a known irritant to eyes and nose. It is incompatible with strong acids, nitrates, nickel, copper. However, interaction is unlikely with current annotation. At room and field temperatures, ammonium bicarbonate will spontaneously decompose into ammonium bicarbonate and ammonia which further decomposes to carbon dioxide, water and another molecule of ammonia.

International Acceptance:
Canadian General Standards Board Permitted Substances List - permitted as an attractant in insect traps.
Codex Alimentarius Commission - not listed
European Economic Community (EEC) Council Regulations - not listed
International Federation of Organic Agriculture Movements (IFOAM) - not listed
Japan Agricultural Standard for Organic Production - not listed

Environmental Issues:
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:
During the April 2015 public comment period, most all respondents supported relisting including a number of respondents who voiced strong opposition to other insect pest management chemicals up for relisting. Having said that, the past two sunset reviews of ammonium carbonate resulted in limited stakeholder input attesting to the efficacy and need of the material. To conduct an objective relisting review of ammonium carbonate stakeholder input attesting to the need and efficacy of the compound would be helpful. It is clear that the use of baited insect traps is consistent with an integrated approach that would also include controlling flies through manure management and enhancement of predators and parasitoids.

Additional information or questions requested by Subcommittee:
1. To what extent is ammonium carbonate used as a bait for trapping and thereby managing fly and other insect pest populations?
2. How effective is the practice for managing flies?
3. To what extent is the population or behavior of beneficial insects altered by the ammonium carbonate bait?

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).
Technical Report: 1994 TAP
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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Insecticidal soaps are used on organic crops for control of soft bodied insects and hard bodied insects in the larval stage.
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 the treatment of fatty acids with potassium hydroxide while ammonium soaps are produced by saponification with ammonium hydroxide.

International acceptance:
European Economic Community (EEC) lists potassium soaps as an insecticide with applications "from traditional use in organic farming." Japan Agricultural Standard (JAS) lists soaps as agents for cleaning or disinfecting livestock and the Canadian General Standards Board Permitted Substances List includes

ammonium soaps as a permitted substance. IFOAM lists potassium soaps as an equipment cleanser and equipment disinfectant.

Environmental issues and human health:
The toxicological profile of Insecticidal soaps differs based on the environment in which it is located. Insecticidal soaps are widely regarded as having low toxicity to terrestrial organisms, like mammals and avian animals. Insecticidal soaps are rapidly biodegradable in the environment and the half-life is estimated to be less than one day. Microbial organisms rapidly degrade fatty acids in soils. Potassium salts are highly toxic to aquatic invertebrates and slightly toxic to both coldwater 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. EPA has given these insecticides Toxicity Category IV (indicating the lowest level of toxicity). 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. They are also generally recognized as safe (GRAS) by the FDA. Recent studies (2018) have shown that insecticidal soaps are non-toxic to desirable insects such as lady bugs and the coccinellid beetle. A recent technical review (TR) (2020) reports that "there is little to suggest that insecticidal soaps pose a threat to the environment when used as approved." In fact, the report goes on to state that because of the low toxicity, even if it is used improperly, environmental impact would be minimal.

Alternatives:
Alternatives include cultural pest control methods or oils, botanicals, or biological control (depending on species). A variety of essential oils have been used as well as pyrethrum however, horticultural oils and pyrethrum are easily degraded under common conditions like UV-radiation. Moreover, differences in the mode of action and in their targets (hard-bodied vs. soft-bodied) make one a poor substitute for the other.

Discussion:
In the previous sunset review in 2015 there was overwhelming support for the continued listing of this material. Public commenters stated that this material remains a necessary tool in organic crop production and in fact has increased in use due to the growth of organic production. Public commenters stated that these oils are allowed for use world-wide by most organic certifying bodies. In 2020, the Crops Subcommittee confirmed with a major certifying agency that insecticidal soaps were listed on over 100 Organic System Plans (OSPs) and that it is still necessary because of its unique mode of action.

Additional information requested by Subcommittee:

Is this substance still necessary for the organic farming community?

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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Vitamin D3 (cholecalciferol) is used to fortify food and aids in the growth and maintenance of bones, typically found in milk and cereals. Forms of vitamin D are also found in margarine and infant formula. In this listing, Vitamin D3 is used as a synthetic rodenticide both 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.

Manufacture:
The TR states: The commercial manufacture of vitamin D3 utilizes cholesterol obtained by organic solvent extraction of animal skins (pig, sheep, or cow) and extensive purification (Norman, 2000). 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 (Norman, 2000). The crystalline 7-dehyrdocholesterol is then dissolved in an organic solvent and irradiated with UV light. This process causes a photochemical 183 transformation of 7-dehyrdocholesterol into cholecalciferol that 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 (Norman, 185 2000). Details of the manufacturing process are subject to several patents (Norman, 2000) and are not 186 publicly available.

International Acceptance:
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."

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". The European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 states rodenticides are only to be used in traps. The Japan Agricultural Standard (JAS) for Organic Production and the International Federation of Organic Agriculture Movements (IFOAM) do not list this product, nor have any specific requirements for rodenticides.

Ancillary Substances:
Since the formulations contain .075% of cholecalciferol, with the remainder "inerts" It is unknown what the other ingredients are, although much of it will be attractive food stuffs to the rodents.

Environmental Issues:
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. Because of its insolubility in water, its use is unlikely to cause contamination to ground or surface waters. Since its use is restricted by EPA 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.

Discussion:
Since birds of prey can be of great use in controlling rodents on the farm, the use of Vitamin D3 is preferred due to its very low risk to bird populations. Birds have a much lower body weight and the consumption of just one or two rodents who had consumed an anticoagulant bait could be detrimental to 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 rodents that are ill from consuming Vitamin D3, it would take many of these rodents to cause harm up the food chain. There are system-based methods that can be used to control rodent populations, such as improving structures to prevent their entry, as well as keeping food/water and harborage to a minimum. However, there are times when the use of a toxic bait is necessary to lessen the rodent population so that other system-based approaches can then take over.

Additional information or questions requested by Subcommittee:

1. Is this product still needed as a rodenticide in organic crop production?
2. Are there any nonsynthetic alternatives to this material with the same functionality?
3. Please provide information on the ancillary substances that may be part of vitamin D3 formulations.

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
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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Plant extracts are composed of chemicals naturally found in aquatic plants (TR 2006 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 (TR 2006 lines 63-6). Aquatic plants contain proteins, lipids, sugars, amino acids, nutrients, vitamins, plant hormones, and other biochemicals (TR 2006 lines 26-7). Aquatic plants contain a wide range of naturally occurring plant nutrients and trace minerals essential to plant growth, health, and productivity (TR 2006 lines 41-42). Cytokinins, a class of plant hormones present in aquatic plant extracts, have been reported to have beneficial effects on crops, including increase in number or size of fruits or seed heads, synchronization of flowering within a field, and delayed decay of mature plants (TR 2006 lines 46-8).

Manufacture:
Seaweeds are classified into three broad groups based on pigmentation: brown, red, and green; respectively, *Phaeophyceae*, *Rhodophyceae* and *Chlorophyceae* (TR 2016 lines 103-4), 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 (TR 2016 lines 108-110). Seaweeds used in aquatic plant extracts are macro-algae.

Seaweed extract is produced from fresh, live plants which 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 (TR 2006 lines 181-189).

International Acceptance:
Canadian General Standards Board Permitted Substances List permits use of aquatic plants products not containing synthetic preservatives, such as formaldehyde, and extracted with potassium hydroxide or sodium hydroxide.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) lists seaweed and seaweed products as a soil conditioner.

European Economic Community (EEC) Council Regulation, 2092/91 allows aquatic plant extracts for organic crop production following "Annex IIB – Seaweed and seaweed products".

Japan Agricultural Standard (JAS) for Organic Production allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) lists seaweed as a soil input in appendix 2.

Environmental Issues:
Aquatic plant extracts are biodegradable and are likely to have a low impact on crops (TR 2006 lines 242-3). They are not expected to cause toxicity to plants, soil organisms, or higher animals (TR 2006 lines 151-2). There are no known human health hazards (TR 2006 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 impact 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 (TR 2016 lines 892-6). 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 (TR 2016 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 (Chojnacka, 2012).
> 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 (Seeley and Schlesinger, 2012). 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)). [TR 2016 lines 522-535].

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 (van Guelpen and Pohle, 2014). 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 (Beal, 2015). [TR lines 326-31]

The TR goes on to explain that:

> Notwithstanding, 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 (Seeley and Schlesinger, 2012). [TR lines 356-60]

Discussion:

During its preliminary sunset review in 2015, the Crops Subcommittee did not pose any questions to the public, and the majority of comments were in favor of keeping aquatic plant extracts on the National List. Commenters noted that aquatic plant extracts are an important element of fertility programs on many organic farms. During the fall public comment period, the Subcommittee identified concern about potential seaweed overharvesting. Extensive public comment was received on this issue, though the Subcommittee noted the comments were at times regional in nature. The board subsequently prioritized review of this topic and determined that a Technical Evaluation Report (TR) was needed on all the marine plants used in organic production across the Crops, Livestock, and Handling Subcommittees. At the end of the fall 2015 meeting, the board recommended keeping aquatic plant extracts on the National List, though the vote was divided with 5 to remove, 6 to keep, and 3 abstentions.

In the winter of 2016, the board received the limited scope TR on Marine Plants and Algae. Subsequently, the Crops Subcommittee published a in spring 2017 Proposal on Marine Algae Listings which was virtually identical to a similar proposal in Handling. In the Crops section, a proposal was put forth to limit aquatic plant extracts to those derived from brown seaweeds. Public comment demonstrated that there were numerous products containing red, green, and brown seaweeds. The work agenda item was then moved to the Materials Subcommittee, and the board explored new approaches to addressing concerns about environmental impact. In fall 2018, the Materials Subcommittee posted a Discussion Document proposing that all seaweed ingredients used in organic crop production be required to be certified organic. The next Discussion Document was posted in spring and fall of 2019 and solicited public comments on the question of organic certification or an annotation specifying harvest methods. Public comments have been diverse on this topic and range from support for organic certification as an appropriate tool to address environmental impacts of harvesting, to caution against setting a precedent of certifying an input ingredient, to concerns that certification could amount to greenwashing, to sentiments that the industry does not need further regulation. Following an expert panel on marine macroalgae used in organic crop inputs at the fall 2019 meeting, the board continues to explore this complex topic.

Additional information or questions requested by Subcommittee:

1. Given the broad range of views on this topic, please describe if/or how aquatic plant extracts should be addressed during this sunset review.
2. Are aquatic plant extracts still needed in organic crop production?
3. The 2006 TR states that aquatic plant extracts can be derived naturally by dehydrating seaweeds and grinding them into meal. Meal can be applied directly to the soil or diluted with water and used as a foliar spray or soil drench. Nonsynthetic products also may be produced using mechanical disruption, or freezing, pulverization, and clarification of the thawed slurry. The relative efficacy of alkali-extracted versus non-alkali- extracted product has not been consistently demonstrated, perhaps partly as a result of a lack of understanding of the mechanism by which aquatic plant extracts exert any purported beneficial effect (lines 205-12). Do the nonsynthetic alternatives to this material provide the same functionality?

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.
Technical Report: 2011 TR; 1995 TAP
Petition(s): N/A, 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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Lignin sulfonate is currently included on the National List as a synthetic substance allowed for use in organic production. It is used as a plant or soil amendment as a dust suppressant or chelating agent.

Manufacture:
There are several processes used for production of lignin sulfonates: sulfite chemical pulping, the Kraft process, acid sulfite pulping (2011 TR 239-258). 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, while the pulp is used for paper production. Lignin sulfonates may also be obtained from the Kraft pulping process and 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.

International acceptance:
The Canadian General Standards Board allows the use of lignin sulfonate as a dust suppressant, formulant ingredient, and chelating agent. IFOAM includes calcium lignosulfonate on its "Indicative List of Substances for Organic Production and Processing." As of 2009, calcium lignosulfonate is allowed by CODEX Alimentarius Commission as a food additive. Lignin sulfonate is not specifically discussed by the European Economic Community Council regulations.

Environmental issues and human health:
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. No evidence of genotoxicity was found in microbial assays and in a test for chromosomal aberration in Chinese hamster cells. Lignin sulfonates are soluble in water, so it is possible for dissolved lignosulfonates to enter waterways through direct contamination or soil runoff. Also, as they break down in water they consume dissolved oxygen in water due to their high biological demand (BOD), which affects aquatic organisms through decreased available oxygen. In a previous TR (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 they would be generated.
Lignin sulfonates break down by physical or microbiological processes but may persist in soil for up to one year. Breakdown of lignin sulfonate occurs in part because it is used as a carbon source by a variety of wood-decaying organisms. It is postulated that large amounts of lignin sulfonate applied to soils could stimulate soil microbial activity.
The EPA issued an exemption from the requirement of tolerance for lignin sulfonates when they are used as inert ingredients pre- and post-harvest in agricultural production. The exemption is based on the conclusion that there is a reasonable certainty that no harm will result to the general public, infants and children from aggregate exposures to lignosulfonantes.

Alternatives:
Magnesium chloride and calcium chloride from non-synthetic sources are allowed for use as a dust suppressant under certain circumstances and magnesium chloride from synthetic sources is allowed for use in organic agriculture for dust suppression only if it is derived from seawater. Non-synthetic amino acids and non-synthetic citric acid are allowed for use as chelating agents. Physical manipulation of the landscape can also be used for dust suppression - water sprays, gravel, and no-till farming practices can also be used.

Discussion:
At the last Sunset review in 2017 public comment was supportive of relisting lignin sulfonate as a chelating agent and dust suppressant. Lignin sulfonate is in wide use by the trade and is considered to be necessary for both dust suppression and as the chelating agent for many micronutrient formulations. No significant new issues were raised by the public at that time. A petition requesting the addition of sodium carbonate lignin at 205.601(j) is currently under review by the Crops Subcommittee and a limited TR has been requested. This compound is essentially the same as lignin sulfonate and there is the potential that new information about the manufacturing process or environmental or human health issue could be brought forward on these compounds.

Additional information or questions requested by Subcommittee:
None

Sodium silicate

Reference: 205.601 (l) As floating agents in postharvest handling. (2) Sodium silicate—for tree fruit and fiber processing.
Technical Report: 1995 TAP; 2006 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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290 Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Sodium silicate, also known as "waterglass", has had a range of uses that include fiber processing, fire prevention, adhesives, egg preservation, and as an anti-corrosion agent (2011 TR). 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.

The 2011 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.

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 most of 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).

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.

International Acceptance:
Sodium silicate is allowed for organic use by several international organizations (from the 2011 TR):

Canadian General Standards Board – allows for its use for tree fruit and fiber processing
Codex Alimentarius Commission – permits its use for the production of organic foods
IFOAM – it is included in the silicates group and allowed under substances of mineral origin in the crop protectants and growth regulators with no additional conditions for use
European Economic Community (EEC) Council Regulations – not listed for use
Japan Agricultural Standard for Organic Production – permits it for manufacturing, packaging, storage, processing, other processes in the case that ordinary- …means are not effective enough; it is restricted for the purpose of pest control on plants.

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. 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. Sodium silicate has been characterized as Generally-Recognized as Safe (GRAS) by the U.S. Food and Drug Administration. The 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).

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).

Discussion:
During the previous sunset review, the Crops Subcommittee received no comments in favor of relisting sodium silicate. Even though the previous reviews had concluded that this material was compatible with a system of organic agriculture, based on evidence that it wasn't in use, the Subcommittee voted to delist this material. Several commenters noted that the material was unnecessary and that most fruit packers had already found alternatives, either through mechanical modifications to dump tanks to physically move fruit from the bottom of the tanks to the packing line or through the use of other materials. Contrarily, other commenters voiced concerns that modifications to equipment were expensive and that delisting sodium silicate might prevent smaller packers from converting conventional packing lines to organic use.

One alternative to sodium silicate is lignin sulfonate. During the same sunset review the NOSB voted to remove lignin sulfonate for use in packing operations from the National List. Therefore the question was raised whether sodium silicate should remain on the list as a viable alternative to lignin sulfonate. The Board ultimately voted to relist this material.

Additional information or questions requested by Subcommittee:

1. Are there non-synthetic practices (mechanical, physical or chemical) for pear or other tree fruit handling during the packing process that would be a reasonable alternative to using sodium silicate?

2. Is sodium silicate still used and should it remain on the National List?

3. Is there any use of sodium silicate for organic fiber production?

EPA List 4 - Inerts of Minimal Concern

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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
"Inert" ingredients in pesticide formulations, also described as "adjuvants," 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 (2017), "The relatively few registered pesticides allowed in organic production are contained in product formulations with so-called "inert" ingredients that are not disclosed on the product label. The "inerts" make up the powder, liquid, granule, or spreader/sticking agents in pesticide formulations. The "inerts" are typically included in products with natural or synthetic active pesticide ingredients recommended by the National Organic Standards Board (NOSB) and listed by the National Organic Program (NOP) on the National List of Allowed and Prohibited Substances."

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

International Acceptance:
Since this listing covers many different materials, a specific listing of international acceptance cannot be provided.

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

The standards of OFPA are different from those used by the U.S. Environmental Protection Agency (EPA) to regulate pesticides. Over the last decade, the NOSB and NOP have struggled with how to evaluate the EPA List 4 – Inerts of Minimal Concern during sunset review. Due to the 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.

Initially it was thought that there should not be a grouping of these materials, but that each individual substance should be evaluated and, if appropriate, added to the National List. However, this process was cumbersome, slow, and difficult to implement. It was also likely to cause uncertainty in the marketplace if materials already used in organic products were not recommended for listing and if a known timeline was not available to manufactures. At each sunset review the Board has balked at the blanket renewal of List 4 inerts but has not had a viable alternative to relisting. During the most recent sunset review in 2015, the Crops Subcommittee and full Board moved forward a solution to review inerts that were formerly on EPA List 4 by collaborating with the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The specific language of the NOSB recommendation is linked here and pasted below: https://www.ams.usda.gov/sites/default/files/media/CS%20LS%20EPA%20List%204InertsAnnotation_final%20rec.pdf.

Statement of the Recommendation:

The purpose for the annotation change is to remove reference in the regulation to the EPA List 4 which is no longer in use and which the EPA requested that it be removed in 2010. In order to thoroughly evaluate inerts for compatibility with organic materials, the NOSB has decided to work with the EPA Safer Choice Program and in order to move forward with a formal relationship, an annotation change to recognize this collaboration is needed. The recommendation acknowledges the current nomenclature in use by the EPA regarding FIFRA 25(b) and 40 CFR 180.1122, while laying a framework for some inerts to be reviewed individually.

205.601(m) and 205.603(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.

(i) Substances permitted for use as inerts in minimal risk products exempt from pesticide registration under FIFRA section 25(b).1,

(ii) Substances included on the EPA's Safer Chemical Ingredient List.

(iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.

[Reserved] (for any other inerts individually petitioned and reviewed)]

The NOSB approved the recommendation above by a 10 to 4 vote. They then renewed the existing inerts listing under §205.601(m) with the expectation that a working relationship would be established between the NOP and EPA, with NOSB engagement, to develop a working list of acceptable inert materials for organically approved pesticide formulations. Acceptable inerts would be approved on a class basis, with room for individual material reviews and listing on the National List. To date, , the NOP has made no changes to the regulations.

The current situation, where NOP policies are tied to long outdated US EPA guidance, is broken. Numerous environmental and consumer groups have submitted comments raising concerns about the slow progress on resolving this problem. Private companies and advisors also assert that the lack of a transparent and consistent approach for reviewing and approving "inerts" stifles development of organically approved plant protection tools. This undermines organic production and the larger agricultural economy. The issues identified in 2015 remain nearly the same during this sunset review.

There are specific recommendations by the NOSB *and* a recommendation by the U.S. EPA to remove references to List 4 on the National List that must be acted upon. Several factors are in place for the NOSB, NOP, and EPA to work together to solve these problems now. The EPA Safer Choice Program is well established and offers a strong partner to identify acceptable inert materials. The Crops Subcommittee strongly requests that the NOP act on the 2015 recommendation. The concerns of product developers, stakeholders, and the NOSB must be addressed. This would encourage innovation of new products, lessen concerns of stakeholders over environmental and health concerns, and make future reviews of inert materials much easier.

Additional information or questions requested by Subcommittee:

1. Can you provide examples of product development that have been stifled by the lack of clarity on the regulation and approval of inert ingredients in organically approved pesticide formulations?
2. Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?
3. Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?
4. What would be the consequences of a NOSB recommendation to delist List 4 Inerts?

Figure 1. Timeline of NOSB Actions on "Inerts" (from Shistar, 2017[1]).

1992	First NOSB appointed.
1995	NOSB says it will review "inerts" after the National List is published in the Federal Register and passes the resolution, "Inerts on the EPA List 4 are considered generally recognized as safe and will be accepted for organic production, unless an NOSB evaluation finds a specific List 4 inert to be unacceptable. Inerts proposed for organic production on EPA's List 2 which are potentially toxic and List 3 which are unknown will be compiled by the NOSB and forwarded to the EPA as materials for fast-track review and possible reclassification. List 1 inerts are prohibited by the OFPA."

[1] Shistar, T. "Inert" Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017

1997	First proposed rule would have allowed all but List 1 “inerts.”
1999	NOSB recommends allowing List 4 and prohibiting all others, with the exception of particular List 3 “inerts” approved on a case-by-case basis.
2000	Following the NOSB recommendation, the final rule allowed “inerts” on Lists 4A and 4B.
2002	NOSB votes to allow the use of List 3 “inerts” in passive pheromone dispensers and to temporarily allow List 3 “inerts” while under review.
2004	NOSB and the public objected to a directive by the NOP that allowed the use of pesticides containing undisclosed “inerts,” including those on Lists 2 and 3.
2006	EPA tells USDA that it had completed the review mandated by FQPA and would no longer be maintaining the “inerts” lists on which the NOP regulations depended.
2007	NOSB relists List 3 “inerts,” limiting the renewal to those identified as List 3 by October 9, 2007 and says, “Future petitions to add, remove or renew an inert ingredient to the National List will need to reference a specific inert ingredient.”
2008	NOSB discussion document on “inerts” options.
2009	Another NOSB discussion document on “inerts.”
2010	Spring: NOSB establishes the baseline position, “The NOSB needs to review all inert ingredient components used in current NOP compliant pesticide formulations for consideration for inclusion on the National List.” The 2010 recommendation also recommended six steps to accomplish the changes in regulation. Inerts Working Group (IWG) is established. Fall: NOSB votes to re-list List 4, with a minority opinion stressing the importance of moving ahead with NOSB review. The summary of the recommendation stated that the relisting was “pending review by the program of inerts individually and as a class of materials.”
2011	IWG, through the Crops Subcommittee, submits a discussion document that presents some initial considerations and some proposals.
2012	Spring: NOSB recommends an expiration date of October 21, 2017 for List 3 “inerts” in passive pheromone dispensers, to coincide with the sunset date for List 4 “inerts.” The NOP refused to codify the recommendation. Fall: NOSB follows up on the IWG’s 2011 discussion document by unanimously recommending a changed annotation and a plan of action. NOSB proposes to review of “inerts” by classes.
2013	In its response to the fall 2012 NOSB meeting, the NOP said it intends to conduct a public notification and comment process, including notification to the public of “inert” ingredients known to be used in organic production and NOSB’s review plan, and a request for public comments regarding any other “inert” ingredientscurrently used in organic production that are not identified in the list provided by the NOP. It said that changes to the National List would be considered after NOSB completion of “inerts” review. Spring: NOP reiterates its intentions as stated in its response to the fall 2012 meeting and said that a Federal Register notice to this effect was in review.

2014	Spring: NOP update describes meetings with EPA Design for the Environment (DfE) program and suggests the possibility of cooperating with DfE on "inerts." Fall: NOP reports that since the spring meeting: Office of General Counsel (OGC) reviewed the concept of collaborating with EPA; NOP provided more background to DfE; and NOP has been planning for interagency meetings. NOP sees next steps: (1) NOP and EPA meet further to develop plans for collaboration; (2) NOP consults with NOSB on options; and (3) public notice will be given via Federal Register.
2015	Spring: NOP provides a TR for one category of List 4 inerts –nonylphenol ethoxylates (NPEs). NOP and DfE (now Safer Choice) presentations. NOP outlined "next steps": (1) NOSB reviews Safer Choice to consider referring to it for "inerts" review, (2) NOSB reviews current List 4 reference as part of 2017 sunset review, (3) NOSB and IWG may draft alternate language proposal to replace current references to List 4 and List 3-for fall 2015 meeting, (4) NOSB reviews EPA Safer Choice Criteria, and compares to OFPA criteria. Fall: NOSB passes an annotation to the List 4 listing on the National List that allows: substances permitted for use in minimal risk products, (ii) substances included on the EPA's Safer Chemical Ingredients List, (iii) "inert" ingredients that are exempt from the requirement of a tolerance for use only in passive pheromone dispensers, (i) and (iv) other inerts individually petitioned and reviewed.
2016	Spring: Crops Subcommittee presents a discussion document on a proposal to prohibit use of NPEs. Fall: Saying that the listing will be superseded by the annotation change approved at the Fall 2015 meeting, the NOSB votes to relist List 3 "inerts." No further action on NPEs.

[1] Shistar, T. "Inert" Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017

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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

Use:
Arsenic and its compounds, especially 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:
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.

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. Additionally, the Canadian Food Inspection Agency carries out monitoring and surveillance work for arsenic in foods, including those commonly consumed by infants and children. Health Canada will also continue to evaluate the potential human health risks associated with dietary arsenic exposure.

Environmental Issues:
Contamination from mining, fracking, coal-fired power plants, arsenic-treated lumber, and arsenic-containing pesticides also 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).

Discussion:
Arsenic is prohibited by the Organic Foods Production Act (OFPA) 7 U.S.C. §6508(c)(1) CROP MANAGEMENT — "For a farm to be certified under this title, producers on such farm shall not –

(1) Use natural poisons such as arsenic or lead salts that have long-term effects and persist in the environment, as determined by the applicable governing State official or the Secretary."

The Senate Committee report says, "The Committee recognizes that certain natural materials present environmental and health hazards. An example would be the use of arsenic which, although natural, is known to be extremely toxic, and which is therefore explicitly prohibited from use in organic production under this title."

In the 2017 review, the Crops Subcommittee determined that arsenic did not meet the OFPA criteria and saw no reason to remove arsenic from its prohibited status on the National List. Both the Crops Subcommittee and the full NOSB voted to not remove arsenic from §205.602, non-synthetic substances prohibited for use in organic crop production.

Additional information or questions requested by Subcommittee:
None

Strychnine

Reference: 205.602(h)
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
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:

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 and is a common adulterant of many illicit (street) drugs. 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, for 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:
Under the authority of the Pest Control Products Act and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing strychnine for control of ground squirrels do not meet current standards for environmental protection and, are therefore, proposed to be cancelled.

Canada is a member of the Organization for Economic Co-operation and Development (OECD), which provides a forum in which governments work together to share experiences and seek solutions to common problems. Strychnine is currently registered for certain uses in other OECD member countries, including the United States and Australia, although registered uses do not include control of ground squirrels. As of 18 April 2018, no decisions by an OECD member country to prohibit all uses of strychnine for health or environmental reasons have been identified.

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

Discussion:
In 2017, The Crops Subcommittee determined that strychnine did not meet the OFPA criteria and saw no reason to remove it from its prohibited status on the National List. Both the Crops Subcommittee and the full NOSB voted to not remove strychnine from §205.602, non-synthetic substances prohibited for use in organic crop production.

Additional information or questions requested by Subcommittee:
None