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Sunset 2026 Meeting 1 - Request for Public Comment Crops Substances § 205.601 & § 205.602 April 2024

USDA ORGANIC

Introduction

As part of the <u>Sunset Process</u>, 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 <u>Petitioned Substances</u> <u>Index</u>.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2024 public meeting. Written comments should be submitted via Regulations.gov at <u>www.regulations.gov</u> on or before April 3, 2024, 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 <u>Support</u> the Continued Use of Substances in Organic Production at § 205.601:

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 <u>Do Not Support</u> the Continued Use of Substances in Organic Production at § 205.601:

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 <u>new</u> 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 <u>Support</u> **the Continued Prohibition of Substances in Organic Production at § 205.602:** If you provide comments supporting the prohibition of a substance at §205.602, 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 <u>Do Not Support</u> the Continued Prohibition of Substances in Organic Production at § 205.602:

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 at § 205.602 should provide <u>new</u> 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 through April 3, 2024 <u>www.regulations.gov</u>. 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:

Hydrogen peroxide (a)(4) Hydrogen peroxide (i)(5) Soaps, ammonium Oils, horticultural (e)(7) Oils, horticultural (i)(7) Pheromones Ferric phosphate Potassium bicarbonate Magnesium sulfate Hydrogen chloride

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

Ash from manure burning Sodium fluoaluminate

Hydrogen peroxide—§205.601(a)(4) and §205.601(i)(5)

Reference: § 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (4) Hydrogen peroxide. and § 205.601(i) As plant disease control (5) Hydrogen peroxide.
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation - deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Hydrogen peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H₂O₂. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR 205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605(b)).

Manufacture

According to the 2015 TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H2) and oxygen (O2): H2+ O2 \rightarrow H2O2

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020) a) Allowed for use as a production aid. (Table 4.2, CAN/CGSB-32.311-2020, page 13)

Note: Crop production aids may be applied to the crop or soil, or used to control pests (including diseases, weeds, and insects). Examples include adjuvants, insect traps and plastic mulch, vertebrate animal pest management substances, plant disease and insect pest management substances.

i) Allowed for use as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event (Table 7.3, CAN/CGSB-32.311-2020, page 42)

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

a) Not explicitly mentioned

i) Allowed (Annex I, Basic substances, 2021/1165)

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u> a) Not explicitly mentioned

i) Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Norms

a) Not explicitly mentioned for crop production. Hydrogen peroxide is allowed on the list for equipment cleanser and equipment disinfectants. (page 82)

i) Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production a) Not explicitly mentioned

i) Not explicitly mentioned

Environmental Issues

Concentrated solutions may be corrosive to eyes, exposed skin, and mucous membranes. Warnings for high concentrations include:

Corrosive. Causes irreversible eye damage. May be fatal if swallowed or absorbed through the skin. Causes skin burns or temporary discoloration on exposed skin. Do not breathe vapor. Do not get in eyes, on skin or on clothing. Wear protective eyewear such as goggles or face shield. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Extensive toxicological testing of hydrogen peroxide has been completed, and it is unlikely to cause chronic systemic toxicity or reproductive, development, or carcinogenic effects. However, chronic exposure to vapors may damage lungs. Hydrogen peroxide is reported to have low to moderate toxicity to aquatic invertebrates and no danger to fish. Because hydrogen peroxide is unstable and breaks down into water and oxygen gas, long-term impacts on the environment are unlikely. According to the TR, some toxic chemicals used to manufacture hydrogen peroxide including alkyl anthraquinones, aromatic solvents and metal catalysts (e.g., nickel and palladium) are removed from the product and can be returned to the reactors to make more product. Overall, this material is relatively safe but should be used according to FDA, USDA, and EPA labels and regulations.

Ancillary Substances

Other ingredients may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials present including caprylic acid and mono-and di-potassium salts of phosphorous acid, which is an oxidant stabilizer. Phosphorous acid is listed on the EPA Safer Choice list as a yellow triangle. (Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.)

Discussion

Hydrogen peroxide (HP) continues to receive strong support by the organic community and has been

consistently relisted on the National List. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds if not thousands of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. When used appropriately HP should not have adverse impacts on human health and the environment.

Most recently, it was supported by the prior Crops Subcommittee without dissent and was relisted by the full NOSB without dissent.

In this cycle, the substance has inspired limited discussion from the Crops Subcommittee. First and foremost, the subcommittee has acknowledged the importance of hydrogen peroxide as a sanitizer in the suite of materials available to support ongoing food safety expectations in the food system. As has been noted consistently by the NOSB, there is no dedicated review process in place to support a different level of evaluation of sanitizers currently allowed for use in organic and, as such, the board is not eager to recommend removal of currently listed sanitizers.

The subcommittee did discuss whether there might be unnecessary negative issues associated with the disposal of hydrogen peroxide after use. Most published guidance suggests that disposing of spent hydrogen peroxide into a drain is reasonable.

It was noted that the annotation from hydrogen peroxide differs from that of peracetic acid/peroxyacetic acid in that the reference does not specific use (specifically "for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces").

Hydrogen peroxide is considered to be consistent with OFPA and organic production and is not being recommended for removal from the National List.

Questions to our Stakeholders

- 1. Is hydrogen peroxide an alternative to other more problematic sanitizers?
- 2. How essential is hydrogen peroxide in the rotation of sanitizers and is it specifically used in one part of organic production or more broadly?
- 3. Do certifiers allow it to be used in direct contact with products?

Soaps, ammonium

Reference: § 205.601(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.

Technical Report: <u>1996 TAP</u>; <u>2019 TR</u>

Petition(s): N/A

Past NOSB Actions: <u>10/1995 NOSB minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset recommendation</u>; <u>10/2015 sunset recommendation</u>; <u>10/2019 sunset recommendation</u>

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (<u>77 FR 33290</u>); Renewed 03/15/2017 (<u>82 FR 14420</u>); Renewed 8/3/2021 (<u>86 FR 41699</u>) **Sunset Date:** 9/12/2026

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Subcommittee Review

Use

Ammonium soaps have been approved by the United States Department of Agriculture's (USDA) National Organic Program (NOP) for various crop production uses.

These uses are listed in 7 CFR 205.601 and include applications as:

- 1. synthetic substances to act as algicides/demossers ((a)(7)),
- 2. herbicides ((b)(1)),
- 3. insecticides ((e)(8))
- 4. animal repellents (d), which is the specific focus of this sunset
 - a. Ammonium soaps are used as animal repellents to protect organically produced crops from unwanted browsing, primarily from deer and rabbits.

Manufacture

Ammonium soaps are manufactured by hydrolysis of fats (triglycerides) with an alkaline source in saponification. In this process, the base reacts with the fatty ester to break the ester linkages, forming a salt with the cation of the base and the carboxylate anion that remains at the end of the hydrolysis. Many fats may be used in saponification, including plant and animal fats. Because of the relative abundance of fats and their low cost, most soaps are produced by the saponification of natural fats.

Ammonium cations also exist in nature, play an essential role in the metabolic pathways of a range of organisms, and are a key component of the nitrogen cycle. Soaps, however, do not naturally exist in nature but are manufactured.

International Acceptance

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

Allowed for use as a large animal repellent. Direct contact with soil or edible portions of crops is prohibited. (page 20 and 45)

<u>European Economic Community (EEC) Council Regulation, EC No.</u> 2018/848 and 2021/1165 Not explicitly mentioned

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (GL 32-1999)</u> Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production Not explicitly mentioned

Human Health and Environmental Issues

Human Health: The EPA has given ammonium soaps the lowest possible toxicity classification (Toxicity Category IV). They have also concluded that the oral intake of dangerous levels of the substance is highly unlikely due to the recognizable and undesirable soap taste. Despite the low toxicity of ammonium soaps, there are some health risks. They are primarily irritation-based. Occasional skin irritation upon prolonged exposure has been reported as a potential problem with direct exposure in the eye.

Environment: Studies conducted by the EPA estimate that ammonium soaps will undergo rapid environmental degradation, primarily through microbial metabolism, yielding an environmental half-life of less than one day. It is interesting to note that the toxicological profile of the substance differs based on the environment in which it is located. They are regarded as having low toxicity to terrestrial organisms, with little impact on mammals and avian animals. They are, however, moderately toxic in aquatic environments. Ammonium soaps have been classified as "highly toxic" to crustaceans by the EPA. The EPA has placed them in Toxicity Category IV, the lowest available classification. Due to the potential toxicity to aquatic environments, ammonium soap repellent product labels stipulate, "This product may be hazardous to aquatic invertebrates. Do not apply to water bodies such as ponds or creeks."

Discussion

During the previous sunset review, there were several comments in support of relisting, and no comments for removal were received. There are other means of pest prevention outside of soaps and ammonium, including population control of animals, alteration of habitat, or physical barriers (fencing is widely acknowledged as the most effective means of preventing crop damage from unintended browsing). There are also natural (non-synthetic) substances that may be used in place of ammonium soaps. These all have similar limitations to the soaps and include fear-based area repellents such as coyote urine, smell-based area repellents such as human hair, and contact repellents that contain capsaicin and black pepper oil.

Questions to our Stakeholders

Is there still a need for ammonium soaps, considering the many alternatives for large animal deterrents?

Oils, horticultural—§205.601(e)(7)

Reference: § 205.601(e) As insecticides (including acaricides or mite control).

(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

Technical Report: <u>1995 TAP</u>; <u>2019 TR</u>

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (<u>77 FR 33290</u>); Renewed 03/15/2017 (<u>82 FR 14420</u>); Renewed 8/3/2021 (<u>86 FR 41699</u>) **Sunset Date:** 9/12/2026

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Subcommittee Review

Use

Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as miticides and insecticides. According to the 2019 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2019 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2019 TR).

Manufacture

Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2019 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2019 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International Acceptance

<u>Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)</u>Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.2. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (Table 4.2, CAN/CGSB-32.311-2020, pages 10 & 21)

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

Paraffin oils may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below (Annex I part 4, 2021/1165)

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

Paraffin oil is a substance permitted for plant pest and disease control, with the limitation "Need recognized by certification body or authority" (Table 2, page 22)

International Federation of Organic Agriculture Movements (IFOAM) Light mineral oils (paraffin) allowed for plant pest and disease control (Appendix 3, Section II, page 77).

<u>Japan Agricultural Standard (JAS) for Organic Production</u> Mixed oil emulsion allowed (Appended Table 2: Agricultural chemicals)

Human Health and Environmental Issues

The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2019 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for

degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2019 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2019 TR).

Discussion

Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself.

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to mineral oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils. The 2019 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga*, and *Bacillus thuringiensis* (*Bt*). Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2019 TR).

Previous sunset reviews included discussions around whether vegetable or fish oils could serve as a natural replacement for the horticultural oils. More commercial plant-derived or fish oil products appear on the market each year. These include products based on fish, castor, neem or soybean oils, as well as essential oils from plants like mint or thyme. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Many commenters noted the extensive benefits and need for these oils. Organic stakeholders provided a clear message that this material remains a necessary tool in organic crop production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Questions to our Stakeholders

Are plant or fish oils in use that can take the place of mineral oils in organic insect or mite management programs?

Oils, horticultural—§205.601(i)(7)

Reference: § 205.601(i) As plant disease control.

 (7) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
 Technical Report: <u>1995 TAP</u>; <u>2019 TR</u>
 Petition(s): N/A
 Past NOSB Actions: <u>04/1995 NOSB minutes and vote</u>; <u>11/2005 sunset recommendation - deferred</u>; <u>06/2006 sunset recommendation</u>; <u>10/2010 sunset recommendation</u>; <u>10/2015 sunset recommendation</u>;

10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (<u>77 FR 33290</u>); Renewed 03/15/2017 (<u>82 FR 14420</u>); Renewed 8/3/2021 (<u>86 FR 41699</u>) **Sunset Date:** 9/12/2026

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Subcommittee Review

Use

Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as miticides and insecticides. According to the 2019 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2019 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2019 TR).

Manufacture

Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2019 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2019 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International Acceptance

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

Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.2. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (Table 4.2, CAN/CGSB-32.311-2020, pages 10 & 21)

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

Paraffin oils may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below (Annex I part 4, 2021/1165)

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

Table 2 of the Codex Alimentarius Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods lists "Paraffin oil" as a substance permitted for plant pest and disease control, with the limitation "Need recognized by certification body or authority" (FAO/WHO Joint Standards Programme 1999).

International Federation of Organic Agriculture Movements (IFOAM)

The IFOAM—Organics International standards Appendix 3 permits the use of "light mineral oils (paraffin)" without annotation for plant pest and disease control (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for Organic Plants, Table 2 allows mixed oil emulsion, petroleum oil aerosol, and petroleum oil emulsion for plant pest and disease control without annotation (Japan MAFF 2000).

Human Health and Environmental Issues

The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2019 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2019 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2019 TR).

Discussion

Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself. Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to mineral oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils. The 2019 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga*, and *Bacillus thuringiensis* (*Bt*). Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2019 TR).

Previous sunset reviews included discussions around whether vegetable or fish oils could serve as a natural replacement for the horticultural oils. More commercial plant-derived or fish oil products appear on the market each year. These include products based on fish, castor, neem or soybean oils, as well as essential oils from plants like mint or thyme. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Many commenters noted the extensive benefits and need for these oils. Organic stakeholders provided a clear message that this material remains a necessary tool in organic crop production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Questions to our Stakeholders

Are plant or fish oils in use that can take the place of mineral oils in organic disease management programs?

Pheromones

Reference: § 205.601(f) As insect management. Pheromones. Technical Report: <u>1995 TAP; 2012 TR</u> Petition(s): N/A Past NOSB Actions: <u>04/1995 NOSB minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>10/2019 sunset recommendation</u> Recent Regulatory Background: Sunset renewal notice published 06/06/12 (<u>77 FR 33290</u>); Renewed 03/15/2017 (<u>82 FR 14420</u>); Renewed 8/3/2021 (<u>86 FR 41699</u>) Sunset Date: <u>9/12/2026</u>

Subcommittee Review

Use

The EPA defines pheromones as volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior. Synthetic versions of natural pheromones are employed in insect pest management There are various types of pheromones which elicit various behavioral responses; these include pheromones that signal dominance status, sex pheromones that

indicate sexual receptivity, alarm pheromones which signal danger, aggregation pheromones that bring organisms of the same species together for feeding or reproduction purposes, and trail pheromones that communicate directions to food resources and provide information for movement or relocation of colonies.

Both non-synthetic and synthetic pheromones are used in pest management. They perform this function by eliciting behavioral changes in the target pest to achieve crop protection goals. There are three major uses of pheromones in pest management.

- (a) They serve as traps and lures for determining the incidence and population density of insects in an area. The lures are often held in polyethylene or rubber which facilitates a slow release of the pheromone. This method is used to conduct mass trapping of male insects thereby reducing pest populations by reducing the availability of males for mating purposes.
- (b) Pheromones are also used in attract and kill systems which are a mixture of pheromones and insecticides. The pheromones serve to attract the target pests which are then exposed to lethal doses of the insecticide in the mixture. The use of pheromones as attractants in such mixtures reduces the quantity of insecticides required to achieve effective management of target insects. Attract and kill systems have been employed effectively in the management of the boll weevil and grape root borer moth.
- (c) Pheromones are also used to disrupt mating in target pests. This involves saturating an area with synthetic pheromones making it difficult for males of the target pest to locate receptive females for mating purposes. This mating disruption is either competitive or non-competitive. The competitive disruption refers to males of target insects following a plume of non-synthetic pheromone released by a dispenser instead of natural pheromone blends released by actual females in the population. Non-competitive mating disruption involves the release of unnatural blend of synthetic pheromones which masks the natural pheromones released by females of target insects thereby making it difficult for males to orient themselves correctly to locate female insects for mating purposes.

Pheromones are dispensed in various ways. These include passive dispensers which refer to materials that release pheromones via volatilization instead of spraying resulting in the concentration of pheromones in a limited area. The idea behind the use of pheromones is to draw insect pests away from crops.

1. Passive dispensers include polymer spirals, ropes, and tubes. The problem with such passive dispensers is that the release of pheromones is dependent on ambient temperature which is also dependent on time of day. More pheromones tend to be released during the day which does not coincide with the nocturnal activity of moths.

2.Retrievable polymeric dispensers on the other hand are dispensers that are constructed in sizes that render them easily recognizable and retrievable. These dispensers are not in contact with crops. Microencapsulated pheromones (MEC) refer to very small droplets of pheromones held within polymer capsules that determine the rate of their release. MECs are designed to be small enough so they can be applied in water medium in sprayers used in conventional application of pesticides. Polymer capsules prevent the registration of sprayable pheromones for use in organic fruit production. Hollow fibers represent another method of dispensing pheromones. These dispensers consist of impermeable short tubes that are sealed at one end and filled with pheromones. These dispensers release a burst of pheromones shortly after installation after which emission becomes fairly constant.

3. High emission dispensers are those that deliver larger quantities of pheromones thereby reducing the number of dispensers needed to cover large areas; their use also results in reduction of labor costs.

There are other methods of dispensing pheromones such as the Specialized Pheromone Lure Application Technology (SPLAT[™]) which is a propriety formulation of biologically inert materials that are used control the release of semiochemicals including pheromones with or without pesticides.

Manufacture

Even though natural pheromones can be obtained from female insects, commercial pheromones are synthetic products involving chemical processes that are unique to the various pheromones. Pheromones are made of specific esters obtained from reactions between an oxoacid with a compound such as an alcohol or phenol that contains a hydroxyl group. Pheromones are also synthesized by condensing an acid with alcohol. Methods of pheromone synthesis include derivation from natural products such as insect pheromones, chemical or biochemical processes, and enantiomer separation. Moth pheromones are usually made up of hydrocarbon chains that are about 10 to 18 carbons in length with 1 to 3 double bonds with an acetate, alcohol, or aldehyde at the terminal end.

International Acceptance

<u>Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)</u> All sources allowed for pest control; use in pheromone traps or passive dispensers. (Tables 4.2 & 8.2, CAN/CGSB-32.311-2020, page 17 and 45)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165 Allowed (1.10.3, 2018/848 & Annex I, Table 4, 2021/1165)

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (GL 32-1999)</u> Allowed in traps. (pages 19 and 23)

International Federation of Organic Agriculture Movements (IFOAM) Norms Allowed in traps and dispensers only. (Appendix 3: Crop Protectants and Growth Regulators, page 78)

Japan Agricultural Standard (JAS) for Organic Production

Allowed. Limit use to chemical agents with an insect pheromone action as the active ingredient, except when used on plant products for the purpose of controlling pests and diseases. (Appended Table 10: Chemical agents & Appended Table 2: Agricultural chemicals)

Ancillary Substances

Many pheromone products are formulated as mixtures with inert ingredients. Pheromone formulations may also contain antioxidants and ultra-violet stabilizers to protect the pheromones from rapid degradation. It is important to note that the specific composition of pheromones formulated with inert constituents is not declared to the public because it is considered confidential business information.

It is important to note that 7 CFR 205.601 does not allow the use of List 3 inerts (i.e., inerts with unknown toxicity) with active dispensers.

Human Health and Environmental Issues

Inert ingredients used in pheromone formulations include compounds that are potentially linked to asthma, cancer, and endocrine disruption. The fact that dispensers serve as physical barriers to exposure to these chemicals makes the risk or level of exposure to terrestrial and aquatic organisms low. This is particularly so when dispensers are placed away from water sources. Microencapsulated pheromones may have negative impacts on human health; these include respiratory irritation caused by inhalation of particles. Such effects are due to the size of the microencapsulated products and not specifically due to the pheromone

chemicals. Based on observed toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of synthetic and non-synthetic insect pheromones. The TR states that no effects on human health are reported for any of the pheromone products registered with the EPA. The EPA in 2011 affirmed that no adverse effects had been reported from the use of synthetic pheromones. Material Safety Data Sheets information pertaining to skin and eye irritation from pheromones are based on exposure to very high concentrations of the undiluted active ingredient. It must be noted that in the case of passive dispensers, the pheromone is enclosed and diluted within a plastic tube and allowed to dissipate into the atmosphere at low concentrations.

An environmental Impact Report (EIR) by the California Department of Food and Agriculture in 2009 covered the impact of three mating disruption application methods namely: twist-ties, ground applications of a thick pheromone-containing matrix applied to trees and utility poles as well as aerial applications. The EIR found that none of these application methods had significant unavoidable impacts. Twist ties were found to have no impact on beneficial insects and agriculture, no potential for exceedance of toxicity reference values for non-target invertebrates and pollinators, and no impact associated with terrestrial wildlife, fish, or human health due to accidental spills. The other two methods had less than significant potential impacts on the afore-listed categories.

Aerial application poses some ecological risks compared to dispenser methods. Non-target organisms such as honeybees may be coated with viscous material while in flight or these might be picked from sprayed plant surfaces. Aerial application methods may also result in disposal of pheromones into small streams which could potentially impact aquatic organisms. Evaluation of aerial and ground application methods however revealed that the risk to aquatic systems was slightly higher for twist-ties or ground application methods compared to aerial methods. The California Department of Food and Agriculture also reported that the fate and transport properties of pheromones formulations applied aerially render them unlikely for a significant amount of pheromone to deposit into an aquatic system.

Discussion

Public comments from the last sunset review were in favor of relisting pheromones. There were many comments noting their widespread use, insect specificity, use in monitoring populations, and benign nature.

Several commenters did support relisting with the caveat that the pheromones are identical to or substantially similar to natural pheromones, in passive dispensers, without added toxicants and with only approved inert ingredients. There is currently no annotation for pheromones, but comments received indicate that their use generally fits this request.

Microencapsulated pheromones which might be sprayed and have direct fruit contact have not become commercially available. Active dispensers (also known as puffers) are in current use, but act in similar fashion to the passive dispensers in terms of fruit contact or type of pheromone used. Based on the NOSB review and public comment, the NOSB finds pheromones compliant with OFPA criteria, and does not recommend removal from the National List.

Questions to our Stakeholders

- 1. Is there an interest in knowing more about the inert ingredients that are used in formulating pheromone products?
- 2. How much information would be considered acceptable given proprietary information rights of pesticide manufacturers.

Ferric phosphate

Reference: § 205.601(h) As slug or snail bait.

(1) Ferric phosphate (CAS #s 10045-86-0).
 Technical Report: 2004 TAP; 2010 TR; 2012 Supplemental TR; 2023 Limited Scope TR pending
 Petition(s): 05/2003, Supplemental Information 02/2005, Petition to remove: 07/2009
 Past NOSB Actions: 03/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2012
 recommendation on petition to remove from National List; 04/2015 sunset recommendation; 10/2019
 sunset recommendation

Recent Regulatory Background: Added to National List 09/11/06 (<u>71 FR 53299</u>); Renewed 08/03/2011 (<u>76 FR 46595</u>); Renewed 09/12/16 (<u>81 FR 8821</u>); Renewed 8/3/2021 (<u>86 FR 41699</u>) **Sunset Date:** 9/12/2026

Subcommittee Review

Use

Ferric phosphate is used as a molluscicide for slug and snail suppression. Ferric phosphate accumulates in the calcium spherules of slug and snail digestive glands, thereby interfering with calcium metabolism, and in turn, disrupting feeding and mucus production. After ingesting ferric phosphate slugs and snails stop feeding and death due to starvation will occur three to six days later. Ferric phosphate occurs naturally in soil but at considerably lower concentrations than that present in the formulated, baited product.

Manufacture

Ferric phosphate occurs naturally in the soil; however, to achieve concentrations toxic to molluscs, ferric phosphate must be supplemented through applications, most often with ferric phosphate formulated with a chelating agent. To produce ferric phosphate synthetically, an aqueous iron sulfate solution is mixed with an aqueous disodium phosphate solution in a stainless-steel boiler. The mixture is heated to 50-70 °C in order to precipitate ferric phosphate. The precipitate is filtered from the solution, washed with distilled water, and dried with hot air. The baited pellets contain approximately 1% by mass of ferric phosphate with the remainder of the pellet comprised of a chelating agent and carbohydrate inerts. The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied.

International Acceptance

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

Allowed as a molluscicide for slug and snail control. Use in a manner that runoff into water bodies is prevented. Contact with crops is prohibited. (Table 4.2, CAN/CGSB-32.311-2020, page 11)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165 Allowed (Annex I, 2. Low risk active substances, 2021/1165)

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

Allowed as a molluscicide. (Table 2 Substances for Plant Pest and Disease Control; Iron phosphates, page 23)

International Federation of Organic Agriculture Movements (IFOAM)

Allowed for use as a molluscicide. (Appendix 3: Crop Protectants and Growth Regulators, page 78)

Japan Agricultural Standard (JAS) for Organic Production

Allowed. (Appended Table 2: Agricultural chemicals; Ferric phosphate granules)

Human Health and Environmental Issues

The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied. Small concentrations of ferric phosphate are made available in soil solution when it is solubilized by commonly occurring soil microorganisms such as *Penicillium radicum*.

Ferric phosphate by itself appears to be less toxic to a range of soil borne organisms (including slugs and snails) than when formulated with a chelating agent (EDTA or EDDS for example). The chelating agent enhances iron uptake by organisms in general. A number of published studies document that when formulated with a chelating agent, the efficacy for control of slugs and snails increases significantly. However, the increased efficacy also means its activity on non-target organisms like earthworms, domestic animals and humans also increases. The LD50 for earthworms for ferric phosphate alone is greater than 10,000 mg kg while it drops to 80 mg kg when it is formulated with the chelating agents EDTA or EDDS (Ethylene diamine tetracetic acid – EDTA and Ethylene diamine disuccinic acid (EDDS).

Discussion

The 2012 technical review addressed a series of concerns about the biological activity of ferric phosphate both in terms of its effectiveness in suppressing slugs and snails as well as its non-target effects on the ecology and abundance of soil dwelling organisms. Because the commercial formulations of ferric phosphate always include a chelating agent the NOSB was concerned about the effects of the formulated products. The 2012 TR indicated that without the chelating agent, ferric phosphate did not provide sufficient or consistent suppression of slugs and snails. In fact, the efficacy was so low that it is hard to see why it would be used for slug and snail suppression without the chelating agent. The TR then asked, what risk does the use of ferric phosphate and its associated chelating agents pose to soil organisms and water quality. Here the existing data are scant. What has been researched (three studies published between 2006 and 2009) indicate a range of responses from non-significant to highly significant adverse effects of chelated ferric phosphate on a range of non-target

The Subcommittee recognizes the efficacy of ferric phosphate is inextricably linked with the formulation; when formulated with a chelating agent, ferric phosphate effectively suppresses slugs and snails, unfortunately, the non-target effects on other soil organisms increase as well.

In 2019, the NOSB received considerable public comment on ferric phosphate, learning that it is seen as an integral part of vegetable and fruit pest management and is widely used for slug and snail management in organic systems. At that time, there were no alternative commercial organic products for suppression of slugs and snails. However, products using sulfur as the active ingredient are now approved for this purpose. Thus far they are not widely available. Bio-Sul, such a product, is comprised of 99% proprietary "inert" ingredients (as are ferric phosphate products). These, according to a label in the petition to allow sulfur as a molluscicide, include iron. It is not clear whether Bio-Sul includes a chelating agent.

Questions to our Stakeholders

A new technical review on ferric phosphate is in process to answer the following questions, but has not been received yet.

- 1. Is there new information about the effects of EDTA or other chelating agents on the toxicity of ferric phosphate to non-target organisms, including earthworms and dogs?
- 2. Are their ferric phosphate products that don't include chelating agents?

- 3. Do sulfur-based slug management products provide an effective alternative to ferric phosphate? Do they also include chelating agents?
- 4. When used in ferric phosphate products, does EDTA chelate heavy metals in soils? Are there studies that show the combination of ferric phosphate + EDTA (chelator) cause toxic effects in soil microorganisms, including earthworms, or plants?

Additional Questions to our Stakeholders

- 1. Are ferric phosphate products widely used by organic farmers to control slugs and snails?
- 2. Are sulfur-based slug and snail products effective and can they be used in place of ferric phosphate products?

Potassium bicarbonate

Reference: § 205.601(i) As plant disease control. (9) Potassium bicarbonate.
Technical Report: 1999 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Potassium bicarbonate is a useful plant disease control material best suited for powdery mildew diseases and early blight control and has proven to be an important tool for a wide range of organically produced crops. Potassium bicarbonate is used to control Alternaria in cucurbits and Cole crops; anthracnose in cucurbits, blueberries, grapes, spinach, and strawberries; black dot root rot and early blight in potatoes; sooty blotch and powdery mildew in apples; downy mildew in cucurbits, Cole crops, grapes, and lettuce; gray mold in beans, lettuce and strawberries. (For a complete list of uses please see lines 70 through 87 in the 2015 limited scope TR.)

Manufacture

Potassium bicarbonate is produced by carbonating potassium hydroxide to K_2CO_3 , which is then carbonated to KHCO₃. Carbonation is accomplished by injecting carbon dioxide gas into an aqueous solution of potassium hydroxide.

International Acceptance

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

Allowed for pest and disease control for crops grown in greenhouses, other structures, and other crops. (Table 4.2, CAN/CGSB-32.311-2020, page 19)

Allowed on organic product contact surfaces as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event. (Table 7.3, CAN/CGSB-32.311-2020, page 42)

<u>European Economic Community (EEC) Council Regulation, EC No.</u> 2018/848 and 2021/1165 Allowed for the production and conservation of organic grapevine products (Annex V, Part D, 2021/1165)

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

Allowed - listed as potassium hydrogen carbonate (Table 2, Section II, page 23)

International Federation of Organic Agriculture Movements (IFOAM) Allowed. (Appendix 3: Crop Protectants and Growth Regulators, page 77)

Japan Agricultural Standard (JAS) for Organic Production

Allowed. (Appended Table 2: Agricultural chemicals; Potassium hydrogen carbonate aqueous solution)

Human Health and Environmental Issues

When the National Organic Program added potassium bicarbonate to the National List, effective in April of 2001, it stated that: "This material appears to be a least toxic, agronomically desirable material, with greater efficacy for controlling powdery mildew or late blight than does the currently available organic options." The original 1999 Technical Advisory Report (TAP), under: "The effect of the substance on human health" stated that there is "no carcinogenicity" and that: "No effects of over exposure were documented."

The FDA has declared Potassium bicarbonate to be Generally Recognized as Safe (GRAS).

The EPA states that Potassium bicarbonate is a naturally occurring compound that is not expected to have adverse effects on humans or the environment when used as a fungicide. The EPA further states that Potassium bicarbonate is ubiquitous in nature, naturally present in human food and required for normal function in human, plant, and environmental systems.

Discussion

The 1999 TAP review found potassium bicarbonate to be compatible with organic crop production. It also found this material to be safer and more environmentally friendly than many of the alternatives.

During the 2015 sunset review, a limited scope technical report (TR) was requested. This TR focused almost exclusively on two questions: 1) Describe all natural (non-synthetic) substances or products which may be used in place of potassium bicarbonate and provide a list of allowed substances that may be used in place of potassium bicarbonate. 2) Describe any alternative practices that would make potassium bicarbonate unnecessary. *Bacillus amyliquifaciens* strain D747, *Bacillus subtilis, Bacillus pumilis,* gibberellic acid and *Streptomyces griseovirdis* and *lydicus, Gliocladium catenulatum* and extracts of giant knotweed are all listed as natural alternatives for numerous plant diseases across many crops. Bordeaux mix, kaolin, lime sulfur and sulfur, hydrogen dioxide and neem extracts are also suggested as alternatives. The TR also deals with a variety of cultural and mechanical practices as methods of disease prevention. Further clarification was sought in 2015 from stakeholders using potassium bicarbonate to help understand what conditions the alternatives might be used. The organic producers responded that, while alternative materials and/or practices exist, potassium bicarbonate remains essential for their specific production practices.

Questions to our Stakeholders

As "necessity" appears to be a key question, we are asking the same two questions of our stakeholders as presented in the previous two sunset reviews:

- 1. Have you used any of the many alternative materials to potassium bicarbonate on your farm, and did they provide the desired results for disease control?
- 2. Is potassium bicarbonate still needed in your organic farming operations? If so, why?

Magnesium sulfate

Reference: § 205.601(j) As a plant or soil amendment.

(6) Magnesium sulfate—allowed with a documented soil deficiency.

Technical Report: <u>1995 TAP</u>; <u>2011 TR</u>

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699) Sunset Date: 9/12/2026

Subcommittee Review

Use

Magnesium sulfate has a wide variety of uses including agricultural, food processing, personal care products, and medicine. In crop production, it serves as a soil amendment for addressing magnesium deficiency or to improve the uptake of nitrogen and phosphorous (Epsom Salt Council, 2007). It may be used in combination with non-synthetic or synthetic crop fertilizers. The compound helps seeds to germinate, increases the production of chlorophyll, and aids in the production of flowers. The high solubility of the compound makes it highly suitable for adding magnesium to the soil. It is a common addition to growth media in potted plants.

Food processing uses of magnesium sulfate include its functions as a flavor enhancer in bottled water, as a firming agent in soybean curd, as a nutrient constituent of salt-replacer products, as a dietary supplement, as a fermentation and malting aid in ale, beer, and other malt beverages (Kawamura and Rao, 2007). Medicinal functions include its uses as an anticonvulsant, agent for lowering the blood pressure of pregnant women suffering from pre-eclampsia, for treating asthma, as a laxative, as well as for relieving muscle and join aches/pains. Veterinary uses include its use as a laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, treatment of malignant hypothermia in swine, and for treating cardiac arrhythmias. The compound can be added to livestock feed to treat magnesium deficiency.

Manufacture

This compound can be obtained from naturally occurring sources or chemically synthesized. Magnesium sulfate exists in nature in the hydrated form. Epsomite and kieserite are the heptahydrate and monohydrate forms of the compound that occur in nature.

The synthetic form of magnesium sulfate is produced by a two-step chemical reaction. The first step involves the ignition of magnesite ore (containing magnesium carbonate) or magnesium hydroxide to produce magnesium oxide which is then reacted with sulfuric acid to produce magnesium sulfate.

Recrystallization and separation of the resulting crystals from the parent solution results in magnesium sulfate with a high grade of purity.

International Acceptance

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

Allowed when soil and plant deficiencies are documented by visual symptoms, by testing of soil or plant tissue, or when the need for a preventative application is documented. (Table 4.2, Magnesium listing, CAN/CGSB-32.311-2020, page 14)

Allowed as a food additive ingredient. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

Allowed as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event. (Table 7.3, CAN/CGSB-32.311-2020. page 42)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165 Natural origin allowed. (Annex II, 2021/1165)

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

Allowed for use in soil fertilizing and conditioning. (Table 1, page 20)

International Federation of Organic Agriculture Movements (IFOAM) Allowed regardless of soil deficiency documentation. (Appendix 2: Fertilizers and Soil Conditioners, page 76)

Japan Agricultural Standard (JAS) for Organic Production

Allowed regardless of soil deficiency documentation. (Appended Table 1: Fertilizers and soil improvement substances; Natural substances or substances derived from natural sources which have not undergone any chemical treatment)

Ancillary Substances

Varies based on the chemical properties of the synthetic or non-synthetic fertilizers that may be combined with magnesium sulfate for application as a soil amendment.

Human Health and Environmental Issues

Accumulation of magnesium ions in body fluids can result in toxic effects such as flaccid paralysis, cyanosis, and heart changes. Reduction and eventual disappearance of tendon reflexes as well as heart block and respiratory paralysis are outcomes of the elevation of magnesium in blood plasma to levels that exceed the threshold level (of 4 mEq/liter) and approach 10 mEq/liter. Administration of an excessive dose of magnesium sulfate in the treatment of pre-eclampsia results in toxic effects in neonates that include hypotension, flushing, sweating, flaccid paralysis, circulatory collapse, depression of cardiac function and reflexes. Vasodilation from low doses of magnesium results in symptoms such as flushing and sweating while that from higher doses of the compound results in circulatory collapse. It is important to note that agricultural uses of the compound are not likely to result in such exposures.

According to the 2011 TR, the use of magnesium sulfate in accordance with 7 CFR 205.603 is unlikely to result in adverse effects on the environment.

The fact that magnesium exists in the atmosphere in a particulate state makes it unlikely to be released after most manufacturing processes. It is highly soluble in water and is very mobile. Its physicochemical properties make it an unlikely contaminant of aquatic environments. Additionally, the compound is removed from the atmosphere by wet and dry deposition. The ionic properties of magnesium make it unlikely to volatilize. The ion exchange between calcium and magnesium sulfate makes it possible to remove the compound in sediments. Available data shows that magnesium ions are weakly sorbed on river sediments.

Discussion

During the NOSB review in 2019, public commenters expressed continued support for this material, stating that it is important in high tunnels and greenhouses as well as fruit tree production. Some growers commented that dolomite is not a suitable substitute in all cases as it cannot be used in high pH soils nor as a foliar application. It was also noted that there are few non-synthetic products on the market. The use of magnesium sulfate in high pH soils to add sulfur without further increasing pH was discussed. One commenter noted that use of magnesium sulfate should not take the place of soil building practices. Based on the NOSB review and public comment, the NOSB found magnesium sulfate compliant with OFPA criteria, and did not recommend removal from the National List.

Questions to our Stakeholders

None

Hydrogen chloride

Reference: § 205.601(n) Seed preparations. Hydrogen chloride (CAS # 7647-01-0)—for delinting cotton seed for planting.
Technical Report: 2003 TAP, 2014 Limited Scope TR; 2023 Limited Scope TR pending
Petition(s): 2002
Past NOSB Actions: 05/2004 NOSB recommendation for National List; 11/2009 sunset recommendation; 4/2015 recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299); Renewed 08/03/2011 (76 FR 46595)
Renewed 09/12/16 (81 FR 8821): Renewed 8/3/2021 (86 FR 41699)

Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699) Sunset Date: 9/12/2026

Subcommittee Review

Use

Hydrogen chloride is used in the cotton seed delinting process. The liquid anhydrous hydrogen gas is vaporized and then sprayed on cotton seeds after the ginning process. The gas mixes with the moisture in the seeds, resulting in acidic properties to which the seeds are subjected. The lint on the seeds becomes weakened by the acid and is more readily buffed off before planting occurs. (TAP)

Manufacture

There are several methods used to produce hydrogen chloride. It can be synthesized directly or as a byproduct from manufacturing other chlorinated or fluorinated compounds.

International Acceptance

<u>Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)</u> Not Explicitly Mentioned

<u>European Economic Community (EEC) Council Regulation, EC No</u>. <u>2018/848</u> and <u>2021/1165</u> Not explicitly mentioned for crop production. Allowed in the preparation of foodstuffs of animal origin for gelatine production (Annex V, Section A2, 2021/1165)

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (GL 32-1999)</u> Not Explicitly Mentioned

International Federation of Organic Agriculture Movements (IFOAM) Not Explicitly Mentioned

Japan Agricultural Standard (JAS) for Organic Production

Not Explicitly Mentioned

Human Health and Environmental Issues

Human Health – Hydrochloric acid is not considered a carcinogenic substance to humans. A major HCl effect is local irritation. HCl will only exist in the air if transported through an aerosol or as a soot particle deposit. HCl inhalation causes coughing, inflammation, pain, and edema of the upper respiratory tract. HCl exposure normally will not affect those vital organs furthest from the point of contact in the body. Eye contact with HCl may induce vision reduction or blindness. HCl concentrations, of 35 ppm or greater, can cause throat irritation after short-term exposure. Hydrochloric acid is very corrosive, and, if contacted with the skin, irritation and burns may occur (TAP)

Environmental - If exposed to the environment, hydrochloric acid will neutralize carbonate-based soil components. Soil and sand will absorb hydrochloric acid--these are recommended practices for cleaning up HCl spills. Large hydrochloric acid spills can be neutralized with lime or diluted alkaline solutions of soda ash. The EPA 1985 CFNP Hydrogen Chloride TAP August 2003 9 emission inventory indicates that less than one percent of HCl emissions come from production practices. Nearly 89 percent of all HCl emissions come from the combustion of coal. (TAP)

Discussion

Hydrogen Chloride was petitioned in 2002 to be added to the National List and was added in 2004. In all of the reviews since, hydrogen chloride was deemed the only available solution for organic farmers needing to delint cotton seed. In the most recent sunset review in October 2019, a motion to remove hydrogen chloride from the National List was unanimously rejected by all 13 attending voters. (TR 24-26)

A good portion of the conversation regarding this material has been dedicated to looking at natural alternatives or additional practices. The 2023 NOSB Crops Subcommittee requested a limited scope TR to review in further detail any updates in innovation for natural or alternative practices that are at a commercial scale. The TR stated, "given the extremely low pH (1.5-3) required for effective acid delinting, no non-synthetic substances are available as alternatives to synthetic acids for cotton seed delinting" (TR 99-100). The TR mentioned that Sulfuric Acid, the most common substance used in delinting cotton, could be a suitable synthetic alternative (TR 105-106).

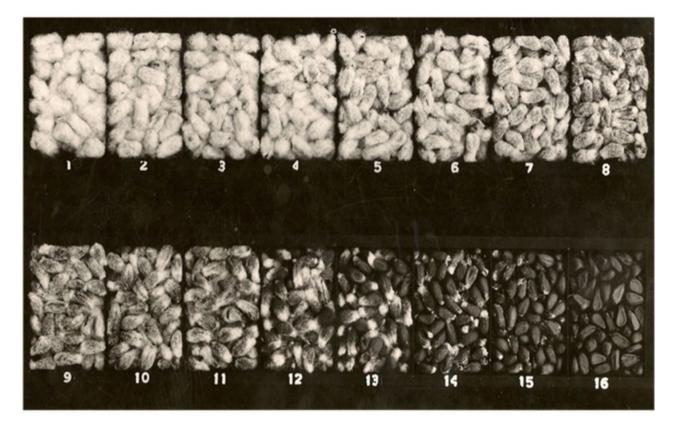
The TR also provided insight into alternative practices that could be used to delint cotton outside of chemical means involving acid, which includes mechanical delinting, flaming, or breeding fuzzless seed.

Mechanical delinting can reduce the lint amount down to 1.5% (weight/weight) (Olivier et al., 2006). The original weight/weight of lint is not provided. The duration of mechanical delinting can affect cottonseed quality. Hopper et al. (2003) reported that mechanical delinting for 10 minutes was generally equal to or superior to 20- and 60-minute delinting times. The USDA cotton research group in Texas has successfully built a commercial-scale mechanical delinter. However, up to the date of writing this report, there has been no industrial partner ready to manufacture it (TR 173-178).

Flame delinting or zipper delinting is a process used by seed processing facilities on mechanically delinted seeds which are dropped through an intense flame to singe or burn off loose linters. The seeds exposed to flaming need to be cooled down quickly to avoid damage to the embryo that might affect germinability and vigor (Delouche, 1986) (TR 193-194, 197·198).

A fuzzless upland cotton mutant (9023 n_4^t) was developed from the cultivar 'SC 9023' through chemical mutagenesis by the Texas USDA cotton research group and Texas Tech University in Lubbock (TR 212-213).

(TR – Figure 2): Variable degrees of cotton seed delinting. Fully delinted seed (16) is likely achieved using acid delinting (Anonymous author, source: https://file.scirp.org/Html/13-2600348_20046.htm).



The 2019 NOSB review concluded that circumstances since 2014 are unchanged and that appears to be the same for 2024. Although progress has been made, viable alternatives to hydrogen chloride are not yet available. A key challenge is the small size of the U.S organic production market which does not economically incentivize companies to develop organic-specific technologies.

Spring and Fall 2019 public comments were universally supportive of relisting hydrogen chloride as essential and asserted that failure to do so would irreparably harm the U.S. organic cotton industry.

Allowing the limited use of hydrogen chloride for seed preparation accrues economic and environmental benefits by supporting domestic organic cotton production and avoiding the associated impacts of heavy pesticide use on conventional cotton. The need for additional specialized research to support alternatives to hydrogen chloride, a caustic and potentially harmful material, was emphasized and is supported by the Crops Subcommittee.

Questions to our Stakeholders

Are there any recent advances in alternative practices or methods for delinting cotton or planting cotton seed that hasn't been delinted?

Ash from manure burning

Reference: § 205.602 Nonsynthetics prohibited

(a) Ash from manure burning.

Technical Report: 2021 TR (Biochar)
Petition(s): 2014; 2019 annotation change
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 4/2016 NOSB formal recommendation; 10/2019 sunset recommendation; 10/2021 recommendation to not annotate
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

This material can be used as a soil amendment, used to address soil remediation, and sequester carbon. Burning the manure would lessen the volume of material (manure) transported to a field for fertilizer and to recover some of the nutrients in a more concentrated form (phosphorus, calcium, potassium, and magnesium). The ash can then be used as a fertility input that is high in these nutrients. This ash from manure has also been touted as a feed ingredient for livestock. The NOP organic standards do not allow refeeding of manure to organic livestock.

Manufacture

Manure can be thermally decomposed through combustion and pyrolysis to produce ash. The NOP articulated a position that pyrolysis is not its own unique mode of processing but in fact should be viewed as analogous to burning or combustion, and thus a source of ash [NOP 5033-1, section 4.8]

According to the TR, nearly all biochar is produced by the thermochemical degradation of biomass in the absence of oxygen from animal and plant feedstocks from both plant and animal including; shells, sugarcane bagasse, coconut husks, cotton, crop remnants, grain remnants, grass residues, wood chips, tree back, organic waste, animal bedding, livestock manure, poultry litter, sewage sludge, paper sludge, and municipal waste

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Ash from plant and animal sources is allowed. However, ash from burning manure or from burning

minerals, coloured paper, plastics or other non-biological substances is prohibited. (Table 4.2, Ash listing, CAN/CGSB-32.311-2020, page 4)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165 Not explicitly mentioned

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (GL 32-1999)</u> Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production Not explicitly mentioned

Ancillary Substances

None identified

Human Health and Environmental Issues

There do not appear to be any documented human health impacts from the petitioned substance. The TR states that biochar can help decontaminate soil from pesticides and heavy metals but can also harbor toxins such as polycyclic aromatic hydrocarbons (PAH), which are typically formed using hightemperature production methods and heavy metals that are typically carried over from the feedstock.

Discussion

Ash from manure burning, is a non-synthetic material present on the prohibited list for crop production. Since the carbon present in manure is considered valuable for soil building, it's destruction would not be consistent with foundational organic production principle.

In 2016, the Board denied petition to add the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients," stating that:

"Utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of CAFOs by creating an organic industry demand for ash. Utilizing ash from manure burning in order to assist CAFOs in their reduction of environmental and human health contamination is not a compelling argument for consideration for addition to the National List."

In 2021, the Board denied the petition to annotate 205.602(a) to "(a) Ash from manure burning – unless derived as part of the production of biochar from pyrolysis of cow manure," stating that:

"While pyrolysis may be different from burning, the NOP has issued guidance (NOP Guidance 5033, 2016) stating that pyrolysis may be treated as equivalent to burning or combustion. Public comments were mixed as to whether the annotation should be changed; however, more comments supported maintaining the current annotation. Additionally, the NOSB found that while biochar may have many benefits, there are allowed alternative methods for producing biochar from other materials. Manures may be used in organic agriculture without conversion to biochar, thus a majority of the NOSB considered the use of biochar from animal manures not essential to organic agriculture and not meriting an annotation change." One subcommittee member stated that there is not an excess supply of manures in the agricultural industry and burning off the material to handle the supply is not necessary. The market for manure is currently competitive.

Questions to our Stakeholders

None

Sodium fluoaluminate (mined)

Reference: § 205.602 Nonsynthetics prohibited (g) Sodium fluoaluminate (mined).

Technical Report: none

Petition(s): 2002 Cryolite

Past NOSB Actions: 05/1996 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699) Sunset Date: 9/12/2026

Subcommittee Review

Use:

According to the EPA fact sheet from 1996, "Cryolite is an insecticide used on many fruits, vegetables and ornamental crops to protect against leaf eating pests. Currently, the predominant uses are on grapes, potatoes and citrus. Cryolite is formulated as dusts, wettable powders and water dispersible granulars and can be applied by ground or air equipment. Multiple applications at high rates are typical. The highest single application rate is 30 lbs./acre on citrus and ornamentals; the highest seasonal rate from multiple applications is 154 lbs./acre on lettuce."¹

Sodium fluoaluminate (Na3AlF6)—also known as "sodium fluoroaluminate," "aluminum sodium fluoride," "trisodium hexafluoroaluminate," and "cryolite"—is a colorless to white halide mineral. It is used as a solvent for bauxite in the electrolytic production of aluminum and has various other metallurgical applications, and it is used in the glass and enamel industries, in bonded abrasives as a filler, and in the manufacture of insecticides.

Manufacture

Sodium fluoaluminate is a colorless to white halide mineral. It occurs in a large deposit at Ivigtut, Greenland, and in small amounts in Spain, Colorado, U.S., and elsewhere. Cryolite is a naturally occurring mineral that is also synthetically produced.

International

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020) Not explicitly mentioned

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165 Not explicitly mentioned

¹ <u>https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-075101_1-Aug-96.pdf</u>

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of

Organically Produced Foods (CXG 32-1999)

Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Norms Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production Not explicitly mentioned

Environmental Issues

According to an EPA memorandum dated March 16, 2011, on the subject of "Cryolite. Human Health Assessment Scoping Document in Support of Registration Review"² The toxicity of sodium fluoaluminate/cryolite is due to the release of fluoride into the environment due to the dissociation of cryolite into fluoride. The EPA memorandum cited above references a number of animal toxicological studies on this substance; other studies related generally to fluoride toxicity are also referenced, since fluoride enters the environment in multiple ways—including fluoridated water—and therefore can have a cumulative adverse impact on health.

Discussion

Previously in the sunset process, the NOSB found that sodium fluoaluminate was not compliant with OFPA criteria and recommended this material remain on the National List of prohibited substances. Given the toxicity associated with fluoride pollution in the environment and the multiple sources of such pollution, continued prohibition of the use of this substance in organic production is the current climate of the Crops Subcommittee.

Questions for stakeholders

Is there any new research or relevant information in the marketplace that should be considered in conjunction with OFPA criteria and the long-standing prohibition on using sodium fluoaluminate in organic production?

²<u>https://www.fluoridealert.org/wp-content/uploads/cryolite.summary.epa_.2011.pdf</u>