# Sunset 2024 Meeting 1 - Request for Public Comment Crops Substances § 205.601 & § 205.602 April 2022

#### 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 are on the National List which 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, 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 <u>Petitioned Substances Database</u>.

#### **Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2022 public meeting. Comments should be provided via Regulations.gov at <u>www.regulations.gov</u> on or before April 1, 2022, 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 (see <u>7 U.S.C. 6518(m)</u>) and the USDA organic regulations (<u>7 CFR 205.600</u>). 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 §205.601 Substances in Organic Production:

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

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

#### For Comments that <u>Do Not Support</u> the Continued Use of §205.601 Substances in Organic Production:

If you provide comments that do not support a substance at §205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide <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 §205.602 Substances in Organic Production:

If you provide comments supporting the prohibition of a substance on the §205.602 section of the National List, you should provide information demonstrating that the substance is:

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

# For Comments that <u>Do Not Support</u> the Continued Prohibition of §205.602 Substances in Organic Production:

If you provide comments that do not support the prohibition of a substance at §205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.602 section of the National List should provide <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 1, 2022, via <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:

- Herbicides, soap-based
- Biodegradable biobased mulch film
- Boric acid
- <u>Sticky traps/barriers</u>
- Elemental sulfur (h)(2)
- <u>Coppers, fixed</u>
- Copper sulfate (i)(3)
- Polyoxin D zinc salt
- Humic acids
- Micronutrients:
  - Soluble boron products
  - <u>Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt</u>
- Vitamins B<sub>1</sub>, C, E
- Squid byproducts

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

- Lead salts
- <u>Tobacco dust (nicotine sulfate)</u>

#### Herbicides, soap-based

**Reference:** §205.601(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Technical Report: <u>1996 TAP</u>; <u>2015 TR</u>.

#### Petition: N/A

**Past NOSB Actions: Actions:** <u>1996 recommendation</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset recommendation</u>; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>.

**Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577)</u>

Sunset date: 10/30/2024

#### Subcommittee Review

#### Use

As herbicides, soap-based herbicides are used as weed barriers, for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops as a last resort.

#### Manufacture

Soap-based herbicides are potassium salts of fatty acids and are produced through saponification, where aqueous potassium hydroxide is added to fatty acids commonly found in animal fats and plant oils. Ammonium salts of fatty acids, such as ammonium nonanoate, are produced through room temperature reaction of aqueous ammonia or ammonium hydroxide with fatty acids.

#### International Acceptance

#### Canadian General Standards Board Permitted Substances List

The Canadian Organic Production Systems Permitted Substances List provides several use patterns for soaps in organic crop and livestock production, as well as organic processing

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

European organic regulations allow the use of soap salts in crop and livestock production as insecticides and disinfecting agents but are not mentioned for use as herbicides.

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

The use of soaps in organic productions is an allowed synthetic substance for plant pest and disease control but no mention of specific use as an herbicide.

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

A number of uses of soaps are listed for organic crop production and disinfection but no mention of specific use as an herbicide.

#### Japan Agricultural Standard (JAS) for Organic Production

Soaps can be used for control of pests in organic crop production. No mention of specific use as an herbicide.

#### **Environmental Issues**

Potassium and sodium salts of fatty acids decompose rapidly and do not persist in the environment. They need to be sprayed directly on the target plant and thus, environmental contamination is not expected. Studies have not shown any negative interactions with other chemicals used for organic farming.

#### Discussion

In 2017, the NOSB received several comments in favor of keeping soap-based herbicides on the National List. Comments indicated that although soap-based herbicides are sometimes only marginally effective, they are a safe alternative, and some farmers rely on them for weed control on farmsteads, roadways, and other places they are approved for use. There were no comments in favor of removing soap-based herbicides. The subcommittee discussed soap-based herbicides and considers them to be benign to the environment and human health,

#### **Questions to our Stakeholders**

None

### Biodegradable biobased mulch film

**Reference:** §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches.

(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

**Technical Report**: <u>2012 TR</u>; <u>2015 Report</u>; <u>NOP Policy Memorandum 15-1</u>; <u>2016 Supplemental TR</u>. **Petition**: <u>2012</u>.

Past NOSB Actions: Actions: <u>10/2012 recommendation</u>; <u>11/2017 sunset recommendation</u>. Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>) Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

Biodegradable biobased mulch film (BBMF) is used to suppress weeds, conserve water, and facilitate production of row crops. Some commenters have noted that having a degradable plastic mulch is likely to be more environmentally friendly than using landfills for the non-degradable plastic mulches. The requirement for 100% biobased feedstocks to manufacture the film is articulated in the preamble of the final rule that added Biodegradable biobased mulch film to the National List. Past commenters have acknowledged that there are currently very few options (other than difficult to use paper mulch) for 100% BBMF but have generally felt this listing should remain despite the fact that no 100% BBMF is available (see below). At the Fall 2021 NOSB meeting, the Board voted to allow 80% BBMF

(https://www.ams.usda.gov/sites/default/files/media/NOSBFall2017ProposalsDDTOC.pdf).

As noted in numerous public comments on past documents relating to BBMF, the current listing allowing the use of these films is impractical. No biobased films meet the 100% annotation and are unlikely to meet this criterion in the near future. There is also broad consensus among the Board and stakeholders that the use of allowed polyethylene mulch has serious negative environmental impacts. After input from stakeholders on the practicality and environmental impacts from biodegradable mulch, the Board passed a proposal modifying the annotation for BBMF. While there are no currently available products that meet the modified criteria, commenters noted that it is possible that materials meeting the proposed annotation could be available in the near future. The use of BBMF that meets this proposed annotation would alleviate the environmental impact of disposal of non-recyclable polyethylene mulch. The proposed language, "When greater than 80% biodegradable biobased mulch films become commercially available, producers are required to use them, given that they are of the appropriate quality, quantity, and form", also reflects the Boards intent to ensure

that famers must use BBMF with biobased content greater than 80% when these materials become commercially available.

The timing of this sunset review predates the rulemaking process to implement the annotation allowing 80% BBMF. The Crops Subcommittee has voted to relist BBMF at §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods until the annotations is implemented.

#### Manufacture

BBMF is a synthetic plastic material manufactured from polymers using plant-based carbon sources.

#### International Acceptance

#### Canadian General Standards Board Permitted Substances List

Plastic mulches: non-biodegradable and semi-biodegradable materials shall not be incorporated into the soil or left in the field to decompose. Use of polyvinyl chloride as plastic mulch or row cover is prohibited. Biodegradable mulches: 100% of biodegradable mulch films shall be derived from bio-based sources. Biodegradable polymers and Carbon Black from GE or petroleum sources are not permitted.

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

Mulches are not specifically addressed in EEC. Under plant protection it states that all plant production techniques used shall prevent or minimize any contribution to the contamination of the environment.

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

No reference in CODEX on biodegradable mulch.

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

Under 4.5.1, mulches are permitted as a pest management practice under and 4.5.2 references appendix 3 as an approved list including "mulch" as a barrier. 4.6.3 states "for synthetic structure coverings, mulches, fleeces, insect netting and silage wrapping, only products based on polyethylene and polypropylene, or other polycarbonates are permitted. These shall be removed from the soil after use and shall not be burned on the farmland."

#### Japan Agricultural Standard (JAS) for Organic Production

Mulches are permitted for the control of noxious animals and plants in fields or cultivation sites. Mulches derived from used papers (those without chemically synthesized materials added in production) or plastic mulches (those intended to be removed after use). There is no listing of biodegradable mulches.

#### **Environmental Issues**

Concerns about BBMF have been extensively discussed in prior documents including discussion documents, reports, and proposals for the annotation change. Concerns have been raised about incomplete degradation and migration of partially decomposed particles into the environment.

#### Discussion

There have been numerous public comments requesting the NOSB work with the NOP to allow a BBMF that contains unique polymers. Some noted that having a

degradable plastic mulch is likely more environmentally friendly than using landfills for the non-degradable plastic mulches. Past commenters also acknowledged that there are currently very few options (other than

difficult to use paper mulch) for 100% BBMF but felt the listing should remain despite the fact that 100% BBMF is not available. As noted above, at the Fall 2021 NOSB meeting, the Board voted to allow 80% BBMF (<u>https://www.ams.usda.gov/sites/default/files/media/NOSBFall2017ProposalsDDTOC.pdf</u>).

#### **Questions to our Stakeholders**

Is there new information on the availability of 100% BBMF?

#### **Boric acid**

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

(3) Boric acid - structural pest control, no direct contact with organic food or crops.

Technical Report: <u>1995 TAP</u>.

Petition: N/A

**Past NOSB Actions:** <u>04/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>.

**Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577)</u>

Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

As an insecticide, boric acid is odorless. It attacks insect nervous and metabolic systems. It can also dehydrate insects and be abrasive to insect exoskeletons. It has been used as an insecticide since 1948 and is common in household insecticides.

As a structural pest control tool, it is used as a bait which insects ingest and return to their colonies. As a result, it can eliminate entire pest colonies.

This material is often used in packing sheds and other facilities. Many times, it is used as a powder introduced into cracks and crevices, and is essential for controlling ants and roaches.

It has a number of industrial and medical uses and is often used as an amendment in boron-deficient soils.

#### Manufacture

Boric acid is a white powder that is soluble in boiling water. It is a mined substance, occurring naturally in areas of high volcanic activity, and its primary source is the Mojave Desert of Nevada and California. It also occurs in plants, is prevalent in most fruits, and appears in rocks and soil.

Boric acid produced through the manufacturing process includes a broad range of formulations in concentrations from 1-100% in liquids (solutions, emulsifiable concentrates), granules, wettable powders, dusts, pellets, tablets, and baits.

#### International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian Organic Production Systems Permitted Substances List includes boric acid for structural pest control.

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

European organic regulations do not reference boric acid.

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u> CODEX regulations do not reference boric acid.

International Federation of Organic Agriculture Movements (IFOAM) Norms IFOAM regulations do not reference boric acid.

#### Japan Agricultural Standard (JAS) for Organic Production

JAS regulations allow boric acid for pest control for plants.

#### **Environmental Issues**

Boric acid is generally regarded as safe (GRAS) and of low toxicity, although it can be an eye, skin, and respiratory and nasal irritant. Ingestion by humans or pets can cause gastrointestinal distress. Long-term exposure can affect the kidneys, although it is not generally considered to be carcinogenic. There is no evidence it can be an endocrine disruptor or can create reproductive toxicity in humans (although birds may experience some reduced growth rates after ingestion). Several species of fish have been tested for impacts from boric acid, and the World Health Organization determined very low sensitivity to the material in those species. It has low toxicity to bees.

Boric acid is mined from the environment in deserts where sensitive habitats and species may exist. Boric acid is released into the environment due its wide range of applications, including borate salt laundry products, power generation, chemical manufacturing, copper smelters, rockets, mining operations, and the manufacture of glass, fiberglass, porcelain enamel, ceramic glazes, metal alloys and fire retardants.

#### Discussion

Boric acid, derived from the mineral borax/borate salts, is a weak acid that has long been considered a "least-toxic" pesticide because it is non-volatile when placed in bait or gel formulations and therefore eliminates risk of direct exposure. It is essentially hydrated boron.

At the Fall 2015 NOSB meeting, the Crops Subcommittee proposed to remove boric acid from §205.601(e) on the basis of not fully meeting all sub-components of OFPA criteria, particularly criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency. The motion to remove failed after receiving 1 "Yes" and 13 "No" votes. While boric acid does not fully meet the OFPA criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency, the alternatives often have equally challenging issues.

In 2017, there was no new information provided from the stakeholder community through public comment during subcommittee review and prior to full consideration before the NOSB in-person vote. There was also no support for removing boric acid from the National List. Neither the Subcommittee nor the full board recommended its removal from the National List.

The Crops Subcommittee discussed the use of this material and noted it is both common and useful in these applications.

Questions to our Stakeholders:

None

### Sticky traps/barriers

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

(9) Sticky traps/barriers.
Technical Report: <u>1995 TAP</u>.
Petition: N/A
Past NOSB Actions: <u>10/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset</u>
recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>)
Sunset date: 10/30/2024

#### Subcommittee Review

#### Use

Pest control and monitoring. Also used with traps as a production aid.

#### Manufacture

This listing covers a wide range of traps and coatings made with a number of different materials, including coated paper, coated plastic, and brushed on sticky chemicals applied directly to plants. Some sticky traps are made with petroleum wax or linear hydrocarbons.

#### **International Acceptance**

None noticed

#### **Environmental Issues**

Sticky traps are used in limited quantities in confined areas such as traps or tree trunks, and have limited mobility, making it unlikely to have environmental impacts.

#### Discussion

There was broad support for relisting sticky traps/barriers from farmers, certifiers, and trade organizations the last time sticky traps came up for sunset review. Based on the previous Subcommittee review and public comment, the NOSB found sticky traps/barriers compliant with OFPA criteria, and did not recommend removal from the National List.

Sticky traps do not come into contact with food.

#### **Questions to our Stakeholders**

None

# Elemental sulfur (h)(2)

Reference: §205.601(h) As slug or snail bait.
(2) Elemental sulfur.
Technical Report: <u>1995 TAP</u>; <u>2018 TR</u>.
Petition: <u>2017</u>.
Past NOSB Actions: <u>04/2018 recommendation</u>.
Recent Regulatory Background: Added to National List on 11/22/2019 (<u>84 FR 56673</u>).
Sunset Date: 11/22/2024

#### **Subcommittee Review**

#### Use

When used to manage slugs and snails, sulfur is formulated with attractants plus other "inert" ingredients and extruded into pellets. These are broadcast or hand-applied near crops needing protection. For this purpose, a 1% sulfur formulation is used at a labeled rate of up to 44 lbs. per acre, with an actual elemental sulfur application rate of up to 0.44 lbs. per acre. This is much lower than labeled rates for sulfur when used as a fungicide in formulations of 80% or 90% elemental sulfur.

#### Manufacture

Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery processes. The latter appears to be the source of most elemental sulfur currently being used. Because the sulfur is chemically extracted from fossil-fuel feedstock, it is considered synthetic.

#### **International Acceptance**

#### Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board (CGSB) includes elemental sulfur from either mined and reclaimed sources as permitted substances for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

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

The European Economic Community (EEC) Council Regulation (EEC No 2092/91) and carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

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

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

The International Federation of Organic Agriculture Movement's (IFOAM) lists sulfur as an approved substance for pest and disease control, for use as fertilizer/soil conditioner, and for use as a crop protectant and growth regulator.

#### Japan Agricultural Standard (JAS) for Organic Production

The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance, and as a substance for plant pest and disease control.

#### **Environmental Issues**

When used as a fungicide with several applications per season, sulfur can lower soil pH over time, and have negative effects on beneficial mite populations. However, rates in use for slug and snail management are much lower and would not be expected to have those effects.

#### Discussion

Sulfur for use as a slug or snail bait was added to the National List at §205.601(h) in 2019. This is its first sunset review. Its 2017 petition includes studies showing that a sulfur slug bait product is somewhat more effective than other products approved for this use in organic production.

Other synthetic products commonly used by organic farmers to kill slugs use the active ingredient ferric phosphate. It is invariably combined with a synergist, the chelator EDTA, which is an inert ingredient on the defunct EPA list 4. The EDTA + ferric phosphate combination has been implicated in harm to earthworms in soil and also pet dogs due to enhanced iron toxicity. In 2012 these products were petitioned for removal from the National List at § 205.601(h) for this reason, but the NOSB motion to remove failed. At that time, the NOSB Recommendation indicated that there were no commercial alternatives to ferric phosphate. In 2018, the listing for ferric phosphate was renewed on the National List.

In light of questions about the toxicity of ferric phosphate and the availability of relatively new sulfur alternatives, organic farmers may consider the sulfur products to be desirable. The label of one sulfur-based slug bait product states that it can be used around pets and wildlife when used as directed. The label shows 1% sulfur and 99% inert ingredients, which include iron. It is not known whether this product also contains EDTA.

At labeled rates, sulfur used for this purpose is thought to have little or no negative environmental impacts, even if applied multiple times per season. However, other components of a product's formulation are unknown and may have negative effects.

#### **Questions to our Stakeholders**

- 1. Are there cultural practices that can make slug and snail baits unnecessary?
- 2. Is it necessary to have sulfur-based products for slug management in addition to ferric phosphate?

## Coppers, fixed

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

(2) Coppers, fixed —copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

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

Petition: N/A

Past NOSB Actions: <u>10/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>4/2011 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>. **Recent Regulatory Background:** Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>) **Sunset date**: 10/30/2024

#### **Subcommittee Review**

#### Use

Coppers, fixed was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers

were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Copper sulfate is also undergoing sunset review, and the Crops Subcommittee submitted a separate review.

#### Manufacture

Fixed coppers, such as copper hydroxide, are formed by treating copper sulfate with another compound (in this case sodium hydroxide). In another example, copper carbonate is formed by treating copper sulfate with sodium carbonate.

#### International Acceptance

Canadian General Standards Board Permitted Substances List

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
- Visible residue of copper products on harvested crops is prohibited.

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

• The EEC states that, "it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates."

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

 Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of —Guidelines for the production, processing, labeling and marketing of organically produced foods|| (CODEX-GL 32, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

• Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

Japan Agricultural Standard (JAS) for Organic Production

• While the document refers to 'copper powder" repeatedly, only copper sulfate is specifically mentioned. Copper sulfate is only <u>permitted in organic agriculture as a fungicidal spray</u>.

#### **Environmental issues**

Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice must be questioned.

#### Discussion

Copper products are difficult substances to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that they are hazardous to both human health and the environment. Despite this, their use period has been extended in all three jurisdictions. There doesn't yet appear to be a viable organic alternative for copper in certain applications, including in the lucrative organic wine industry. Banning the use of coppers entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper compounds for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus, *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.

One method to remove toxic copper levels from the soil of vineyards uses plants and bacteria to pull the heavy metal from the soil (Mackie et al, 2012). Phytoremediation with mustard (*Brassica juncea*) can help remove toxic Cu levels from the soil (Ariyakanon and Winaipanich, 2006). There appears to be varying tolerance of crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

#### 2017 NOSB Review:

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were reviewed in 2015 ahead of the 2017 sunset date. There was strong public support for relisting of copper materials. Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found coppers, fixed, compliant with OFPA criteria, and did not recommend removal from the National List. At the 2017 sunset review, the Board voted unanimously to not remove coppers from the National List.

#### 2022 NOSB Review:

Overview: Distinguishing between copper sulfate and fixed coppers seems redundant as they are used in a similar manner and are reviewed in the same TRs. In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more "free" copper ions vs. "fixed" and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

Main Considerations in 2022 Review

• Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.

- Copper compounds bind to soil and tend to accumulate significantly in clay soils and with increasing soil pH. Soils with pH over 6.5 are particularly susceptible to metal toxicity from repeated application.
- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
- Widespread use of copper compounds has led to the evolution of copper-resistant disease varietals.
- There is a well-studied link between dysfunctional copper metabolism and Alzheimer's disease. Recent research finds a link between the epidemic of Alzheimer's disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers.

In December 2021, the Crops Subcommittee discussed the need for an updated technical report. Not only has ten years passed since the previous report was written, but there are new concerns regarding human and environmental health.

The Crops Subcommittee requested a new technical report during its December 7 call. The Subcommittee requested that the new technical report highlight five areas that should be expanded and updated with the latest research: human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also ask that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

#### **Questions to our Stakeholders**

- 1. Are there organic alternatives to copper products that are more suitable for use in disease control?
- 2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in soil and water?

#### References

- 1. Ariyakanon N, Winaipanich B (2006) Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
- 2. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
- 3. Mackie KA, Müller T, Kandeler E (2012) Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.
- 4. Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

# Copper sulfate (i)(3)

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

(3) Copper sulfate - Substance must be used in a manner that minimizes accumulation of copper in the soil.

Technical Report: <u>1995 TAP</u>; <u>2011 TR</u>. Petition: N/A Past NOSB Actions: <u>10/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>4/2011 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>. Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>) Sunset date: 10/30/2024

#### Subcommittee Review

#### Use

Copper sulfate was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Fixed coppers is also undergoing sunset review, and the Crops Subcommittee has submitted a separate review.

#### Manufacture

Copper sulfate is manufactured by treating copper ore with concentrated sulfuric acid. It is also known as copper vitriol. In order to enhance its fungicidal properties, it is mixed with calcium hydroxide to produce a "Bordeaux mixture" which is sprayed on crops for disease control.

#### International Acceptance

Canadian General Standards Board Permitted Substances List

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
   Visible residue of copper products on harvested crops is prohibited.

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

• The EEC states that, "it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates."

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u>  Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of —Guidelines for the production, processing, labeling and marketing of organically produced foods|| (CODEX-GL 32, 1999).

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

#### Japan Agricultural Standard (JAS) for Organic Production

Copper sulfate is only permitted in organic agriculture as a fungicidal spray.

#### **Environmental Issues**

Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice may be questioned.

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

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

#### Discussion

Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, its use period has been extended in all three jurisdictions, as there isn't yet a viable organic alternative for copper in certain applications, including in the lucrative organic wine industry. Banning the use of copper sulfate entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper sulfate for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus, *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.

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crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper sulfate intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

#### 2017 NOSB Review

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were reviewed in 2015 ahead of the 2017 sunset date. There was strong public support for relisting of copper materials. The NOSB made a motion to remove copper sulfate from the National List. The motion to remove failed after receiving 2 "Yes" and 12 "No" votes. - Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found copper sulfate compliant with OFPA criteria, and did not recommend removal from the National List.

#### 2022 NOSB Review

Overview: Distinguishing between copper sulfate and fixed coppers seems redundant as they are used in a similar manner and are reviewed in the same TRs. In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more "free" copper ions vs. "fixed" and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

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- Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.
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- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
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- There is a well-studied link between dysfunctional copper metabolism and Alzheimer's disease. Recent research finds a link between the epidemic of Alzheimer's disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers.

In December 2021, the Crops Subcommittee discussed the need for an updated technical report. Not only has ten years passed since the previous report was written, but there are also new concerns regarding human and environmental health.

The Crops Subcommittee requested a new technical report during its December 7 call. The Subcommittee requested that the new technical report highlight five areas that should be expanded and updated with the latest research; human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also ask that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

#### **Questions to our Stakeholders**

- 1. Are there organic alternatives to copper sulfate that are more suitable for use as a fungicide?
- 2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in soil and water?

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- 1. Ariyakanon N, Winaipanich B (2006) Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
- 2. Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.
- 3. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
- 4. Mackie KA, Müller T, Kandeler E (2012) Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.
- 5. Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

#### Polyoxin D zinc salt

Reference: §205.601(i) As plant disease control. (11) Polyoxin D zinc salt.
Technical Report: 2012 TR; 2017 Limited Scope TR.
Petition: 2016 (Addendum #1, #2, #3).
Past NOSB Actions: 04/2018 recommendation.
Recent Regulatory Background: Added to National List on 11/22/2019 (84 FR 56673).
Sunset Date: 11/22/2024

#### Subcommittee Review

#### Use

Polyoxin D zinc salt is used as an agricultural fungicide. It has a locally systemic function, meaning that it is absorbed into surface plant tissues. It currently appears on the National List as plant disease control at 7 CFR 205.601(i). Few fungicides used in organic production are systemic, and polyoxin D zinc salt products may have greater efficacy against some plant disease organisms.

#### Manufacture

Polyoxin D is produced by controlled fermentation of the naturally occurring (non-GMO) soil microorganism *Streptomyces cacaoi* var. asoensis. While polyoxin D might be considered a nonsynthetic product, its chemical conversion to a zinc salt makes it synthetic. The zinc salt makes this product more useful by lessening its high water-solubility, thereby preventing the product from washing off the application area too quickly.

#### International Acceptance

Polyoxin D zinc salt does not appear on any of the following lists.

Canadian General Standards Board Permitted Substances List

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

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

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

#### Japan Agricultural Standard (JAS) for Organic Production

#### **Environmental Issues**

The 2017 Technical Review (TR) states that polyoxin D zinc salt rapidly degrades on plant surfaces, in approximately 2-3 days, and has a half-life of 16 days in soil. The 2018 NOSB review concluded there was low environmental risk, and further that there is no concern during the manufacture, use, or disposal of polyoxin D zinc salt other than that this product should not be used nearby to, or in, water since it is moderately toxic to aquatic invertebrates and fish. The 2021 TR concurs and states "Based on the results [of numerous studies cited], polyoxin D zinc salt is presumed to carry very low environmental risk and because polyoxin D zinc salt is formed through fermentation, it is considered to be less toxic to the environment than a fungicide that was chemically manufactured such as copper, sulfur or petroleum distillates."

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19). As described in the 2012 petition (page 18): "The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals."

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees, or ladybird beetles, the petitioner commissioned their own studies and found no negative effects of polyoxin D zinc salt on any of these organisms. If directly mixed with products used by organic producers containing living beneficial fungi, the fungi could be rendered ineffective.

#### **Human Health Issues**

The 2017 TR of polyoxin D zinc salt states there is very low acute toxicity to humans by oral, dermal, or inhalation routes, and it did not demonstrate mutagenic potential. There are warnings on the label about possible skin and eye irritation effects. Polyoxin D Zinc Salt is poorly absorbed with the vast majority of the product (>90%) being excreted unchanged, directly in the feces. Polyoxin D zinc salt has been in use as an antifungal agent for over 40 years in Japan on rice, without any notable, consistent, adverse human reactions being recorded. It has been approved in the USA and Mexico on food crops for over 5 and 3 years, respectively and for non-food crops in the USA for over 16 years. The direct risk to humans is considered to be extremely low.

A separate issue relates to how its agricultural use could affect anti-fungal medicines in human health. Considerable research has focused on polyoxins as less-toxic alternatives to currently available therapeutic antifungal medications in humans. These studies have led to mostly unsuccessful results, and polyoxins are not used clinically at the present time. - Polyoxin D has thus far been ineffective in therapeutic exploratory studies for potential human use against fungi, except at very high concentrations. It has shown some efficacy against yeasts, but is considered unlikely to be used as a human medicine. Thus, human pathogen resistance to polyoxin D would have little or no medical impact.

It is possible that from polyoxin D use in agriculture, cross-resistance could develop to related antibiotics such as Nikkomycin Z, currently being tested as a human anti-fungal medicine. In order for such resistance to develop, polyoxin D would need to be used widely. A human fungal pathogen would need to acquire the resistance to polyoxin D, either from direct exposure or via transfer from other resistant organisms. Finally, the pathogen's resistance to polyoxin D would need to confer resistance to the to-be-developed new medicine. This seems to be a highly unlikely chain of events.

#### Discussion

Based on its efficacy, low environmental impact, and low risk to human health, the Crops Subcommittee recommends renewing polyoxin D zinc salt at §205.601(i) As plant disease control.

#### **Questions to our Stakeholders**

- 1. Is there a concern that cross-resistance to polyoxin D could negatively affect human health?
- 2. Is Polyoxin D zinc salt an effective fungicide?

#### Humic acids

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

3) Humic acids-naturally occurring deposits, water and alkali extracts only.
Technical Report: <u>1996 TAP</u>; <u>2006 TR</u>; <u>2012 TR (oxidized lignite/humic acid derivatives)</u>.
Petition: N/A
Past NOSB Actions: <u>09/1996 minutes and vote</u>; <u>4/2006 sunset recommendation</u>; <u>10/2010 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation</u>.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>)
Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

Humic acids can be soil-applied or foliar applied depending on the specific product. Humic acid affects soil fertility by making micronutrients more readily available to plants rather than contributing additional nutrients to the soil. According to the 2006 TR, humic substances can chelate (bind) soil nutrients, improve nutrient uptake, reduce the need for nitrogen fertilizer, remove toxins from soils, stimulate soil biological activity, solubilize minerals, improve soil structure, and improve water holding capacity.

#### Manufacture

According to the 2006 TR, humic substances (which include humic acids) naturally constitute a significant fraction of the organic matter in the soil and are formed through the process known as "humification." Humification is the natural conversion of organic matter into humic substances by microorganisms in the soil (Mayhew, 2004).

Commercially available humic acids are derived from leonardite, lignite, or coal. Extracts from non-synthetic humates by hydrolysis using synthetic or non-synthetic alkaline materials are permitted, including the use of sodium, potassium, or ammonium hydroxide. The TR states the process begins with separating organic matter from the inorganic matrix of sand, silt, and clay. Next, a sodium hydroxide solution creates a liquid solution (Weber, undated). The extracted liquid solution is incompatible with acids because it is very alkaline, in the range of 8 to 12 pH (Mayhew, 2004). Alkali extraction can also be conducted using potassium hydroxide, a typical alkali used by manufacturers to extract humic acid from leonardite.

#### International Acceptance

#### Canadian General Standards Board Permitted Substances List

The Canadian standards state: permitted if mined; produced through microbial activity; extracted by physical processes; or with: a) Table 4.2 Extractants; or b) potassium hydroxide—potassium hydroxide levels used in the extraction process shall not exceed the amount required for extraction. Levels (mg/kg) of arsenic, cadmium, chromium, lead and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilizing Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil.

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

Humic acid derivatives and oxidized lignite do not appear on Annex I, Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2) (EC, 2008). The EU requires all substances used as a fertilizer, soil conditioner or nutrient in organic production in the EU appear on that Annex (EC, 2007). However, humic acids do appear on Annex VII, Products for Cleaning and Disinfection (EC, 2008).

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

No information was identified at the listed site.

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

Humic acid derivatives do not appear on Appendix 2: Fertilizers and Soil Conditioners. However, the use of humic acids are covered under a derogation found in §4.4.6, which reads: "Mineral fertilizers shall be applied in the form in which they are naturally composed and extracted and shall not be rendered more soluble by chemical treatment, other than addition of water and mixing with other naturally occurring, permitted inputs.

#### Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for Organic Production does not include humic acid derivatives or oxidized lignite on Table 1, Fertilizers and Soil Improvement Substances (JMAFF, 2012).

#### **Environmental Issues**

Humic acids themselves are not known to cause environmental issues. The TR states that there is no information available from EPA to suggest that environmental contamination results from their manufacture, use, misuse, or disposal. Improper disposal of acids or bases used in the extraction process could be a source of environmental contamination. The mining of lignite/leonardite or other source materials has environmental impacts.

#### **Questions to our Stakeholders**

None

#### Micronutrients: soluble boron products

**Reference:** §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(i) Soluble boron products.
 Technical Report: <u>2010 TR (Micronutrients)</u>.
 Petition: N/A
 Past NOSB Actions: <u>04/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset</u>

# recommendation; <u>10/2015</u> sunset recommendation; <u>10/2015</u> micronutrient annotation change; <u>11/2017</u> sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 1/28/2019 (<u>83 FR 66559</u>) Sunset Date: 01/28/2024

#### **Subcommittee Review**

#### Use

Soluble boron is a crop micronutrient that can be soil-applied or applied foliarly. According to the technical review (TR), when compared to the other recognized plant micronutrients, boron deficiency is the most common. Every year, boron deficiency is responsible for significant crop losses, whether in volume or quality.

Soluble boron products have appeared on the National List for use as micronutrients since it was first published in 2000.

#### Manufacture

The TR states that all soluble boron products are derived from mined borate mineral deposits. Borate minerals can be extracted by surface mining or solution mining (Garrett, 1998).

#### Borax/borate salts

Refined sodium borate salts are typically produced by crushing solid borate ores and dissolving in the water alongside trona (a double salt of sodium carbonate and sodium bicarbonate), or supersaturating brine with carbon dioxide in the case of solution mining (Office of Energy Efficiency and Renewable Energy, 2002; Smith, 2000). Insoluble waste materials are filtered out of the liquor, and disodium tetraborate pentahydrate and decahydrate are selectively crystallized by temperature control and vacuum crystallization, followed by centrifugation and drying (Smith, 2000). To prevent crystallization water loss and caking, disodium tetraborate decahydrate crystals are sometimes washed with a boric acid solution that coats the crystals with a thin layer of the pentahydrate variety (Smith, 2000).

High purity borax can also be produced in a reaction between boric acid and hot sodium hydroxide (Smith, 2000). Various dehydration and rehydration methods can be utilized to selectively produce the different hydration states of disodium tetraborate (Smith, 2000). Boric acid reactions with sodium hydroxide can also be used to produce disodium octaborate tetrahydrate (Kutcel, 2001).

#### Boric acid

In the United States, boric acid is typically prepared by reacting naturally occurring solid sodium borate minerals with strong mineral acids like sulfuric acid (Smith, 2000). This results in a concentrated solution of boric acid and sodium sulfates, after which the boric acid is crystallized by evaporation.

#### **International Acceptance**

#### Canadian General Standards Board Permitted Substances List

The Canadian Organic Standards permit soluble boron products at CAN/CGSB 32.311-2020 Table 4.2, column 1, entry for Boron. Borate (boric acid), sodium tetraborate (borax and anhydrous), and sodium octaborate are permitted only when one of the following has been established:

- soil and plant deficiencies are documented by visual symptoms
- testing of soil or plant tissue demonstrates the need
- the need for a preventative application can be documented (CGSB, 2020)

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

Several boron substances are allowed for soil management and fertilization by the European Union organic regulations. EC Regulation No. 889/2008 Article 3 permits the use of substances appearing in Annex I when the nutritional needs of plants cannot be met by certain preventative measures (European Parliament, Council of the European Union, 2008). Annex I permits the use of boric acid, sodium borate, calcium borate, and boron ethanolamine (European Parliament, Council of the European Union, 2008).

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

The Codex guidelines include "Trace elements (e.g., boron, copper, iron, manganese, molybdenum, zinc)" in Table 1, substances for use in soil fertilizing and conditioning (FAO 2007).

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

Boric acid, sodium borate, calcium borate, and "borethanolamin" (presumably referring to boron ethanolamine) of mineral origin are permitted as fertilizers and soil conditioners in the IFOAM NORMS, where soil or plant nutrient deficiency can be documented by soil or tissue testing or diagnosed by an independent expert. Chloride and nitrate forms are prohibited, as are micronutrients used as defoliants, herbicides, or desiccants (IFOAM Organics International, 2019).

#### Japan Agricultural Standard (JAS) for Organic Production

Trace elements (manganese, boron, iron, copper, zinc, molybdenum, and chlorine) are permitted by the Japanese Agricultural Standard for Organic Plants as fertilizers and soil improvement substances if a crop cannot grow normally because of a micronutrient shortage (MAFF, 2017).

#### **Environmental Issues**

Mining the original base material could cause an environmental impact. In addition, the TR states that sulfuric acid is used as a reactant to make boric acid from colemanite, and calcium sulfate is sometimes produced as a by-product. This results in a significant waste stream and can have environmental consequences related to the build-up of industrial waste. Wastewater discharge is also a source of boron pollution since boron appears in some soaps and washing chemicals

#### Discussion

The Crops Subcommittee reviewed soluble boron products and the role they can play in crop development. Also reviewed were the ways that organic producers demonstrate deficiency.

#### **Questions to our Stakeholders**

None

# Micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt

**Reference:** §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

Technical Report: 2010 TR (Micronutrients).

Petition: N/A

Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset

# recommendation; 10/2015 annotation change recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 1/28/2019 (<u>83 FR 66559</u>) Sunset Date: 01/28/2024

#### Subcommittee Review

#### Use

Micronutrients are essential for plant growth and are used across all types of crop production, but are typically required in very small quantities. Although some forms of micronutrients are found naturally in the soil, many producers find deficiencies of some or all of the micronutrients on the National List. These deficiencies can be a limiting factor in water and macro-nutrient uptake, and can result in limited growth and vitality of crops.

#### Manufacture

Plant micronutrients at this listing are made up of both compounds and natural minerals. After physical processing such as breaking and grinding, these natural minerals might be used as micronutrients in agriculture. Many commercial micronutrients are manufactured as by-products or intermediate products of metal mining and processing industries.

#### **International Acceptance**

Canadian General Standards Board Permitted Substances List

The Canadian Organic Production Systems Permitted Substances List permits micronutrients with a similar annotation to the USDA.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 European organic regulations do not reference micronutrients.

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u> CODEX does not reference micronutrients.

#### International Federation of Organic Agriculture Movements (IFOAM) Norms

Micronutrient use is restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert. Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant.

# Japan Agricultural Standard (JAS) for Organic Production

JAS does not reference micronutrients.

#### **Environmental Issues**

Simple inorganic compounds such as Co, Cu, Fe, Mn, Mo, Se, and Zn, are found naturally in soil. Applied micronutrients are not expected to be significantly different from naturally occurring compounds in terms of concentration and physiological activity, when the applied under set limits. Micronutrients are "heavy metals", but the annotation prevents contamination by restricting its use to correct a deficiency.

#### Discussion

The Crops Subcommittee supports renewing micronutrients.

#### **Questions to our Stakeholders:**

None

## Vitamins C, E

**Reference:** §205.601(j) As plant or soil amendments. (9) Vitamins C, and E.

Technical Report: 1995 TAP; 2015 TR.

Petition: N/A

Past NOSB Actions: <u>10/1995 minutes and vote</u>; <u>11/2005 sunset recommendation</u>; <u>10/2010 sunset</u> recommendation; <u>10/2015 sunset recommendation</u>; <u>11/2017 sunset recommendation (relist C and E, remove</u> <u>B1</u>).

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>) Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

Vitamins, including synthetically derived C (ascorbic acid) and E (tocopherols), are generally considered nontoxic essential nutrients for terrestrial and aquatic organisms. Vitamins C and E are used to promote both growth and yields and to protect plants from oxidative stress due to salinity. During the previous sunset review (11/2017), vitamin B1 (thiamine) – which had been previously paired with the other two vitamins on the National List – was recommended for removal from the list on the basis that foliar and soil applications of the material did not stimulate root growth in transplanted crops. Rulemaking to remove B1 is in progress.

A TR was completed on these materials in 2015. It did, however, lack practical information regarding the use of Vitamins C and E, and thus relied on peer-reviewed scientific literature.

#### Manufacture

Although Vitamins C and E are naturally occurring in commonly consumed foods, they are typically derived for commercial use from laboratory processes.

#### International Acceptance

<u>Canadian General Standards Board Permitted Substances List</u> Vitamin C is listed for crop production; Vitamin E is not.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 Neither substance is listed.

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u> Neither substance is listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms Neither substance is listed.

#### Japan Agricultural Standard (JAS) for Organic Production

Neither substance is listed.

#### **Environmental Issues**

It is unclear whether there are particular environmental concerns regarding the manufacture and use of Vitamins C and E for these purposes.

#### Discussion

The subcommittee had a general discussion of the historical review of these substances, including the recommendation to remove vitamin B1 from this listing. Notably, the vitamin B1 removal is in rulemaking and slated for near-term completion.

#### **Questions to our Stakeholders**

1. Do vitamins C and E provide essential functions in organic crop production?

## Squid byproducts

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

(10) Squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

Technical Report: <u>2016 TR</u>.

Petition: 2015 (Amendment #1).

Past NOSB Actions: 04/2016 recommendation.

Recent Regulatory Background: Added to National List on 01/28/2019 (<u>83 FR 66559</u>). Sunset Date: 01/28/2024

#### Subcommittee Review

#### Background

Squid are invertebrates classified into the phylum Mollusca, class Cephalopoda and order Loligo (later renamed Doryteuthis). There are an estimated 300 squid species known throughout the world. Common to the northeastern Atlantic coast is the longfin squid, species *Doryteuthis (Loligo) pealli*. Common to the US west coast is the market squid, species *Doryteuthis (Loligo) opalescens*. The use of squid and squid byproducts in agriculture dates back to the 1800's when much of the product was shipped from California market squid fisheries to Asian countries for consumption and fertilizer applications.

#### Use

Squid and squid byproducts are the starting ingredients in the production of enzymatically produced hydrolysates with N-P-K values ranging from 2-2-2 to 3.3-7.3-2 or more. Seafood derived hydrolysates, including squid and squid byproducts, have been used both as foliar sprays and soil amendments for propagating cranberries, cherries, and apples.

#### Manufacture

Squid byproducts make up 52% of the total body weight and include the squid ink, pen, skin, milt, liver, and viscera, which are typically discarded as waste. In general, squid byproducts are chopped, heated, digested with natural enzymes, and stabilized with an acid such as phosphoric, sulfuric, or citric acid to prevent

microbial growth.

#### **International Acceptance**

Canadian General Standards Board Permitted Substances List

The Canadian Organic Standard allows for the use of fish products; in Canadian fisheries, the definition of fish includes marine invertebrates such as squid.

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

The EU Organic Standard allows the use of molluscan (squid) products from sustainable fisheries and may be used in organic production of feeds for non- herbivores; squid products are not explicitly authorized for use in organic production.

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

CODEX does not reference squid byproducts.

International Federation of Organic Agriculture Movements (IFOAM) Norms IFOAM permits the use of fish and shell products and food processing of animal origin.

# Japan Agricultural Standard (JAS) for Organic Production

The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources; mollusks (squid) are included in Japanese fisheries.

#### **Environmental Issues**

Squid are commercially harvested using nets directly above spawning grounds during mating season primarily for calamari. Fisherman target spawning squid because they die shortly after reproduction. There are two main squid fisheries in the US including along the Atlantic coast for long-finned squid and along the Pacific coast for market squid. The US Pacific squid fishery is managed by the California Department of Fish and Game, the National Oceanographic and Atmospheric Administration (NOAA) Fisheries, and the Pacific Fishery Management Council. Atlantic squid are managed in federal waters by NOAA Fisheries in conjunction with the Mid-Atlantic Fishery Management Council. Management includes seasonal catch limits, timed fishery closures, administration of permit issuance, and limitations on using lights to attract squid to ensure uninterrupted spawning.

#### Discussion

The manufacturing and use of squid byproducts has little to no environmental impact or human health concerns and provides organic growers with another nitrogen source.

#### **Questions to our Stakeholders**

None

#### Lead salts

Reference: §205.602(d) Lead salts. Technical Report: N/A Petition: N/A Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation. Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (<u>82 FR 14420</u>). Sunset renewal notice effective 10/30/2019 (<u>84 FR 53577</u>) Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

Lead salts are used as both pesticides and herbicides.

#### Manufacture

Lead salts are usually produced using the following reaction, which leads to formation of the desired product as a solid precipitate:

 $Pb(NO_3)_2 + H_3AsO_4 \rightarrow PbHAsO_4 + 2 HNO_3$ 

#### International Acceptance

None found

#### **Environmental Issues**

Lead poisoning can cause a number of adverse human health effects but is particularly detrimental to the neurological development of children. Lead accumulates in soils, so it is important to avoid soil applications of materials containing lead, whether the lead is in synthetic materials or naturally occurring (nonsynthetic) lead salts. Notably, the CDC has found that there is no safe level of lead exposure and in 2021 lowered the reference level from 5 ug/dl to 3.5 ug/dl.

#### Discussion

Public comments received in previous sunset reviews were and are in favor of keeping lead salts on the list of nonsynthetic substances prohibited for use in organic crop production.

The NOSB Crops Subcommittee also supports keeping lead salts in its prohibited status on the National List and will vote on the proposal at the Fall 2022 meeting.

#### **Questions to our Stakeholders**

None

### Tobacco dust (nicotine sulfate)

Reference: §205.602(j) Tobacco dust (nicotine sulfate). Technical Report: N/A Petition: N/A Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation. Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577) Sunset date: 10/30/2024

#### **Subcommittee Review**

#### Use

Nicotine is a natural insecticide produced as a secondary metabolite in tobacco. Tobacco dust can be used in agriculture for pest control.

#### Manufacture

Tobacco dust is a by-product of agro-industrial waste from the commercial processing of tobacco products. It was noted during a previous review that tobacco dust is no longer commercially available as a crop pest control product, however it could still be homemade by mixing tobacco with water.

#### **International Acceptance**

<u>Canadian General Standards Board Permitted Substances List</u> There is no reference to tobacco dust.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 There is no reference to tobacco dust.

<u>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of</u> <u>Organically Produced Foods (CXG 32-1999)</u> There is no reference to tobacco dust.

International Federation of Organic Agriculture Movements (IFOAM) Norms There is no reference to tobacco dust.

Japan Agricultural Standard (JAS) for Organic Production There is no reference to tobacco dust.

#### **Environmental Issues**

Present on the <u>Occupational Safety and Health Administration</u> Hazardous Substance list and regulated by the Environmental Protection Agency (EPA) as a pesticide.

#### Discussion

According to the previous NOSB Review: Tobacco dust (nicotine sulfate), has been present on the National List as a prohibited substance since the inception of the USDA organic regulations. Due to the negative human health effects caused by this material, it has been relisted as a prohibited nonsynthetic on the National List at every sunset with no objections from the public or from the NOSB. It is present on the Hazardous Substance list and regulated by OSHA and the EPA as well as other agencies.

Previous public comments indicated that certifiers, businesses, and public interest organizations agree that tobacco dust should remain listed as a prohibited nonsynthetic. The Crops Subcommittee supports keeping tobacco dust on the National List at §205.602.

#### **Questions to our Stakeholders**

None