



**National Organic Standards Board Meeting  
April 23 & 25 (Comment webinars), and April 29 - May 1, 2024 (NOSB meeting - Milwaukee, WI)**

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**PLEASE NOTE:**

Discussion documents, proposals, reports and/or other documents prepared by the National Organic Standards Board, including its subcommittees and task forces, represent the views of the National Organic Standards Board and do not necessarily represent the views and policies of the Department of Agriculture. Please see the [NOP website](#) for official NOP policy, regulations, guidance, and instructions.





## Sunset 2026

### Meeting 1 - Request for Public Comment Livestock Substances § 205.603 & § 205.604 April 2024

#### Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's [Petitioned Substances Index](#).

#### Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2024 public meeting. Written comments should be submitted via Regulations.gov at [www.regulations.gov](http://www.regulations.gov) 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 Support the Continued Use of Substances in Organic Production at § 205.603:**

If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

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

#### **For Comments that Do Not Support the Continued Use of Substances in Organic Production at § 205.603:**

If you provide comments that do not support a substance at § 205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

**For Comments that Support the Continued Prohibition of § 205.604 Substances in Organic Production:**

If you provide comments supporting the prohibition of a substance at § 205.604, you should provide information demonstrating that the substance is:

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

**For Comments that Do Not Support the Continued Prohibition of Substances in Organic Production at § 205.604:**

If you provide comments that do not support the prohibition of a substance at § 205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance at § 205.604 should provide new information since its last NOSB review to demonstrate that the substance is:

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

**For Comments Addressing the Availability of Alternatives:**

Comments may include information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

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

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

Written public comments will be accepted through April 3, 2024 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

**§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:**

[Atropine](#)

[Hydrogen peroxide](#)

[Iodine \(a\)\(16\)](#)

[Iodine \(b\)\(4\)](#)

[Magnesium sulfate](#)

[Fenbendazole](#)

[Moxidectin](#)  
[Peroxyacetic/peracetic acid](#)  
[Tolazoline](#)  
[Xylazine](#)  
[Oxalic acid dihydrate](#)  
[DL-methionine](#)  
[Trace minerals](#)  
[Vitamins](#)

**§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:**

None

## Atropine

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian; and
- (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

**Technical Report:** [2002 TAP](#); [2019 TR](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [05/2003 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

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by the plants in the nightshade family (EFSA 2008, Timberlake 2015). Atropine is primarily isolated from *Atropa belladonna* (also known as deadly nightshade) and is a component in both human and veterinary medicines for a range of treatments. Although, it is most widely used in both human and veterinary practices as a treatment for organophosphate poisoning. [2019 TR 35-39]

Atropine is currently allowed by the United States Department of Agriculture (USDA) organic regulations as a medical treatment for organic livestock production (7 CFR 205.603(a)). USDA organic regulations restrict atropine to “use by or on the lawful written or oral order of a licensed veterinarian,” and it must be followed by “a meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals. [2019 TR 24-28]

#### Manufacture

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by plants in the nightshade family (EFSA 2008, Timberlake 2015). The primary source of atropine is accessed by extraction from *Atropa belladonna*, which yields the racemic mixture of (+)-hyoscyamine and (-)-hyoscyamine (atropine) (Figure 1). Atropine may also be synthesized in an acid-catalyzed esterification reaction in between tropine and tropic acid, although the primary source of atropine is from plant extracts (PubChem 174174, Karkee 1980, Merck 2001, USDA 2002, EFSA 2008). [2019 TR 51-56]

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as a health care product and production aid. Botanical preparations (such as atropine, butorphanol, and other medicines from herbaceous plants) shall be used according to label specifications. Substances containing petroleum-derived formulants (such as propylene glycol) shall not be fed to livestock. (Table 5.3, Botanical compounds listing, CAN/CGSB-32.311-2020, page 26)

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

Not explicitly mentioned.

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

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

### **Human Health and Environmental Issues**

Atropine alkaloids are naturally produced by plants in the nightshade family, which exists exclusively (pre-extraction) as L-hyoscyamine (PubChem 174174, Bunke et al. 1996, Reist et al. 1997, EFSA 2008). Because L-hyoscyamine is the lone enantiomer that is biologically produced, atropine does not exist naturally, but rather is formed during the racemization. [2019 TR 343-347]

There are no reported studies on the persistence or concentration of atropine (neither D-hyoscyamine nor L-hyoscyamine) or the metabolized products tropine and tropic acid, although tropine has been identified as “readily biodegradable” (Sigma-Aldrich 2018b). [2019 TR 371-373]

Due to the limited application of atropine (for veterinary medicine, approved for use only when used or ordered by a veterinarian), and the small quantities administered (milligrams), atropine is unlikely to be a source of environmental contamination (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). Moreover, the L-hyoscyamine enantiomer is largely degraded to tropine and tropic acid prior to excretion, further reducing the likelihood of environmental persistence and concentration build-up (Sigma-Aldrich 2018b). [2019 TR 375-380]

The metabolism of atropine in humans is like that of most animal species. Atropine is both readily absorbed and distributed within the human body and readily excreted in urine (EMEA 1998, Williams et al. 2000, Aardema et al. 2008, EFSA 2008). Similar to the metabolic pathways in veterinary applications, humans also metabolize L-hyoscyamine (one enantiomer of the racemic atropine mixture) to tropine and tropic acid (Equation 2), which are excreted in urine along with the non-metabolized D-hyoscyamine enantiomer present in atropine (EMEA 1998, EFSA 2008). The short biological half-life of atropine (2-5 hours), and incorporation of the substance in human medical applications makes negative health effects from the approved usage of atropine unlikely (Williams et al. 2000, Aardema et al. 2008, Mayo Clinic 2017, MedlinePlus 2017). Moreover, atropine is approved for use only when used or ordered by a veterinarian coupled with the withdrawal restrictions placed on animals receiving atropine treatments, makes human health effects unlikely (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). [2019 TR 544-555]

## Discussion

In written comments submitted for the spring and fall 2019 NOSB meetings, all commenters supported relisting atropine as essential for use in organic animal production, and several commenters stated that atropine was included in the organic system plan of operations they certified. No commenters expressed opposition to relisting. This material satisfies the OFPA Evaluation criteria and the NOSB supports the relisting of Atropine.

## Questions to our Stakeholders

None

## Hydrogen peroxide

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.  
(15) Hydrogen peroxide.

**Technical Report:** [1995 TAP \(Crops\)](#); [2015 TR \(Crops\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [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

Historically, agricultural disinfectants containing hydrogen peroxide have been used for the disinfection of livestock housing surfaces and production equipment. Synthetic hydrogen peroxide is permitted for use in organic livestock production as a disinfectant, sanitizer, and medical treatment [7 CFR 205.603(a)]. It is also permitted for use in or on processed products labeled as “organic” or made with organic (specific ingredient or food group(s)) per 7 CFR 205.605(b), and for various uses in organic crop production per 7 CFR 205.601.

### Manufacture

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. This is followed by the autoxidation of the hydroquinone in air to regenerate the anthraquinone and release hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H<sub>2</sub>) and oxygen (O<sub>2</sub>). Almost all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. [2015 TR 34-39]

### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as a health care product and production aid. Pharmaceutical grade hydrogen peroxide is allowed for external use as a disinfectant. Food-grade hydrogen peroxide is allowed for internal use (for example, added to livestock drinking water). (Table 5.3, CAN/CGSB-32.311-2020, page 27)



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

Not explicitly mentioned

[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](#)

Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house)

### **Ancillary Substances**

Water is the primary inert ingredient in hydrogen peroxide formulations. Some product labels list salicylic, phosphoric acid, benzyl alcohol, acetic acid, citric acid, butoxy-propan-2-xyloxy- propan-2-ol [2015 TR 170-173]

### **Human Health and Environmental Issues**

Hydrogen peroxide is inherently unstable due to the weak peroxide (O–O) bond. At typical pesticide concentrations, hydrogen peroxide is expected to degrade rapidly to water and oxygen (US EPA, 2007). [2015 TR 316-317]

When used as a fungicide, hydrogen peroxide is likely to contact soils under a variety of environmental conditions. Hydrogen peroxide degrades with an anaerobic (without oxygen) soil half-life of four hours in soils containing petroleum (US EPA, 2007). [2015 TR 320-322]

Since the substance has physical properties very similar to those of water, hydrogen peroxide is unlikely to preferentially bind to soils when used in agricultural production (US EPA, 2007). [2015 TR 325-327]

Research data indicates that volatilization of the substance from moist soils and surface water is expected to be low (EC, 2003).

When released to water, hydrogen peroxide should be rapidly consumed through biodegradation and photolysis.

The half-life of hydrogen peroxide metabolism in water generally decreases with increasing size of the microbial populations in the receiving water. Consequently, hydrogen peroxide degradation half- lives in natural waters range from a few hours to several days. [2015 TR 331 -334]

Hydrogen peroxide is not expected to bioaccumulate in aquatic organisms due to its low octanol-water partition coefficient ( $K_{ow}$ ) of 0.032 (US EPA, 2007).

Degradation of hydrogen peroxide released to the atmosphere is primarily a result of indirect photolysis reactions with smaller contributions from direct photolysis and chemical reaction with organic substances. Light, oxygen, ozone, hydrocarbons and free radicals in the atmosphere mediate hydrogen peroxide formation and release to the

atmosphere, likely at a significantly greater rate than the agricultural uses of the substance (Goor, 2007; Eul, 2001). Considering the various atmospheric degradation pathways, the overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (Goor, 2007; EC, 2003). [2015 TR 342-351]

Multiple EPA terrestrial effects characterizations have evaluated the toxicity of hydrogen peroxide and other “peroxy compounds” to mammals and birds. Studies submitted by the registrants indicate that hydrogen peroxide solutions used in pesticide products are corrosive to washed and unwashed eyes, as well as exposed skin (i.e., Toxicity Category I for eye and skin irritation). [2015 TR 355-358 The environmental protection agency reported in 2009 the results of a skin sensitization study which suggests that Hydrogen peroxide is not likely to be a sensitizer to mammals. The compound is considered slightly toxic to practically non-toxic to birds on an acute oral basis.

Hydrogen peroxide is an unstable inorganic compound and is expected to degrade rapidly to water and oxygen in the environment. The half-lives for aerobic and anaerobic degradation of hydrogen peroxide in various soils are between one and seven hours. Hydrogen peroxide is mobile in soils, but does not readily volatilize from moist soils and surface waters (EC, 2003; US EPA, 2007). When released to water, hydrogen peroxide is rapidly consumed through biodegradation and photolysis. The half-life for biodegradation of hydrogen peroxide in water generally ranges from minutes to several hours (Goor, 2007; US EPA, 2007). Light, oxygen, ozone, hydrocarbons and free radicals contribute to hydrogen peroxide formation in the atmosphere, likely at significantly greater rates than the agricultural uses of the substance. The overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (EC, 2003; Eul, 2001; Goor, 2007). Under typical use conditions, diluted and pure forms of hydrogen peroxide are reactive with transition metals (e.g., iron, copper, chromium) and organic materials (US EPA, 2007; ATSDR, 2014). [2015 TR 480-490]

Ecological receptors are insensitive to moderately sensitive to hydrogen peroxide solutions. Hydrogen peroxide is considered slightly toxic to practically non-toxic to birds on an acute oral basis. Likewise, aquatic toxicity studies indicate that hydrogen peroxide is slightly toxic to aquatic invertebrates and practically non-toxic to fish on an acute exposure basis. In contrast to birds and aquatic animals, microorganisms are particularly sensitive to various concentrations of hydrogen peroxide. The scientific literature and agricultural experience have demonstrated that hydrogen peroxide is toxic to pathogen soil organisms, such as the downy mildew fungus *Pseudoperonospora cubensis* and pink rot of potato fungus *Phytophthora erythroseptica* (Kuepper, 2003; Al-Mughrabi, 2006). Considering the oxidizing mode of action for hydrogen peroxide, it is likely that the substance is also toxic to beneficial soil organisms, including *Mycorrhizal* fungi and nitrogen-fixing bacteria. This non-target effect is most relevant for spray drift and soil drench scenarios, and should not present a population-level concern for controlled hydrogen peroxide applications.

Environmental contamination is not expected when purified forms of hydrogen peroxide are released to the environment. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007).

The toxic solvents and reagents used in the manufacture of hydrogen peroxide are removed prior to product formulation and, in many cases, are reused in subsequent synthetic reactions (Eul, 2001; Goor, 2007). As such, it is unlikely that these chemicals are readily introduced into the environment as a result of hydrogen peroxide production.

Hydrogen peroxide is generally considered safe for human exposure at low doses. Indeed, the US Food and Drug Administration (FDA) affirmed hydrogen peroxide as Generally Recognized as Safe (GRAS) when used as a direct food additive with certain limitations (see “Approved Legal Uses of the Substance” for details). Acute irritation and systemic toxicity is possible in humans exposed to moderate to high doses of hydrogen peroxide. Systemic effects of the substance generally result from the release of oxygen gas and water as the enzyme catalase decomposes available hydrogen peroxide. Specifically, venous embolism (gas bubble in bloodstream) may occur when the amount of oxygen gas produced exceeds its blood solubility (ATSDR, 2014).

Hydrogen peroxide is unlikely to cause chronic toxicity in humans because it is rapidly decomposed in the body. The available toxicity and epidemiology studies provide no evidence of reproductive or developmental toxicity in experimental animals and humans (ATSDR, 2014). On the other hand, hydrogen peroxide is a known mutagen and is associated with genotoxicity in mammalian and human cell lines (IARC, 1999; Driessens, 2009). IARC determined that there is *inadequate evidence* in humans and *limited evidence* in experimental animals for the carcinogenicity of hydrogen peroxide, classifying the substance as *Group 3 – Not classifiable as to its carcinogenicity to humans* (IARC, 2014).

Moderate spills of hydrogen peroxide to marine and estuarine environments are unlikely to adversely affect the receiving water bodies. On the contrary, a method describing the addition of hydrogen peroxide to natural waters as an oxidizing agent for oil spill remediation was published in patent literature (Hoag, 2014). Likewise, hydrogen peroxide has been used to treat wastewater, and aids in the removal of soil contaminants, including creosote, polycyclic aromatic hydrocarbons (PAHs), and other inorganic and organic substances (Atagana, 2003; Conte, 2001; US EPA, 2007).

Toxic substances used in the manufacture of hydrogen peroxide, including alkyl anthraquinones, aromatic solvents and transition metal catalysts (e.g., Raney nickel and palladium), are generally removed from hydrogen peroxide prior to formulation of commercial pesticide products. Further, certain fractions of these reagents, catalysts and solvents are often returned to the reactors for use in subsequent synthetic reactions (Goor, 2007; Eul, 2001). Therefore, the chemicals used in the production of hydrogen peroxide should not be released to the environment when manufacturers adhere to standard operating procedures for safe handling and disposal of toxic substances. Populations of beneficial soil fungi, such as *Mycorrhizal* fungi, and nitrogen-fixing bacteria may be negatively impacted by large-scale soil treatments of fungicides containing hydrogen peroxide.

Overall, the available information suggests that large volumes of concentrated hydrogen peroxide solutions will adversely affect the viability and reproduction of non-target microorganisms, including beneficial soil fungi and nematodes. Hydrogen peroxide is an unstable inorganic compound and is expected to degrade rapidly to water and oxygen in the environment. The half-lives for aerobic and anaerobic degradation of hydrogen peroxide in various soils are between one and seven hours. The half-life for biodegradation of hydrogen peroxide in water generally ranges from minutes to several hours (Goor, 2007; US EPA, 2007). In contrast to birds and aquatic animals, microorganisms are particularly sensitive to various concentrations of hydrogen peroxide.

Considering the oxidizing mode of action for hydrogen peroxide, it is likely that the substance is also toxic to beneficial soil organisms, including *Mycorrhizal* fungi and nitrogen-fixing bacteria. This non-target effect is most relevant for spray drift and soil drench scenarios, and should not present a population-level concern for controlled hydrogen peroxide applications. Environmental contamination is not expected when purified forms of hydrogen peroxide are released to the environment. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). The toxic solvents and reagents used in the manufacture of hydrogen peroxide are removed prior to product formulation and, in many cases, are reused in subsequent synthetic reactions (Eul, 2001; Goor, 2007). As such, it is unlikely that these chemicals are readily introduced into the environment because of hydrogen peroxide production.

Hydrogen peroxide is generally considered safe for human exposure at low doses. Indeed, the US Food and Drug Administration (FDA) affirmed hydrogen peroxide as Generally Recognized as Safe (GRAS) when used as a direct food additive with certain limitations (see “Approved Legal Uses of the Substance” for details). Acute irritation and systemic toxicity are possible in humans exposed to moderate to high doses of

hydrogen peroxide. Systemic effects of the substance generally result from the release of oxygen gas and water as the enzyme catalase decomposes available hydrogen peroxide. Specifically, venous embolism (gas bubble in bloodstream) may occur when the amount of oxygen gas produced exceeds its blood solubility (ATSDR, 2014). Inhalation or ingestion of hydrogen peroxide at high concentrations may lead to seizures, cerebral embolism or even tissue death (infarction).

The most common symptoms reported were acute symptoms based on acute corrosion and irritation effects. The symptoms include eye irritation, skin burns, esophageal burns, nausea, dizziness, rash, and headaches. Inhalation effects include chest congestion, respiratory irritation, coughing of blood, tightness of chest and shortness of breath. Dermal effects include edema, erythema, skin burns, blistering, and swelling. These cases led to hospitalization in some cases.

### Discussion

During the Spring and Fall 2019 NOSB meetings, the Livestock Subcommittee received comments in favor of relisting hydrogen peroxide and no comments against relisting. One commenter stated hydrogen peroxide is one of the most widely used hard surface sanitizers and is generally recognized as safe (GRAS) as an antimicrobial agent and for other purposes by the FDA. Unlike many alternatives available to organic producers, it is an excellent choice as it rapidly degrades to oxygen and water, leaving no residue. Hydrogen peroxide has been recommended for relisting by the NOSB At each of its previous sunset reviews.

### Questions to our Stakeholders

None

## Iodine §205.603(a)(16) and §205.603(b)(4)

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (16) Iodine.  
§ 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.  
(4) Iodine.

**Technical Report:** [1994 TAP](#); [2015 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 meeting 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

Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre-milking and post-milking. Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor, and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus antimicrobial teat dips used in pre- and post-milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine-based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

### **Manufacture**

Molecular iodine (I<sub>2</sub>) production processes generally utilize raw materials containing iodine, including 39 seaweeds, mineral deposits, and oil well or natural gas brines. Various chemical substances are added in the production of commercially available teat dip products. Many of the iodophors commonly used for disinfection in the dairy industry consist of iodine mixed with polymeric nonionic surfactants, such as the polyalkylene glycol and polyvinylpyrrolidone carriers. The nonylphenol ethoxylates (NPEs), polyoxyethylene nonylphenol (CAS# 9016-45-9) and ethoxylated nonylphenol (CAS# 26027-38-3), as well as polyvinylpyrrolidone (CAS# 9003-39-8) and other potential polymeric carriers are US EPA List 4 Inerts (US EPA, 2004a) when used in pesticides, including antimicrobial sanitizers. When used in animal drugs (e.g. teat dips), these substances are considered excipients, and are subject to restrictions at section 205.603(f). This rule states that a given excipient may be used in the manufacture of drugs used to treat organic livestock when the excipient is: (1) identified as GRAS by FDA, (2) approved by FDA as a food additive, (3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application, or (4) approved by APHIS for use in veterinary biologics.

Manufacturers commonly incorporate conditioners into iodine teat dip products to replace the protective oils that polymeric surfactants (i.e., detergents) used as complexing agents remove from animal skin during treatment. Moisturizers such as glycerin and propylene are normally added at concentrations ranging from two to ten percent of the product formulation (Universal, 2011; Nickerson, 2001). Further, glycerin produced through the hydrolysis of fats or oils is allowed as a livestock teat dip on the National List (7 CFR 205.603(a)(12)). Lanolin may also be added to iodophor teat dip products as an emollient to replace natural oils lost from the affected skin of dairy cows (Nickerson, 2011).

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as a topical disinfectant. Allowed iodine sources include potassium iodide and elemental iodine. If used as a cleaning agent, non-elemental iodine shall be used. Iodine shall not exceed 5% solution by volume (example: iodophors). Use shall be followed by a hot-water rinse. (Table 5.3, CAN/CGSB-32.311-2020, page 27)

Substances such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada’s Food and Drug Regulations. (Table 5.3, Teat dips and udder wash listing, CAN/CGSB-32.311-2020, page 29)

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

Not explicitly mentioned.

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

Not explicitly mentioned

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; iodine agent)

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house)

#### **Ancillary Substances**

Excipients are almost always used in iodine sanitizing products, and the review of these substances is outlined above in manufacturing. One class of excipients, NPEs, has been identified as hazardous to the environment and potentially no longer necessary in manufacturing.

#### **Human Health and Environmental Issues**

A limited scope TR for Iodine was requested for this sunset review of the substance. One of the questions explored by the TR was the impact that NPEs (an excipient used in combination with iodine) has on the environment and human health.

NPEs have long been known to be toxic to aquatic organisms, they bioaccumulate in plants, and they have been shown to exhibit estrogenic properties in human studies. Their use in cleaning and sanitizing products has slowly been phasing out. However, they remain in use in dairy iodine teat dips, and the residues of these substances can find their way into milk bulk tanks, equipment, and manure lagoons where they will likely be applied to the soil. The TR identifies iodine teat dips as the largest potential contributing source of NPEs on dairy operations.

#### **Discussion**

NOSB acknowledges that iodine sanitizers remain necessary to livestock operations as a sanitizer for medical procedures as well as for topical use, particularly as a teat dip for dairy animals. NOSB has also heard from numerous stakeholders that it is time to ensure that iodine products used on organic farms are free from NPEs. A limited scope TR was conducted to evaluate the availability of NPE-free iodine products and their suitability, the potential for NPEs contained in iodine products to contaminate organic products and the environment, and what detrimental effects may occur should NPEs enter the supply chain or be applied to soil.

The Livestock Subcommittee believes iodine continues to meet National List criteria and should not be removed. The LS would like to consider an annotation to prohibit NPEs in iodine products used on organic livestock operations, and may submit a proposal for the Fall 2024 meeting.

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

1. Based on the feedback received at previous reviews of iodine and the recently conducted limited scope TR of iodine, it appears that there is a significant supply of NPE-free iodine formulas for numerous types of iodine products, and a prohibition on NPE containing formulas would not have significant impact on the industry. Is this analysis correct? Are there specific types of iodine products where NPE-free formulas are not available?
2. For certifiers and MROs: Would an annotation restricting iodine formulas to those that are free of NPEs pose significant challenges to the review of iodine products in organic system plans?
3. What specific language should NOSB consider for a proposed annotation in order to fully restrict NPEs from iodine products used on organic livestock operations?

## Magnesium sulfate

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.  
(19) Magnesium sulfate.

**Technical Report:** [1995 TAP](#); [2011 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 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 number of veterinary uses. It acts as an anticonvulsant, laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically, in swine, magnesium sulfate is administered to treat malignant hypothermia.

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed.

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium. If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously.

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle's use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium.

Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation.

#### Manufacture

Magnesium sulfate can be obtained from naturally-occurring sources or manufactured by a chemical process.

Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite and epsomite, respectively (Kawamura and Rao, 2007).

The synthetic form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (containing  $MgCO_3$ ) or magnesium hydroxide ( $Mg[OH]_2$ ) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. To produce a high grade of purity, the magnesium sulfate is re-crystallized and separated from the parent solution (Kawamura and Rao, 2007).

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as an animal health care product and production aid; origin must be mined sources. Usage includes being a source of magnesium and sulphur. (Table 5.3, CAN/CGSB-32.311-2020, page 27)

Non-synthetic chelated or sulphated minerals are allowed for use as an animal health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

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

Allowed (Annex III, Part A(1), 2021/1165)

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

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**

Magnesium and sulfur are ubiquitous in the natural environment. According to the 2011 TR, if used in accordance with 7 CFR 205.603, it is unlikely that magnesium sulfate will cause harm to the environment.

Magnesium sulfate is considered by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) when used as a nutrient or dietary supplement (21 CFR 184.1443). The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population (FAQS, 2010).

Multiple products containing magnesium sulfate are approved by the FDA for medicinal use in humans. Magnesium sulfate can be administered via injection or can be orally ingested (U.S. FDA, 2010). In 2010, the FDA approved a product containing magnesium sulfate, which acts as a colon cleanser in preparation for a colonoscopy (Braintree Laboratories, 2010). If large quantities of magnesium sulfate are ingested by or injected into humans, blood electrolyte balance can be disturbed, resulting in circulatory collapse and death. However, this is far beyond the bounds of veterinary use.



## Discussion

During the previous NOSB review, the Livestock Subcommittee received several comments in favor of relisting magnesium sulfate and no comments against relisting. Some of the comments in favor of relisting included:

- Magnesium sulfate is essential for organic livestock production. It is used when grass tetany and organophosphate poisoning occur. Both are acute situations, and an effective immediate treatment is necessary.
- This product is administered by the intravenous or intramuscular routes as an electrolyte replenisher or anticonvulsant. Magnesium sulfate is used as a laxative and bronchodilator. This product is also added to feed to treat magnesium deficiency. Accordingly, this product is important to the humane treatment of organic animals.

## Subcommittee Discussion

Magnesium sulfate satisfies the OFPA evaluation criteria, and the Livestock Subcommittee supports relisting.

## Questions to our Stakeholders

Are there effective non-synthetic alternatives to magnesium sulfate for this purpose?

## Parasiticides, Fenbendazole

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

**Technical Report:** [1999 TAP](#) (Fenbendazole, Ivermectin); [2015 TR](#); [2020 TR](#) (Fenbendazole)

**Petition(s):** [03/2007 Fenbendazole](#); [07/2019 \(annotation request\)](#)

**Past NOSB Actions:** [05/2008 NOSB recommendation](#); [10/2015 sunset recommendation](#); [04/2016 recommendation – annotation change](#); [10/2019 sunset recommendation](#); [10/2020 NOSB recommendation to not amend listing](#)

**Recent Regulatory Background:** Added to National List , effective May 16, 2012 ([77 FR 28472](#)); Renewed 03/15/2017 ([82 FR 14420](#)); Proposed rule 01/17/2018 ([83 FR 2498](#)); Annotation change 12/27/2018 ([83 FR 66559](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

## Subcommittee Review

### Use

In veterinary medicine the term parasiticide refers to anthelmintic drugs (medicines used to destroy parasitic worms) [2015 TR 148]. Anthelmintics are medications capable of causing the evacuation of

parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]). The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state does not include the routine use of parasiticides. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed herds. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected and without treatment parasite infestation can lead to disease and potentially death (Stockdale, 2008) [2015 TR 394-398].

The 2020 Technical Report discussed the use of fenbendazole in chickens, which was the subject of a 2019 petition to change the allowance on the National List. The 2020 TR summarized fenbendazole as follows:

The target organisms of the parasiticide fenbendazole are the roundworms *Ascaridia galli* and *Heterakis gallinarum*. These nematodes, along with *Capillaria spp.*, are recognized as the principal helminthic parasites of chickens, with *A. galli* by far the most common. The life cycles of both target nematodes are simple and direct, transmitted bird-to-bird via fecal droppings. Infected chickens are unthrifty, weak, and emaciated, and have weight loss proportional to the parasite burden. Young birds are particularly susceptible. Although mature hens are less susceptible, their egg productivity may drop, and death may occur in severe cases. Because chickens raised as broilers have a much shorter lifespan than laying hens, parasiticides are generally not required to treat them. Turkeys have a longer grow-out than broilers and are subject to additional helminthic parasite pressure, particularly the roundworm parasite *Ascaridia dissimilis* [2020 TR 25-37].

Fenbendazole is a benzimidazole veterinary anthelmintic – i.e., an antiparasitic drug (US NLM 2020). The mode of action works at the sub-cellular level, preventing cell division. Benzimidazoles bind to  $\beta$ -tubulin, inhibiting the cell's microtubule assembly responsible for intracellular transport and required for mitotic cellular division... The ultimate effect on nematodes is starvation caused by intestinal cell disruption and inhibition of nematode egg production. The late-stage (L5) larvae and adult stages of *A. galli* and *H. gallinarum* are susceptible. Efficacy studies reported that fenbendazole increased mortality of *A. galli* larvae and adult, but did not report any reduction in the number of viable parasite eggs [2020 TR 67-76].

### **Manufacture**

The fenbendazole is manufactured using a condensation of o-phenylenediamine or o-nitroaniline with a carboxylic acid derivative. N-arylamide hydrochlorides can also be transformed to benzimidazoles with sodium hypochlorite and base. (Brown et al., 1961; Grenda et al., 1965; Loewe et al, 1976) [2015 TR Table 4].

Fenbendazole is approved as a New Animal Drug Application (NADA) by the U.S. Food and Drug Administration's Center for Veterinary Medicine (U.S. FDA CVM) ... The FDA has established a tolerance of 1.8ppm fenbendazole in 93 eggs, using the predominant metabolite fenbendazole sulfone as a marker [21 CFR 556.275]. This effectively provides a maximum residue limit (MRL) of 2.4 ppm total fenbendazole, including its metabolites fenbendazole sulfone and oxfendazole. In addition to poultry, the FDA has approved fenbendazole for use in cattle, swine, sheep, horses and turkeys, as well as zoo and wildlife animals [21 97 CFR 520.905, 21 CFR 558.258]. Fenbendazole is also approved for use as an anthelmintic for laying hens in the European Union (EMA 2011) and Canada (Health Canada 2020) [2020 TR 89-98].

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

5.2.2(b) Shall respect requirements set out in 6.6 of CAN/CGSB-32.310 with regard to the use of internal parasiticides. Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

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

As per the 2015 TR - Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas (2015 TR 461-467)

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

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

## **Ancillary Substances**

Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

## **Human Health and Environmental Issues**

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. All FDA livestock approved parasiticides are synthetically produced substances shown by experimental and clinical studies to be safe for application to food animals. The excipients are usually United States Pharmacopoeia (USP) grade chemicals and also subject to FDA approval [2015 TR 379-381].

In the 2020 Technical Report, the Subcommittee reviewed additional information on fenbendazole on the following evaluation questions and focus questions:

1. Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment.
2. Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance.
3. Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance. Provide a list of allowed substances that may be used in place of the petitioned substance.
4. Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary.
5. Focus question – Alternatives: What agricultural practices can be used to reduce parasites (and/or prevent the reintroduction of these parasites) in outdoor areas for poultry?
6. Focus question – Alternatives: Are there currently allowed substances and/or practices (or combinations of allowed substances and practices) to eliminate or reduce parasite infestations in poultry and/or outdoor areas?
7. Focus question – Human Health: What are the specific human health risks associated with consuming eggs from poultry that are infested with parasites?
8. Focus question – Human Health: Is there any research on the human health effects of consuming fenbendazole or its metabolites that might be present in eggs following treatment of birds? Is there any research on the effects in young children, older adults, pregnant women and others with compromised immune systems?
9. Focus question – Human Health: Have any long-term human trials been conducted to determine the effects (to humans) of low doses of fenbendazole consumed over a long period of time?
10. Focus question – Human Health: Is any information available on whether human exposure to fenbendazole interferes with the efficacy of mebendazole, which is used for human treatment?
11. Focus question – Human Health: Do parasites develop resistance to fenbendazole? If so, does parasite resistance to fenbendazole diminish its usefulness as a human treatment for parasites (particularly outside the U.S. where its use for human treatment may be approved)?
12. Focus question – Human Health: Fenbendazole has shown some promise as a cancer treatment. Is any information available on whether the presence of fenbendazole in eggs consumed by humans could have any effect on this cancer treatment?
13. Focus question – Human Health: Does cooking eggs lessen the amount of fenbendazole or its metabolites in eggs?
14. Focus question – Regulatory: Are there other regulatory bodies or independent organizations (including international bodies) that have published findings regarding the toxicity (or lack thereof) of fenbendazole?
15. Focus question – Regulatory: What evidence was used to make the determination by FDA to allow use of fenbendazole for laying hens without an intervening period between treatment and sale of eggs? What studies, specifically, were used by the FDA to make their determination? Who provided funding for the studies?

## **Discussion**

Parasiticides are used in acute, emergency cases and should be administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc. According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that pasture height above six inches results in lower pest loads as the cows don't graze low enough to where the parasites are typically located. Additionally, it was anecdotally noted during Subcommittee discussion that calves allowed to nurse

experience lower pest loads than calves that are bottle fed. The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

### Questions to our Stakeholders

1. How do certifiers mitigate consistent repeat use of parasiticides?
2. Are there suggestions to improve the annotation?
3. Which age/class of animal do certifiers see their clients requesting approval for emergency parasiticide use?
4. How often do certifiers request copies of fecal sample test results to confirm the parasite load in a herd prior to allowing an emergency treatment with parasiticides?

## Parasiticides, Moxidectin

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

**Technical Report:** [2003 TAP](#) (Moxidectin); [2015 TR](#)

**Petition(s):** [2003](#)

**Past NOSB Actions:** [05/2004 NOSB recommendation](#); [10/2015 sunset recommendation](#); [04/2016 NOSB recommendation - annotation change](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Added to National List , effective May 16, 2012 ([77 FR 28472](#)); Renewed 03/15/2017 [82 FR 14420](#); Proposed rule 01/17/2018 ([83 FR 2498](#)); Annotation change 12/27/2018 ([83 FR 66559](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

### Subcommittee Review

#### Use

In veterinary medicine the term parasiticide refers to anthelmintic drugs (medicines used to destroy parasitic worms), [2015 TR 148] although moxidectin is also effective against arthropod parasites (e.g., ticks, mites, fleas, lice, etc.). As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]).

The use of moxidectin in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state that does not include the routine use of parasiticides. Routine management of parasiticides should include proper grazing management (rotating pastures when the grass is less than six inches tall), herbal and natural remedies, and selective breed genetics.

Moxidectin is listed in the National List in 7 CFR 205.603(a) as a “medical treatment” under (23) “parasiticides”. Substances listed under 7 CFR 205.603(a)(23) may not be used in livestock intended for organic slaughter and can only be used for the emergency treatment of dairy and breeder stock. In addition to the use-restrictions listed for parasiticides, organic operations using moxidectin must observe a two-day milk-withhold following treatment of cattle and a 36 day withhold following treatment of goats, sheep, and other dairy species.

### **Manufacture**

Moxidectin, a derivative of nemadectin, is a chemically modified *Streptomyces cyanogriseus* fermentation product (Asato and France, 1990) [2015 TR 224-225]. The synthesis of moxidectin involves protecting the 5-hydroxy group of nemadectin with p-nitrobenzoyl chloride to give the corresponding 5-O(p-nitrobenzoyl)-nemadectin, which is then oxidized to give a 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative in a crystalline state. The 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative is then reacted with methoxylamine to give the 23-(methyloxime)5-O(p-nitrobenzoyl)- nemadectin intermediate in a crystalline state. This intermediate is then deprotected in the presence of base to give the desired 23-(methyloxime)-nemadectin. These reactions take place in the presence of various organic solvents (U.S. Patent Number 4,988,824).

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

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

Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas [2015 TR 461-467].

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

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural

methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

### **Ancillary Substances**

Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

### **Human Health and Environmental Issues**

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. Moxidectin is excreted in feces but is both microbially and photo-degraded in dung pats in the soil. It is the least toxic to dung beetles of the macrocyclic lactone anthelmintics. Moxidectin peaks in 2 days in feces after treatment and decreases to less than 10 ppb by 37 days after treatment. The half-life for degradation of moxidectin in the environment may be up to 130 days [2015 TR Table 5 and 575-577].

### **Discussion**

Parasiticides are used in acute, emergency cases and should be administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc. According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that herds that graze on pasture above a height of six inches experience lower pest loads as the cows don't graze low enough to where the parasites are typically located. Additionally, it was anecdotally noted during Subcommittee discussion that calves allowed to nurse experience lower pest loads than calves that are bottle fed. The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

#### History of moxidectin:

The NOSB recommended adding moxidectin to the National List in 2004 with the restriction that it only be allowed for use to control internal parasites. In a proposed rule published on July 17, 2006 ([71 FR 40624](#)), the USDA announced its decision to not include moxidectin on the National List because of its macrolide antibiotic classification. Based upon the public comments that informed NOSB recommendations sent to the Secretary on May 30, 2004, the NOP verified the information supplied by commenters, and subsequently concurred that moxidectin does not function as an antibiotic when used as a parasiticide. Moxidectin was then added to National List ([77 FR 28472, May 15, 2012](#)).

### **Questions to our Stakeholders**

1. How do certifiers mitigate consistent repeat use of parasiticides?
2. Are there suggestions to improve the annotation?
3. Which age/class of animal do certifiers see their clients requesting approval for emergency parasiticide use?
4. How often do certifiers request copies of fecal sample test results to confirm the parasite load in a herd prior to allowing an emergency treatment with parasiticides?

## Peroxyacetic/peracetic acid

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.

**Technical Report:** [2000 TAP](#); [2016 TR](#)

**Petition(s):** [2008](#)

**Past NOSB Actions:** [11/2000 NOSB 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

Peracetic acid (PAA) is listed in the National List as allowed for use in organic livestock production for sanitizing facilities and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment, and hard surfaces. 2016 Technical Report (TR) line 99 states, peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment.

Beginning at 2016 TR line 288: The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

#### Manufacture

Solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer “peracetic acid.”

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Not explicitly mentioned for livestock use.

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

Allowed for cleaning and disinfection (Annex IV, Part D, 2021/ 1165).

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

Not explicitly mentioned.

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)



Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; peracetic acid, page 83).

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

The Japanese Agricultural Standard for Organic Livestock Products, Table 4, lists “Agents for cleaning or disinfecting of housing for livestock.” Included on this list are “Hydrogen Peroxide Solution” and “Cleaning agents and disinfectants for milking equipment, rooms and buildings.” Peracetic acid is not specifically mentioned.

#### **Ancillary Substances**

Peracetic acid is a sanitizer regulated by the FDA and EPA, and a number of additional substances are allowed in peracetic acid formulations. These additional substances are necessary to stabilize the formulations and do not meet the NOSB’s definition of an ancillary substance.

#### **Human Health and Environmental Issues**

Peracetic acid is considered an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain.[2016 TR 544-547]

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain.

[2016 TR lines 615-618] Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(a)pyrene and methylanthalene in lake sediments through oxidation of the parent compound.

#### **Discussion**

The importance of producers to have access to sanitizers in livestock operations cannot be understated. To maintain efficacy, producers must also have access to substances with multiple modes of action to prevent resistance to a single sanitizer. PAA functions as an effective sanitizer and poses little risk to human health or the environment. There is no new information available to the NOSB that would lead to recommending removal of this substance from the National List at 7 CFR 205.603(a).

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

None

## Tolazoline

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(29) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian, and;
- (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and,
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

**Technical Report:** [2002 TAP](#); [2019 TR](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [09/2002 NOSB 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](#); Proposed rule 01/17/2018 ([83 FR 2498](#)); Annotation change 12/27/2018 ([83 FR 66559](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 10/30/2029

### Subcommittee Review

#### Use

In organic livestock production, tolazoline is limited to use only by a veterinarian prescription and is further restricted for “use only to reverse the effects of sedation caused by xylazine.” Xylazine is primarily used in veterinary medicine as a sedative, tranquilizer, and analgesic. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent pain and suffering and injury to the veterinarians performing the procedures. Tolazoline is commonly used as a reversal agent for xylazine by competing for the  $\alpha$ -2-adrenergic receptors, blocking binding events for xylazine. Structural similarities with xylazine allow tolazoline to compete with xylazine for biological binding sites, providing the mode of action for its approved use in organic livestock production as a reversal agent for xylazine [2019 TR 116-118].

Tolazoline is used only for veterinary applications, with no natural or USDA-approved synthetic alternatives. There are no alternative practices that would make the anesthetic agent unnecessary. Tolazoline may be made unnecessary by allowing the veterinary subject to recover from the effects of xylazine by natural metabolism of the substance, rather than its active reversal. However, the rate of xylazine metabolism is species-dependent; therefore, this may prove problematic in species with slower metabolic rates (e.g., cattle) [2019 TR 658-665].

#### Manufacture

Tolazoline is a synthetic substance produced by a one-pot process (i.e., no intermediates are isolated) by the reaction of phenylacetaldehyde with ethylene diamine, with the incorporation of an iodine-based oxidation process.

#### International Allowance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Although xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances listed in Table 5.3 “health care products and production aids,” as a “sedative,” tolazoline (the

most commonly used substance for a reversal agent for sedatives, including xylazine) is not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) and [2021/1165](#)  
Tolazoline is not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms  
Tolazoline is not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production  
Tolazoline is not explicitly mentioned.

### **Environmental Issues**

Tolazoline is a synthetic  $\alpha$ 2-adrenergic antagonist that also interacts with histamine and cholinergic receptors temporarily and reversibly. Tolazoline affords several physiological effects, including vasodilation (increasing arterial oxygenation), transient hypotension, and histaminic gastrointestinal effects. There are no published toxicity or carcinogenicity studies on tolazoline's toxicity or lethal dosages.

Neither xylazine nor tolazoline are listed by the EPA as an inert ingredient of toxicological concern [2019 TR 398]. There are no studies on tolazoline's environmental toxicity, persistence, or concentration.

### **Discussion**

Tolazoline appears to be a critical tool for organic livestock producers.

### **Questions to our Stakeholders**

None

## **Xylazine**

**Reference:** § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(30) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian, and;
- (ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

**Technical Report:** [2002 TAP](#); [2019 TR](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [09/2002 NOSB 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](#); Proposed rule 01/17/2018 ([83 FR 2498](#)); Annotation change 12/27/2018 ([83 FR 66559](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

## Subcommittee Review

### Use

Xylazine is essential for use in veterinary surgical procedures for livestock, especially cattle.

### Manufacture

Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture, which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine. Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water-based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures. Xylazine is commonly used in conjunction with tolazoline, which is a reversal agent for sedatives such as xylazine. According to information posted on the FARAD (Food Animal Residue Avoidance Databank) website (<http://www.farad.org/amduca-law.html>), extra label use (i.e., off label use) of xylazine is permissible under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) only if such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. According to the FARAD Digest (published in JAVMA, Vol. 223, No. 9, Nov. 1, 2003), xylazine is used as a medical treatment in livestock intended for food production as well as in dairy cows.

### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as a health care product and production aid. (Table 5.3, Sedatives listing, CAN/CGSB-32.311-2020, page 28)

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

Not explicitly mentioned

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

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

Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrhythmias, which has resulted in its lack of approval for human medical applications (Green et al. 1981, EMEA 1999, Reyes et al. 2012). Due to the lack of approval for use in human medical applications, information on the mode of action and toxicity of xylazine is limited. [2019 TR 610-614]. Reported cases of xylazine in humans have shown physiological effects like those seen in veterinary applications (Samanta et al. 1990, JECFA 1998a). Upon absorption of xylazine, patients were difficult to

rouse and showed signs of confusion (indicative of central nervous system and neuropathic depression) and expressed symptoms of bradycardia, hypotension (respiratory depression), and hyperglycemia (Gallanosa et al. 1981, Spoerke et al. 1986, Samanta et al. 1990). With regard to human carcinogenicity, no studies of direct effects have been published; however, the International Agency for Research on Cancer (IARC) has designated the xylazine metabolite, xylidine, as potentially carcinogenic to humans based on studies with laboratory animals (NTP 1990, IARC 1993, JECFA 1998a). The lethal dosage of xylazine in humans is not well known and appears to vary dramatically between individuals (Spoerke et al. 1986, Ruiz-Colon et al. 2014). Fatal doses of xylazine recorded have been as low as 40 mg, while other individuals have survived exposure to levels as high as 2400 mg (Spoerke et al. 1986, Ruiz-Colon et al. 2014) [2019 TR 616-628].

## Discussion

This material appears to be a critical tool for organic livestock producers.

## Questions to our Stakeholders

None

## Oxalic acid dihydrate

**Reference:** § 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(8) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.

**Technical Report:** [2018 TR](#)

**Petition(s):** [2017](#)

**Past NOSB Actions:** [04/2019 NOSB recommendation to add](#)

**Recent Regulatory Background:** Added to NL 07/2021 ([86 FR 33479](#))

**Sunset Date:** 7/26/2026

## Subcommittee Review

### Use

Oxalic acid is used as a parasiticide specifically for apiculture. Oxalic acid is currently labeled and approved by the EPA for use in beehives (Registration #91266-1). It is used both in the hive and during transport of honeybees in cages when sold as “bee packages”. It can be used in rotation with formic acid, currently on the National List, to control varroa mites and is a useful tool for beekeepers to manage honeybee parasites. Oxalic acid can be applied to a hive in two ways: In a sugar syrup to be trickled between frames, and as a vapor treatment. There are numerous types of equipment, both home-made and commercially available, that provide the beekeeper the means of heating the oxalic acid and filling the hive with this vapor. In addition, oxalic acid is used to treat packaged bees before they are shipped to customers. Packaged bees with infestations of varroa mites have been a problem for beekeepers and the use of a sugar/oxalic acid syrup spray is a useful method to address this issue. Varroa mites, an invasive pest, are one of the many production problems affecting the livelihood of beekeepers. Numerous chemical varroa mite treatments have been used over the years in nonorganic operations. Many of these treatments are no longer effective due to the development of resistance by the varroa mite. Formic acid has been used for many years in honeybee hives, with no varroa mite resistance. It is considered unlikely that resistance will occur. Similar to formic acid, it is unlikely that varroa mites will develop resistance to oxalic acid.

The mode of action of this substance is not clearly understood, but it appears to be attributed to its acidity (pH near 0.9). Oxalic acid will cross the exoskeleton of the mites in a few hours of application and cause death. Oxalic acid vapor can enter the mite through the soft pads of its feet, enter the mite’s blood stream

and kill it. When mites parasitize and suck on the bee, it can kill the mite through this method as well. There is no clear research to determine if one or all of these are the main modes of action. Current research does indicate that the amount of oxalic acid typically applied to the honeybee hive is not toxic to the bees and is sufficient to kill varroa mites.

### **Manufacture**

Oxalic acid is a dicarboxylic acid, which is in a crystalline form when solid, but loses this structure when dissolved in water. Commercial oxalic acid is produced through a variety of chemical reactions that include oxidation of carbohydrates or alkenes as well as synthesis from carbon monoxide and water. Oxalic acid crystals are produced through precipitation of the crystals from the mother liquor. Oxalic acid can also be produced through microbial fermentation of products such as citric acid, but these are not the typical method for commercial production.

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

CAN/CGSB-32.310-2015 Clause 6.6.10: “The use of veterinary medicinal substances shall comply with the following: (a) if no alternative treatments or management practices exist, veterinary biologics, including vaccines, parasiticides or the therapeutic use of synthetic medications may be administered, provided that 408 such medications are permitted by this standard and Table 5.3 of CAN/CGSB-32.311 or are required by law.”

Allowed as a health care product and production aid for mite control in honeybee colonies. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

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

Allowed 2018/848 Annex 2, Part II 1.9.6.3 Health Care of Bees (e)

Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with Varroa destructor.”

OR 2021/1165 PART D Products referred to in Article 12(1) of this Regulation The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products: — caustic soda; — caustic potash; — oxalic acid

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

Allowed for pest and disease control in beekeeping. (72, B. livestock & livestock products; page 17)

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed for pest and disease control in beekeeping. (5.8.7, page 52 and Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Japan does not have apiculture standards and oxalic acid is not present on their list of approved materials.

### **Ancillary Substances**

None identified.

## Human Health and Environmental Issues

Since it is an acid, it is considered hazardous in cases of skin contact, eye contact, ingestion, or inhalation. Handling instructions include use of protective equipment, such as long sleeves and pants, chemical resistant gloves, goggles, and a respirator.

There are no concerns of environmental contamination during manufacture or disposal. The amount used for honeybees is fairly small and does not add to concentrations of greenhouse gases in the atmosphere, and it would not have widespread negative impacts due to its biodegradability. Misuse of higher-than-recommended concentrations of oxalic acid could result in killing honeybees.

## Discussion

In prior Board discussions, it was debated whether apiculture materials should be reviewed and approved only after there are NOP apiculture standards. It was noted that the NOP currently allows for organic honeybee products to be sold with the USDA organic seal, and honeybee products are certified organic by numerous NOP accredited certifiers. At the time, all Livestock Subcommittee members supported the implementation of the 2010 NOSB recommendation for organic apiculture standards.

At the October 2018 NOSB meeting, the NOSB recommended to remove sucrose octanoate esters (SOEs) from the National List. At the time, SOEs were not available for use by beekeepers, since they were no longer EPA registered. In addition, SOEs were said to be ineffective for varroa mite control. AMS did not remove sucrose octanoate esters from the National List as recommended by NOSB at §§ 205.601(e)(10) and 205.603(b)(11). Following the 2018 NOSB meeting, the EPA received product registrations for sucrose octanoate esters (in December 2020). Subsequent comments demonstrated that the market situation had changed since the 2018 NOSB recommendation, with recent product registrations and increased use of sucrose octanoate esters. Additionally, commenters noted this substance is not harmful to the environment and cited the lack of alternatives approved for organic use.

Beekeepers have expressed support for oxalic acid dihydrate in prior public comments noting some benefits over formic acid.

Oxalic acid dihydrate is consistent with the requirements of OFPA sec. 2118(c) ([7 U.S.C. 6517\(c\)](#)).

## Questions to our Stakeholders

What factors are weighed when determining to use sucrose octanoate esters, formic acid, or oxalic acid dihydrate for varroa mite control?

## DL methionine

**Reference:** § 205.603(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

**Technical Report:** [2001 TAP](#); [2011 TR](#)

**Petition(s):** [2005](#); [2007](#); [2009](#); [2011](#)

**Past NOSB Actions:** [10/2001 NOSB recommendation](#); [03/2005 NOSB recommendation](#); [05/2008 NOSB recommendation](#); [04/2010 NOSB recommendation on Methionine annotation](#); [04/2010 NOSB](#)

[recommendation on Methionine step-down annotation after October 2012](#); [04/2010 sunset recommendation](#); [08/2014 Organic poultry feed proposal](#); [04/2015 NOSB Formal recommendation to amend](#); [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](#)); Proposed rule 01/17/2018 ([83 FR 2498](#)); Annotation change 12/27/2018 ([83 FR 66559](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

## Subcommittee Review

### Use

Methionine is an essential amino acid for poultry since it cannot be produced biologically by the birds and is necessary for proper cell development for the growing chicks and for proper feathering. The USDA organic standards require that all agricultural ingredients for livestock feed be certified organic, and prohibit feeding meat by-products to organic poultry. This restriction narrows the options for natural sources of methionine.

### Manufacture

Methionine is a sulfur-containing amino acid. The 2011 Technical Report lists these various methods of manufacture:

L-methionine may be isolated from naturally-occurring sources, produced from genetically engineered organisms, or synthesized through many processes. While methionine has been produced by fermentation in the laboratory, racemic mixtures of D- and L-methionine (i.e., DL-methionine) are usually produced entirely by chemical methods (Araki and Ozeki, 1991) [2011 TR 238-240]. Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:

- Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);
- Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);
- Use of the Strecker synthesis method with  $\alpha$ -methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or
- Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998) [2011 TR 242-248].

In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and L-enantiomers (Ajinomoto Corporation, 2012) or by acetylation of synthetic DL-methionine and subsequent enzymatic selective deacetylation of the N-acetylated L-methionine (Usuda and Kurahashi, 2010). Because much of the DL-methionine supply is synthesized using chemical methods, the L methionine produced from it is also synthetic. While nonsynthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005) [2011 TR 479-480].

### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed for use in feed, feed additives, and feed supplements. Organic sources, such as fishmeal, insect meal, brewer's yeast, potato protein, corn gluten and distillers' grains, shall be the first preference. When these organic sources does not meet amino acid requirements to produce a balanced feed, then:

- a) amino acids derived from biological sources by biofermentation and extracted/isolated by hydrolysis, by physical, or other non-chemical means may be used;
- b) when such forms of lysine and methionine are not commercially available for use in monogastrics feeding, all sources of lysine and methionine may be used.



This annotation will be reviewed at the next revision of the standard. ( Table 5.2, Amino acids listing, CAN/CGSB-32.311-2020, page 23).

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

The European Economic Community (EEC) Council Regulations state that “growth promoters and synthetic amino acids shall not be used” in animal feed in organic production.

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

Not explicitly mentioned.

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Not allowed. (3.2 Organic animal management does not use any of the following synthetic feed rations: amino acids (including isolates), page 16).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

### **Human Health and Environmental Issues**

Synthetic methionine used as a nutritional supplement in livestock production can enter the environment through waste streams from its production, use, and disposal. Methionine has a relatively low vapor pressure, indicating that methionine present in soil or water is not likely to evaporate into air. Methionine is highly mobile in soil, and research has shown that most of the methionine in soil breaks down in about 16 days. Methionine can exist as a vapor or particulate in the air. Airborne methionine vapor will be degraded in the atmosphere with a half-life of about 7.5 hours. Methionine is also found naturally in water from metabolism of proteins. The potential for bioconcentration of methionine in aquatic organisms is considered low due to its high water solubility [2011 TR 729-286].

### **Discussion**

The Livestock Subcommittee continues to see a need for synthetic DL-methionine in the organic poultry diet. The feeding of synthetic methionine to organic poultry has been a contentious practice over the years, with some stakeholders opposed to any synthetic feed component. In contrast, comments from organic producers at the last review tended to strongly support the use of synthetic methionine under the current annotation. Research and innovation on this issue continue, but in the meantime the inclusion of DL-methionine on the National List appears warranted.

### **Questions to our Stakeholders**

1. Given supply disruptions of soybeans and soy products experienced by the organic livestock sector since February 2022, what organic crops other than soy could be incorporated into poultry rations to supply methionine?
2. Is there a need for changes to the USDA organic regulations to align with either Canadian (unrestricted amino acid are allowed in organic feed) and/or EU (non-organic feeds containing methionine are allowed) organic regulations? If so, what changes to the USDA organic regulatory text should be made?
3. What other nutritional barriers to organic poultry production do producers face when formulating well balanced rations for all poultry in the organic sector?

4. Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?

## Trace minerals

**Reference:** § 205.603(d) As feed additives.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

**Technical Report:** [2013 TR \(aquatic trace minerals\)](#); [2019 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB recommendation](#); [11/2005 sunset recommendation](#); [04/2010 sunset recommendation](#); [09/2014 subcommittee proposal - aquatic trace minerals](#); [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

Minerals are required in animal nutrition for their vital roles in various metabolic, enzymatic, and biochemical reactions in the animal body. Forages and grains are good sources of calcium and phosphorus, respectively. Minerals may be provided through the intake of plant matter feedstuffs and through synthetic supplements. Several factors directly or indirectly influence the levels of minerals in plants, including location, nature, and chemical composition of the soil; level of fertilization; and the presence of anti-nutritional factors that may reduce mineral bioavailability. Bioavailability is defined as the total proportion of the nutrient in a feedstuff that is available for use in normal body functions. As a result, the amounts of minerals for animals that depend on plants as feedstuffs will vary.

The dietary importance of each micro-mineral will depend on the animal species in question. When diet is insufficient to meet an animal's nutrient requirements, supplementation of minerals is typically done through inclusion in the diet either as an individual substance or as part of a trace mineral premix. NOP Guidance 5030 *Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed* spells out in more detail which minerals are covered under this listing.

It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock Subcommittee acknowledges this listing also includes macro minerals. The 2019 TR addresses macro minerals that are included in animal diet, though not in great detail as they are outside the focus of trace minerals.

#### Manufacture

Because this is a broad categorical listing, manufacture varies. In most cases, biologically active forms of trace minerals cannot be obtained by mining, so many trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. More recently, organic forms have become available. This would include the various chelates and complex forms. One of the limiting factors to the use of chelated minerals has been high cost. At the time of the 2019 review, chelated minerals cost 10 to 15 times more per milligram of mineral supplied, compared to inorganic sources.

Descriptions of the common processes used to manufacture many of the trace minerals in use are included in the 2019 TR. This level of detail is not provided for the class of substances called metal amino acid chelates since the processes used to manufacture those materials are largely the same.

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed for use in feed, feed additives, and feed supplements. Unprocessed rock dusts; ground animal or plant material (other than blood or bone meal); and seawater are preferred sources. Chelated and sulphated forms are allowed. If none of these sources are commercially available, other versions are allowed, except for forms containing or produced with EDTA or EDDHA. (Table 5.2, CAN/CGSB-32.311-2020, page 24)

Non-synthetic chelated or sulphated minerals are allowed for use as a health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

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

Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165)

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

Allowed when used in preference to veterinary drugs or antibiotics, needs to be recognized by the certification body or authority, and can only be used if they are of natural origin. In case of shortage of these substances, synthetic substances may be used.

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed. Animals may be fed vitamins, trace elements, and supplements from natural sources unless they are not available in sufficient quantity and/or quality.

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed for therapeutic purposes and mineral supplementation.

### **Human Health and Environmental Issues**

Based on information presented in the 2019 TR, the hazards associated with the use of the trace minerals are primarily associated with dust irritation of the skin and eyes.

When used as petitioned, trace minerals from unconsumed feed have the potential to be transferred to ground or surface waters. While trace minerals are essential dietary components for animal feeds, some are considered heavy metals with strong toxic potential. When included in animal feeds above required amounts, trace elements accumulate in urine and feces in low concentrations. In many cases, these may serve to increase deficient soil levels. The environmental risks of overly high micronutrient applications include impairment of plant production, accumulation in edible animal products, and contamination of the water supply. Concerns regarding specific minerals are included in the 2019 TR.

### **Discussion**

The NOSB received comments during the previous review cycle from a wide representation of the organic community supporting the continued use of trace minerals, noting their essentiality to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Some commenters noted organic production should not be dependent on synthetic nutrients and that the current annotation is not restrictive enough to prevent reliance on synthetic materials. These commenters recommend adding “when forage and available natural feeds are poor quality” to the annotation. However, according to the 2109 TR, forages alone do not satisfy the mineral requirements of grazing cattle. Mineral deficiencies and imbalances in grazing ruminants have been reported in almost all regions of the world. The choice of forage crop; the part of the plant consumed, and the plant’s state of maturity; the soil type and condition; and climatic conditions and seasons when plant material is eaten/gathered are all factors in determining the level and availability of trace minerals.

### Questions to our Stakeholders

Are there effective non-synthetic alternatives to some or all synthetic trace mineral feed supplements?

## Vitamins

**Reference:** § 205.603(d) As feed additives.

(3) Vitamins, used for enrichment or fortification when FDA approved.

**Technical Report:** [1995 TAP](#) (Folic Acid); [2013 TR](#) (aquaculture); [2015 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** [2012 \(aquaculture\)](#)

**Past NOSB Actions:** [10/1995 NOSB recommendation](#); [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

The National Organic Program (NOP) currently allows the use of vitamins as feed additives in organic livestock production under 7 CFR 205.603, “Synthetic Substances Allowed for Use in Organic Livestock Production” for enrichment or fortification when FDA approved. Section 205.237(b)(2) prohibits the use of feed supplements and additives in amounts above those needed for maintenance of adequate nutrition and health. Further, the USDA organic regulations require producers to meet certain standards for livestock health care practices. As part of this requirement, livestock feed rations must meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants) (7 CFR 205.238(a)(2)).

The addition of vitamins directly or indirectly into animal food falls under the regulatory oversight of the U.S. Food and Drug Administration (FDA). According to FDA regulations, the addition of vitamins must be used according to the relevant food additive regulation, unless the substance is generally recognized as safe (GRAS) under 21 CFR 582/584 for that use pattern (FDA, 2014a).

Depending on the raw nutrients available, vitamins are combined in livestock feed rations of grains, beans, oilseeds, and other meals along with minerals and amino acids. There are 15 essential vitamins currently allowed for use in organic livestock production for fortification and enrichment: Vitamin A (vitamin A acetate), Vitamin B1 (thiamine hydrochloride), Vitamin B2 (riboflavin), Vitamin B3 (niacin, nicotinic acid), Vitamin B5 (calcium pantothenate), Vitamin B6 (pyridoxine hydrochloride), Vitamin B7 (biotin), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Choline chloride, Vitamin D3 (cholecalciferol), Vitamin E ( $\alpha$ -

Tocopherol acetate), and Inositol. The scope of vitamin compounds is reflective of vitamins defined as “required nutrients” by the National Research Council’s (NRC’s) Nutrient Requirements for cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well-being of all animals, including livestock. Most vitamins aid in the metabolism of proteins, carbohydrates, and fats while some vitamin compounds have important antioxidant properties. Common signs of vitamin deficiency include anorexia, poor growth, reduced feeding efficiency and, in some cases, mortality.

### **Manufacture**

Individual vitamin compounds are normally produced on an industrial scale by chemical synthesis or partial synthesis. While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production. Many recently developed fermentation methods for manufacturing vitamins utilize genetically engineered microorganisms, generating concerns over the use of these vitamin sources in organic food production. The Technical Review conducted in 2015 stated that fermentation production using genetic modification may be commonly used in production of vitamins A, B2, B5, B6, C, E, and B12.

In response to the TR information, NOP published [NOP 5030](#) “Guidance Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed” which instructs certifiers regarding the review of vitamins in livestock feed. Specific to excluded methods in vitamins, [NOP 5030-1](#) (Response to comments) states, "The USDA organic regulations also prohibit use of excluded methods at § 205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods."

The Livestock Subcommittee has requested a limited-scope technical report, which was not received in time to be incorporated into this review. The TR was requested to update which vitamins are produced with excluded methods, and to determine the availability of other sources.

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Biological and mineral sources of all vitamins are allowed. Non-biological and non-mineral sources of vitamins B1, C (ascorbic acid) and E are allowed. (Table 4.2, CAN/CGSB-32.311-2020, page 21)

Allowed in feed, feed additives, and feed supplements as a concentrated mixture of minerals and vitamins, from organic sources if commercially available. Allowed for enrichment or fortification. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of CAN/CGSB-32.311 are allowed. (Table 5.2, Pre-mixes listing, CAN/CGSB-32.311-2020, page 25)

Allowed for use as a health care product and production aid. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of this standard are allowed. Orally, topically, or by injection. (Table 5.3, CAN/CGSB-32.311-2020, page 29)

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

Vitamins, pro-vitamins and chemically well-defined substances having similar effect allowed; agricultural derivatives preferred (Annex III, Part B, 3(a), 2021/1165)

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

Vitamins or provitamins are allowed if they are of natural origin. In case of shortage of these substances or in exceptional circumstances, synthetics may be used. (page 13)

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed from natural sources unless they are not available in sufficient quantity and/or quality. (3.2-page 16; 5.5.6-page 48)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed for therapeutic purposes.

**Human Health and Environmental Issues**

In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for livestock and human consumption at levels typically ingested through the diet and dietary supplements. When given according to label directions, supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans.

No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Strong acids and bases are used in the synthetic or extraction process of vitamin compounds. Improper use or disposal of these chemicals during the production of vitamins could affect both the pH and chemical composition of the soil, potentially resulting in physiological effects on soil organisms. Accidental release of chemical reagents during the production process may lead to ecological impairment.

**Discussion**

**Public Comments** During the Spring 2019 NOSB review the Livestock Subcommittee received limited comments on retaining vitamins at §205.603. The comments that were received were overwhelmingly in favor of relisting vitamins at §205.603(d)(3), with many of the commenters stating that the addition of vitamins to the livestock diet was essential for the health and well-being of the animal. One stakeholder questioned whether B vitamins are essential, especially in ruminants.

The LS discussed the possible increase in use of GMO fermentation for production of vitamins and would like stakeholder input in addition to information in the forthcoming TR.

**Questions to our Stakeholders**

1. What are common uses of vitamin B and K feed supplements? Are they necessary for good ruminant health?
2. How common are livestock vitamin products that are produced with excluded methods?
3. Are there methods to detect livestock vitamin products produced using excluded methods?

**National Organic Standards Board  
Materials/GMO Subcommittee  
Proposal - Technical Review template update  
February 13, 2024**

**Intro/Background:**

The Materials Subcommittee (MS) is proposing updates to the Technical Review (TR) templates to better align with the petition process and OFPA criteria and to directly address excluded methods.

The NOSB Policy and Procedures Manual defines a technical review as follows: “Technical Review - A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.” According to the PPM, “A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material’s impact on the environment, human health and its compatibility with organic principles.” The two revised TR templates, one for Handling and one for Crops/Livestock are included as Appendices to this proposal. Also included as appendices are the two versions with redlining.

**Discussion:**

The Materials Subcommittee submitted a [discussion document](#) on the TR updates for comment at the Spring 2023 meeting. Public commenters were supportive of the initiative to reorganize the flow of questions, reduce redundancy, and suggested additional questions for ancillary substances, nanoparticles, and excluded methods. The suggested changes were incorporated into the templates, and in January 2024, the MS voted unanimously in support of the versions of the TR templates included in the appendices.

**Questions to stakeholders:**

Do the proposed revisions to the technical report (TR) templates for Handling and Crops/Livestock raise any concerns or challenges for stakeholders that create and/or use TRs?

**Subcommittee Vote:**

Motion to accept the technical Report template updates for Handling and Crops/Livestock.

Motion by: Mindee Jeffery

Seconded by: Nate Lewis

Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

**Appendix A1** - Redlined version of TR template: Handling

**Appendix A2** - New version of TR template: Handling

**Appendix B1** - Redlined version of TR template: Livestock/Crops

**Appendix B1** - New version of TR template: Livestock/Crops

# Name of Material

## Handling/Processing

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**Identification of Petitioned Substance**

**Chemical Names:**

List all chemical names

**CAS Numbers:**

List CAS numbers

**Other Name:**

List other names

**Other Codes:**

List other codes (e.g., INS number, E number, etc.)

**Trade Names:**

List trade names

**Summary of Petitioned Use**

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations (7 CFR Part 205).

**Characterization of Petitioned Substance**

**Composition of the Substance:**

Describe Composition of the Substance

**Source or Origin of the Substance:**

Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 1 through 4).

**Properties of the Substance:**

Describe Physical and Chemical Properties of the Substance

**Specific Uses of the Substance:**

Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

**Approved Legal Uses of the Substance:**

Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

**Action of the Substance:**

Describe Action of the Substance - focus should be given to describing mode of action of the substance, when used as petitioned.

**Combinations of the Substance:**

Describe Combinations of the Substance - focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.



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## Status

### Historic Use:

Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

### Organic Foods Production Act, USDA Final Rule:

Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

### International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

#### ~~Canada, Canadian General Standards Board —~~

**CAN/CGSB-32.310- Organic production systems-General principles and management standards**  
**CAN/CGSB-32.311-2015, Organic Production Systems Permitted Substances List**

<http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172>

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

<http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM>

Note: For Codex, the reference should be cited as “guidelines,” rather than as “standards”.

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

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889>

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

[http://www.maff.go.jp/e/jas/specific/criteria\\_o.html](http://www.maff.go.jp/e/jas/specific/criteria_o.html)

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

<http://www.ifoam.bio/en/ifoam-norms>

## Evaluation Questions for Substances to be used in Organic Handling

**[combination of old #1, 2 &3 – word smithed and added D, E and F]**

**Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)). (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or Non-agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. §6502(21); NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Does the substance in its raw or formulated forms contain ancillary substances (F) Is the substance created using Excluded Methods?**

**Data Required:** The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this response, a chemical change could be the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

- (A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

- (B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

- (C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as agricultural or non-agricultural.

- (D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

- (E) Ancillary Substances: Does the substance in its raw or formulated forms contain ancillary substances as defined by the NOSB in the 2016 recommendation?  
(<https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Proposal%20NOP.pdf>)

- (F) Excluded Methods:

- i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

- 160 using invitro nucleic acid techniques, induced mutagenesis developed through in  
161 vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).  
162 ii. If the substance is manufactured from agricultural raw materials, are those  
163 materials derived from genetically engineered crop, or crops resulting from  
164 excluded methods?  
165 iii. If the substance is manufactured from other biological raw materials – such as  
166 those produced by fermentation or enzymatic action – are those biological  
167 materials, derived from genetically engineered organisms, or crops organisms  
168 resulting from excluded methods?

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171 **[old #4] Evaluation Question #2: Discuss whether the petitioned substance is formulated or**  
172 **manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. §**  
173 **6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source. Specify**  
174 **whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used**  
175 **according to FDA’s good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS,**  
176 **describe the regulatory status.**  
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178 **Data Required:** For the purposes of this response, chemical processes are processes include, but are not  
179 limited to, acid-base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation,  
180 mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units  
181 such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.  
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183 If the substance is extracted from a natural material, information should be provided on any materials and  
184 methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-  
185 base extraction methods, or mechanical or physical separation methods.  
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187 If the substance is created by a naturally occurring biological process, those process(es) must be described  
188 in detail. For the purposes of this response, naturally occurring biological processes are processes that  
189 include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various  
190 metabolic processes, and photosynthesis.  
191

192 Information should be provided on whether the substance has been chemically modified from the source  
193 or origin of the substance, including whether the substance has been isolated from a natural source in a  
194 form that does not occur in nature, and whether any synthetic materials used in the production or  
195 extraction of a substance may remain in the final product.  
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197 For the purposes of this response, an agricultural source is any agricultural commodity or product,  
198 whether raw or processed, including any commodity or product derived from livestock that is marketed in  
199 the United States for human or livestock consumption.  
200

### 201 Purpose and necessity of the substance

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203 **[old #5] Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic**  
204 **or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)). Describe whether the primary**  
205 **technical function or purpose of the petitioned substance is a preservative (7 CFR 205.600(b)(4)).**  
206

207 **Data Required:** The response must discuss whether non-synthetic or natural sources of the petitioned  
208 substance exist and are available. The report contractor should examine the effect, form, function, quality,  
209 and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured  
210 versions. The following information on any naturally sourced versions should be provided in the report:  
211

- 212 ● literature, including product or practice description, on performance and test data;
- 213 ● name and address of the manufacturer(s), if applicable; and,

214 • ~~types of products the substance is currently used in.~~

215 The response must explain why the primary function of the substance is or is not as a preservative.

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217 **[old #6] Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**  
218 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR**  
219 **205.600(b)(5)). If not categorized as GRAS, describe the regulatory status. Describe whether the**  
220 **petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive**  
221 **values lost in processing (except when required by law). If so, how? (7 CFR 205.600(b)(4)).**

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223 **Date Required:** The response must indicate whether or not the substance has been determined to be GRAS  
224 by FDA. This information may be found in 21 CFR Parts 182, 184, and 186. If not determined to be GRAS  
225 by FDA, indicate whether it appears on FDA's "GRAS Notice Inventory" available at  
226 <http://www.accessdata.fda.gov/scripts/cen/fenNavigation.cfm?rpt=grasListing>.

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228 The response should cite the FDA regulatory citation confirming GRAS status or whether FDA has  
229 provided a response letter of no objection to a manufacturer's notification of GRAS status. **When**  
230 **replacement or improvement of nutrients is required or allowed by regulation, the report evaluators**  
231 **should cite the appropriate regulations.**

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233 **[old #7] Evaluation Question #5: Describe whether the primary technical function or purpose of the**  
234 **petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a**  
235 **preservative (7 CFR 205.600(b)(4)). Describe any effect or potential effect on the nutritional quality of**  
236 **the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).**

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238 **Data Required:** The response must explain why the primary function of the substance is or is not as a  
239 preservative. The response must indicate whether the use of the petitioned substance affects the levels of  
240 nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product.  
241 Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

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#### 243 **Environment and human health effects**

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245 **[old #8] Evaluation Question #6: Describe whether the petitioned substance will be used primarily to**  
246 **recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required**  
247 **by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR**  
248 **205.600(b)(4)). List any reported residues of heavy metals or other contaminants in excess of FDA**  
249 **tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).**

250

251 **Data Required:** When replacement or improvement of nutrients is required or allowed by regulation, the  
252 report evaluators should cite the appropriate regulations. The response must indicate whether the  
253 petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or  
254 Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found  
255 in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels.  
256 [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed)  
257 [poisonous-or-deleterious-substances-human-food-and-animal-feed](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed) See the latest edition of Food Chemicals  
258 Codex (National Research Council) for accepted reference standards for metals and other contaminants in  
259 food ingredients in the U.S.

260

261 **[old #9] Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the**  
262 **food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)). Discuss and summarize**  
263 **findings on whether the manufacture and use of the petitioned substance may be harmful to the**  
264 **environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

265

266 **Data Required:** The response must indicate whether the use of the petitioned substance affects the levels of  
267 nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product.  
268 Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients. In  
269 consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe

the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (e.g., predators and parasitic hymenoptera), pollinators, bats and birds.

**[old #10] Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)). Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i) and 7 U.S.C. § 6518(m)(4)).**

**Data Required:** The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. These action levels can be found at <https://www.fda.gov/food/guidanceregulation/ucm077969>. See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S. Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

### Alternatives

**[old #3] Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)). Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).**

**Data Required:** In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (e.g., predators and parasitic hymenoptera), pollinators, bats and birds.

The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:

- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and,
- types of products the substance is currently used in.

**[old #12] Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i) and 7 U.S.C. § 6518(m)(4)). Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the NOP regulations.**

**Data Required:** Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;
- Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.

- A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;
- Literature, including product or practice description, on performance and test data; and
- Types of products and range of uses for the alternative substance

**[old #13] Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)). Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).**

**Data Required:** The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research based alternative practices may be found at: <http://eorganic.info/>, <https://www.sare.org/>, and <https://attra.ncat.org/>; these resources should be consulted before exhausting search for alternative practices. When assessing alternative practices, the report should address:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,
- Types of products produced and scope of use of alternative practices.

The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: <https://organic.ams.usda.gov/Integrity/default.aspx>, <http://eorganic.info/>, <https://www.sare.org/>, <https://www.omri.org/>, [www.606organic.com](http://www.606organic.com), and <https://attra.ncat.org/>; these resources should be consulted before exhausting search for alternative practices. Briefly describe the organic agriculturally derived alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;
- Commercial availability of substitute organic products, both domestically and globally
- A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;
- Any literature, including product description, on performance and test data;
- The name and address of the supplier/manufacturer, if applicable; and
- Types of products and range of uses for the alternative substance.

**[old #11] Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)). Describe if there are any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).**

**Data Required:** The response must describe the availability of a non-synthetic or natural substance(s) which could be substituted for petitioned substance. Many natural substances may be found at: <https://organic.ams.usda.gov/Integrity/default.aspx>, <http://eorganic.info/>, <https://www.sare.org/>, <https://www.omri.org/>, [www.606organic.com](http://www.606organic.com), and <https://attra.ncat.org/>; these resources should be consulted before exhausting search for alternative practices. The examination should address:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;

- 380 • ~~Commercial availability of substitute non-synthetic (natural) products, both domestically and~~
- 381 ~~globally.~~
- 382 • ~~A comparison of reported risks to human health associated with the substitute non-synthetic~~
- 383 ~~(natural) product to the petitioned substance;~~
- 384 • ~~A comparison of reported environmental effects (both aquatic and terrestrial) associated with the~~
- 385 ~~substitute non-synthetic (natural) product to the petitioned substance;~~
- 386 • ~~Literature, including product or practice description, on performance and test data; and~~
- 387 • ~~Types of products and range of uses for the alternative substance; and,~~

388 The response to this request for development of technical information must describe the availability of an  
389 alternative practice(s) to the use of the petitioned substance. Many research-based alternative practices  
390 may be found at: <http://eorganic.info/>, <https://www.sare.org/>, and <https://attra.ncat.org/>; these  
391 resources should be consulted before exhausting search for alternative practices. Briefly describe  
392 alternative practices by summarizing:

- 393 • Literature, including practice description, on performance and test data;
- 394 • A comparison of the function and effectiveness of the proposed alternative practice to the
- 395 petitioned substance; and,
- 396 • Types of products produced and scope of use of alternative practices.

397  
398 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for**  
399 **the petitioned substance (7 CFR 205.600(b)(1)).**

400  
401 **Data Required:** The list should be based upon a comparison of the effect, form, function, quality, and  
402 quantity of the recommended organic agricultural product with the petitioned substance. Many organic  
403 products may be found at: <https://organic.ams.usda.gov/Integrity/default.aspx>, <http://eorganic.info/>,  
404 <https://www.sare.org/>, <https://www.omri.org/>, [www.606organic.com](http://www.606organic.com), and <https://attra.ncat.org/>;  
405 these resources should be consulted before exhausting search for alternative practices. In developing the  
406 list, the following should be considered:

- 407  
408 • ~~A comparison of the effect, form, function, quality, and quantity of the substitute organic~~
- 409 ~~agricultural product to the petitioned substance;~~
- 410 • ~~Commercial availability of substitute organic products, both domestically and globally~~
- 411 ~~A comparison of reported risks to human health associated with the substitute organic agricultural~~
- 412 ~~product to the petitioned substance;~~
- 413 • ~~A comparison of reported environmental effects (both aquatic and terrestrial) associated with the~~
- 414 ~~substitute organic agricultural product to the petitioned substance;~~
- 415 • ~~Any literature, including product description, on performance and test data;~~
- 416 • ~~The name and address of the supplier/manufacturer, if applicable; and~~
- 417 • ~~Types of products and range of uses for the alternative substance.~~

### 419 Report Authorship

420  
421 The following individuals were involved in research, data collection, writing, editing, and/or final  
422 approval of this report:

- 423 • Name, Title, Organization
- 424 • Name, Title, Organization
- 425 • Name, Title, Organization
- 426 • Name, Title, Organization

427  
428 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing  
429 Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

432

**References**

433

434 All citations listed in the report must be included in references section using MLA format.

435 A minimum of 20 current scientific references must be cited in the report to provide adequate scientific  
436 credibility and thorough review. Citation using MLA format must be included appropriately within the

437 text to avoid plagiarism.



# Name of Material

## Handling/Processing

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### Identification of Petitioned Substance

**Chemical Names:**

List all chemical names

**CAS Numbers:**

List CAS numbers

**Other Name:**

List other names

**Other Codes:**

List other codes (e.g., INS number, E number, etc.)

**Trade Names:**

List trade names

### Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations (7 CFR Part 205).

### Characterization of Petitioned Substance

**Composition of the Substance:**

Describe Composition of the Substance

**Source or Origin of the Substance:**

Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 1 through 4).

**Properties of the Substance:**

Describe Physical and Chemical Properties of the Substance

**Specific Uses of the Substance:**

Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

**Approved Legal Uses of the Substance:**

Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

**Action of the Substance:**

Describe Action of the Substance - focus should be given to describing mode of action of the substance, when used as petitioned.

**Combinations of the Substance:**

Describe Combinations of the Substance - focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

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## Status

### **Historic Use:**

Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

### **Organic Foods Production Act, USDA Final Rule:**

Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

### **International**

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

#### **Canada**

CAN/CGSB-32.310- Organic production systems-General principles and management standards

CAN/CGSB-32.311, Organic Production Systems-Permitted Substances List

<http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172>

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

<http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM>

Note: For Codex, the reference should be cited as “guidelines,” rather than as “standards”.

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

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R1165&from=EN#d1e32-48-1>

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

[http://www.maff.go.jp/e/jas/specific/criteria\\_o.html](http://www.maff.go.jp/e/jas/specific/criteria_o.html)

**IFOAM-Organics International**

<http://www.ifoam.bio/en/ifoam-norms>

## Evaluation Questions for Substances to be used in Organic Handling

### **Classification of the substance**

**Evaluation Question #1:** (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or Non-agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. §6502(21); NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Does the substance in its raw or formulated forms contain ancillary substances (F) Is the substance created using Excluded Methods?

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**Data Required:**

- (A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

- (B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

- (C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as agricultural or non-agricultural.

- (D) **Nano Particles:** Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

- (E) **Ancillary Substances:** Does the substance in its raw or formulated forms contain ancillary substances as defined by the NOSB in the 2016 recommendation?  
(<https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Proposal%20NOP.pdf>)

- (F) **Excluded Methods:**

- i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

- 158 using invitro nucleic acid techniques, induced mutagenesis developed through in  
159 vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).  
160 ii. If the substance is manufactured from agricultural raw materials, are those  
161 materials derived from genetically engineered crop, or crops resulting from  
162 excluded methods?  
163 iii. If the substance is manufactured from other biological raw materials—such as  
164 those produced by fermentation or enzymatic action—are those biological  
165 materials, derived from genetically engineered organisms, or crops organisms  
166 resulting from excluded methods?

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168 **Evaluation Question #2: Specify whether the petitioned substance is categorized as generally**  
169 **recognized as safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR**  
170 **205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.**

171 **Purpose and necessity of the substance**

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173 **Evaluation Question #3: Describe whether the primary technical function or purpose of the petitioned**  
174 **substance is a preservative (7 CFR 205.600(b)(4)).**

175

176 **Data Required:** The response must explain why the primary function of the substance is or is not as a  
177 preservative.

178

179 **Evaluation Question #4: Describe whether the petitioned substance will be used primarily to recreate**  
180 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law).**  
181 **If so, how? (7 CFR 205.600(b)(4)).**

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183 **Data Required:** When replacement or improvement of nutrients is required or allowed by regulation, the  
184 report evaluators should cite the appropriate regulations.

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186 **Evaluation Question #5: Describe any effect or potential effect on the nutritional quality of the food or**  
187 **feed when the petitioned substance is used (7 CFR 205.600(b)(3)).**

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191 **Data Required:** The response must indicate whether the use of the petitioned substance affects the levels of  
192 nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product.  
193 Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

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196 **Environment and human health effects**

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198 **Evaluation Question #6: List any reported residues of heavy metals or other contaminants in excess of**  
199 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).**

200

201 **Data Required:** The response must indicate whether the petitioned substance may contain residues of  
202 substances that exceed FDA’s Action Levels for Poisonous or Deleterious Substances in Human Food. For  
203 the most part, these action levels will relate to residues found in agricultural products. Heavy metals or  
204 contaminants are addressed through FDA’s action levels. [https://www.fda.gov/regulatory-information/search-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed)  
205 [fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed)  
206 [animal-feed](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed) See the latest edition of Food Chemicals Codex (National Research Council) for accepted  
207 reference standards for metals and other contaminants in food ingredients in the U.S.

208

209 **Evaluation Question #7: Discuss and summarize findings on whether the manufacture and use of the**  
210 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**  
211 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

212  
213 **Data Required:** In consideration of the petitioned substance, its manufacturing process, and its breakdown  
214 products, describe the mode of action of the substance with respect to its effects on biological, chemical and  
215 physical effects on the environment or biodiversity. The analysis must include consideration of potential  
216 effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (e.g., predators and  
217 parasitic hymenoptera), pollinators, bats and birds

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219 **Evaluation Question #8: Describe and summarize any reported effects upon human health from use of**  
220 **the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i) and 7 U.S.C. § 6518(m)(4)).**

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222 **Data Required:** Describe reported health effects and causation that may be attributed to the use of the  
223 petitioned substance and/or its breakdown products.

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226 **Alternatives**

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228 **Evaluation Question #9: Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR**  
229 **205.600(b)(1)).**

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231 **Data Required:** The response must discuss whether natural (nonsynthetic) sources of the petitioned  
232 substance exist and are available. The report contractor should examine the effect, form, function, quality,  
233 and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured  
234 versions. Briefly describe any naturally sourced alternatives by summarizing:

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  - literature, including product or practice description, on performance and test data;
  - name and address of the manufacturer(s), if applicable; and,
  - types of products the substance is currently used in.

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240 **Evaluation Question #10: Describe all nonagricultural non-synthetic substances or products which may**  
241 **be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of**  
242 **those are currently allowed under the NOP regulations.**

243  
244 **Data Required:** The response must describe the availability of a nonagricultural non-synthetic or natural  
245 substance(s) which could be substituted for petitioned substance. . Briefly describe any nonagricultural  
246 nonsynthetically sourced alternatives by summarizing:

- 247
  - A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic  
248 (natural) product with the petitioned substance;
  - Commercial availability of substitute non-synthetic (natural) products, both domestically and  
249 globally.
  - A comparison of reported risks to human health associated with the substitute non-synthetic  
250 (natural) product to the petitioned substance;
  - A comparison of reported environmental effects (both aquatic and terrestrial) associated with the  
251 substitute non-synthetic (natural) product to the petitioned substance;
  - Literature, including product or practice description, on performance and test data; and
  - Types of products and range of uses for the alternative substance

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258 **Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for**  
259 **the petitioned substance (7 CFR 205.600(b)(1)).**

260  
261 **Data Required:** The list should be based upon a comparison of the effect, form, function, quality, and  
262 quantity of the recommended organic agricultural product with the petitioned substance. Many organic  
263 products may be found at: <https://organic.ams.usda.gov/Integrity/default.aspx>, <http://eorganic.info/>,

264 <https://www.sare.org/>, <https://www.omri.org/>, [www.606organic.com](http://www.606organic.com), and <https://attra.ncat.org/>;  
265 these resources should be consulted before exhausting search for alternative practices. Briefly describe the  
266 organic agriculturally derived alternatives by summarizing:

- 267
- 268 • A comparison of the effect, form, function, quality, and quantity of the substitute organic  
269 agricultural product to the petitioned substance;
- 270 • Commercial availability of substitute organic products, both domestically and globally
- 271 • A comparison of reported risks to human health associated with the substitute organic agricultural  
272 product to the petitioned substance;
- 273 • A comparison of reported environmental effects (both aquatic and terrestrial) associated with the  
274 substitute organic agricultural product to the petitioned substance;
- 275 • Any literature, including product description, on performance and test data;
- 276 • The name and address of the supplier/manufacturer, if applicable; and
- 277 • Types of products and range of uses for the alternative substance.
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- 279

280 **Evaluation Question #12:** Describe if there are any alternative practices that would make the use of the  
281 petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).  
282

283 **Data Required:** The response to this request for development of technical information must describe the  
284 availability of an alternative practice(s) to the use of the petitioned substance. Many research-based  
285 alternative practices may be found at: <http://eorganic.info/>, <https://www.sare.org/>, and  
286 <https://attra.ncat.org/>; these resources should be consulted before exhausting search for alternative  
287 practices. Briefly describe alternative practices by summarizing:

- 288 • Literature, including practice description, on performance and test data;
- 289 • A comparison of the function and effectiveness of the proposed alternative practice to the  
290 petitioned substance; and,
- 291 • Types of products produced and scope of use of alternative practices.
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- 293

### Report Authorship

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295

296 The following individuals were involved in research, data collection, writing, editing, and/or final  
297 approval of this report:

- 298
- 299 • Name, Title, Organization
- 300 • Name, Title, Organization
- 301 • Name, Title, Organization
- 302

303 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing  
304 Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.  
305

### References

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309 All citations listed in the report must be included in references section using MLA format.  
310 A minimum of 20 current scientific references must be cited in the report to provide adequate scientific  
311 credibility and thorough review. Citation using MLA format must be included appropriately within the text  
312 to avoid plagiarism.

# Name of Material

## Crops or Livestock

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**Identification of Petitioned Substance**

**Chemical Names:**

List all chemical names

**CAS Numbers:**

List CAS numbers

**Other Name:**

List other names

**Other Codes:**

List other codes

**Trade Names:**

List Trade Names

**Summary of Petitioned Use**

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations.

**Characterization of Petitioned Substance**

**Composition of the Substance:**

Describe Composition of the Substance

**Source or Origin of the Substance:**

Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 2 and 3).

**Properties of the Substance:**

Describe Physical and Chemical Properties of the Substance

**Specific Uses of the Substance:**

Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural crop or livestock production.

**Approved Legal Uses of the Substance:**

Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

**Action of the Substance:**

Describe the Mode Action of the Substance - focus should be given to describing the mode of action of the substance, when used as petitioned.

**Combinations of the Substance:**

Describe Combinations of the Substance - focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

52	<b>Status</b>
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54	<b>Historic Use:</b>
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55	Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).
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58	<b>Organic Foods Production Act, USDA Final Rule:</b>
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59	Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.
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62	<b>International</b>
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64	Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:
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68	<b>Canada –Canadian General Standards Board Permitted Substances List. This list was updated in November 2015.</b>
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69	<b>CAN/CGSB-32.310- Organic production systems-General principles and management standards</b>
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70	CAN/CGSB-32.311-2015 – Organic production systems - Permitted substances lists
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71	<a href="http://www.tpsgc-pwgsc.gc.ca/oncge-cgsb/programme_program/normes_standards/internet/bio-org/lsp-psl-eng.html">http://www.tpsgc-pwgsc.gc.ca/oncge-cgsb/programme_program/normes_standards/internet/bio-org/lsp-psl-eng.html</a>
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73	<b>CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -</b>
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75	Note: For Codex, the reference should be cited as “guidelines,” rather than as “standards”.
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76	<a href="http://www.codexalimentarius.org/standards/list_standards/en/?no_cache=1">http://www.codexalimentarius.org/standards/list_standards/en/?no_cache=1</a>
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77	<a href="http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf">http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf</a>
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79	<b>European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008</b>
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80	<a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF</a>
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81	
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82	<b>Japan Agricultural Standard (JAS) for Organic Production –</b>
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83	<a href="http://www.maff.go.jp/e/jas/specific/criteria_o.html">http://www.maff.go.jp/e/jas/specific/criteria_o.html</a>
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84	
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85	<b>International Federation of Organic Agriculture Movements (IFOAM) –</b>
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86	<a href="http://www.ifoam.bio/en/ifoam-norms">http://www.ifoam.bio/en/ifoam-norms</a>
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94	<b>Evaluation Questions for Substances to be used in Organic Crop or Livestock Production</b>
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96	<b><u>Classification of the substance</u></b>
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98	<b>[combination of old #2 &amp; 3 – word smithed and added D and E]</b>
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99	<b><u>Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (A)</u></b>
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100	<b><u>Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological</u></b>
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concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(e)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180? (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Based on the manufacturing process description, discuss if the substance is classified as synthetic or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033-1]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Is the substance created using Excluded Methods?

**Data Required:**

- (A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

- (B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

- (C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic. Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.

- (D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

- (E) Excluded Methods:

- i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

- 159 using invitro nucleic acid techniques, induced mutagenesis developed through in  
160 vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).  
161 ii. If the substance is manufactured from agricultural raw materials, are those  
162 materials derived from genetically engineered crop, or crops resulting from  
163 excluded methods?  
164 iii. If the substance is manufactured from other biological raw materials – such as  
165 those produced by fermentation or enzymatic action – are those biological  
166 materials derived from genetically engineered organisms, or crops organisms  
167 resulting from excluded methods?

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169  
170 **[old #1] Evaluation Question #2: Describe the most prevalent processes used to manufacture or**  
171 **formulate the petitioned substance. Further, describe any chemical change that may occur during**  
172 **manufacture or formulation of the petitioned substance when this substance is extracted from naturally**  
173 **occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)). For substances classified as synthetic:**  
174 **Is the substance used in production, and does it contain an active synthetic ingredient in the following**  
175 **categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones,**  
176 **soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and**  
177 **medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row**  
178 **covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients**  
179 **that are not classified by the Administrator of the Environmental Protection Agency as inerts of**  
180 **toxicological concern?**

181  
182 **Data Required:** The response must describe the processes used to manufacture or formulate the substance,  
183 including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing  
184 methods and the extent of their commercial use which are not included in the petition, if any, should be  
185 presented. The response must also describe, in detail, any chemical changes effected on any naturally  
186 occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this  
187 response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed  
188 into one or more other distinct substances. This may include the addition or deletion of one atom to the  
189 substance's molecular structure or other description of chemical modification.

190  
191 **[old #7] Evaluation Question #3: Discuss whether the petitioned substance is formulated or**  
192 **manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. §**  
193 **6502 (21)). Describe any known chemical interactions between the petitioned substance and other**  
194 **substances used in organic crop or livestock production or handling. (7 U.S.C. § 6518(m)(1)).**

195  
196 **Data Required:** For the purposes of this response, chemical processes are processes include, but are not  
197 limited to, acid-base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation,  
198 mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units  
199 such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

200  
201 If the substance is extracted from a natural material, information should be provided on any materials and  
202 methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-  
203 base extraction methods, or mechanical or physical separation methods.

204  
205 If the substance is created by a naturally occurring biological process, those process(es) must be described  
206 in detail. For the purposes of this response, naturally occurring biological processes are processes that  
207 include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various  
208 metabolic processes, and photosynthesis.

209  
210 Information should be provided on whether the substance has been chemically modified from the source  
211 or origin of the substance, including whether the substance has been isolated from a natural source in a  
212 form that does not occur in nature, and whether any synthetic materials used in the production or

213 extraction of a substance may remain in the final product. The response to this request for development of  
214 technical information must describe any known chemical interactions between the petitioned substance  
215 and other substances allowed for use in organic production or handling as applicable. Describe any  
216 common combinations of materials used with the petitioned substance. Describe any substances resulting  
217 from these interactions.  
218

219 **[combination of old #4 & 5] Evaluation Question #4: Describe the persistence or concentration of the**  
220 **petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)). Discuss (A) the**  
221 **toxicity and mode of action of the substance; (B) the toxicity and mode of action of its breakdown**  
222 **products or any contaminants; and (C) their persistence and areas of concentration in the environment (7**  
223 **U.S.C. §6518(m)(2)).**

224  
225 **Data Required:** The response must describe whether and how the petitioned substance and/or the  
226 breakdown products are persistent or cumulative when used in organic crop or livestock production as  
227 petitioned.

- 228 (A) Describe whether the petitioned substance has been reported to have toxic effects and if its mode of  
229 action can cause adverse health and/or environmental effects.
- 230 (B) Describe whether the petitioned substance contaminants, or any of its breakdown products have  
231 been reported to have toxic effects and are capable of causing adverse health and/or  
232 environmental effects either present in the substance or arising from the degradation of the  
233 substance over time.
- 234 (C) Describe whether and how the petitioned substance and/or the breakdown products are persistent  
235 or cumulative when used in organic crop or livestock production as petitioned.  
236

237 **[old #6] Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its**  
238 **breakdown products and any contaminants. Describe the persistence and areas of concentration in the**  
239 **environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)). Discuss the**  
240 **probability of environmental contamination during manufacture, use, misuse or disposal of the**  
241 **substance (7 U.S.C. §6518(m)(3)).**

242  
243 **Data Required:** The response must describe whether the petitioned substance, its contaminants, or any of  
244 its breakdown products have been reported to have toxic effects and are capable of causing adverse health  
245 and/or environmental effects either present in the substance or arising from the degradation of the  
246 substance over time. The response must describe the occurrence and severity of environmental  
247 contamination during the manufacture, use, misuse, or disposal of the petitioned substance. Data or  
248 reports from U.S. or International universities, agencies, independent groups, or other news reports should  
249 be included in this response when available. This data may also be available through review of assessments  
250 performed per EPA, FDA, and/or NIEHS review.  
251

252 **[old #8] Evaluation Question #6: Describe any environmental contamination that could result from the**  
253 **petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)). Discuss the effects**  
254 **of the substance on biological and chemical interactions in the agroecosystem. Include the physiological**  
255 **effects of the substance on soil, crops, livestock or other organisms (such as aquatic) that could be**  
256 **affected by the substance when used as petitioned. (7 U.S.C. §6518(m)(5))**  
257

258 **Data Required:** The response must describe the occurrence and severity of environmental contamination  
259 during the manufacture, use, misuse, or disposal of the petitioned substance. This data may be available  
260 through review of assessments performed per EPA, FDA, and/or NIEHS review. Data or reports from  
261 other U.S. or International universities, agencies, independent groups, or other news reports should be  
262 included in this response when available. The response must describe the substances (the petitioned  
263 substance and/or its byproducts in combination with naturally occurring substances over time) that are  
264 capable of affecting the agro-ecosystem.  
265

The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.

**[old #9] Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)). Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

**Data Required:** The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions and whether they may cause adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time. Toxicity, mode of action, and persistence of the substance and its breakdown products should be explained. ~~Considering the information described in questions #1-6 and any other relevant information, discuss if the petitioned substance and/ or its breakdown products can cause harmful effects on the environment. Describe the biological, chemical and physical factors that may be affected by the use of the substance and/ or its breakdown products.~~

### Harm to Human Health

**[old #10] Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)). Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and 7 U.S.C. § 6518 (m) (4)).**

**Data Required:** The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem. The effects of these substances, including toxicity, mode of action and environmental persistence of the substance and its breakdown products should be explained.

The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible. **Drawing upon responses**

to above questions #1-7 and any other relevant information, describe the reported health effects that may be attributed to the petitioned substance and/or its breakdown products.

### Necessity and Alternatives

**[old #11] Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)). Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

**Data Required:** Drawing upon responses to above questions #2-8, and any other relevant information, describe the biological, chemical and physical agents capable of causing harmful environmental effects and the causation, that may be attributed to the use of the petitioned substance and/or its breakdown products. The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and
- For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

**[old #12] Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)). Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

**Data Required:** Drawing upon responses to above questions #2-8 and any other relevant information, describe the reported health effects and causation that may be attributed to the petitioned substance and/or its breakdown products.

The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.

When assessing alternative practices, the report should address:

- Literature, including specific practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,
- Frequency or prevalence of use of alternatives, if known.

**~~Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).~~**

**~~Data Required:~~** The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- ~~• a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;~~
- ~~• literature, including product or practice description, on performance and test data;~~
- ~~• name and address of the manufacturer(s), if applicable; and~~
- ~~• For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.~~

376  
377 **Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned**  
378 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**  
379

380 **Data Required:** The response to this request for development of technical information must describe the  
381 availability of alternative practices, such as cultural, biological, and mechanical controls, to the use of the  
382 petitioned substance.  
383

384 Alternative cultural methods including methods used to enhance crop health and prevent weed, pest, or  
385 disease problems without the use of substances. Examples include the selection of appropriate varieties  
386 and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by  
387 manipulating the microclimate with green houses, cold frames; or wind breaks.  
388

389 Other alternative practices may include, but are not limited to, crop rotation, mulching with fully  
390 biodegradable materials, mechanical cultivation, augmentation or introduction of predators or parasites of  
391 the pest species; development of habitat for natural enemies of pests; nonsynthetic controls such as lures,  
392 traps, and repellents; sanitation measures and management practices which suppress the spread of disease  
393 organisms.  
394

395 Alternative practices used in livestock production may include, but are not limited to, selection of species  
396 and types of livestock with regard to suitability for site specific conditions, resistance to diseases and  
397 parasites; site selection, housing, pasture and sanitation practices that minimize occurrence and spread of  
398 disease and parasites; stocking density; and seasonal production practices.  
399

400 When assessing alternative practices, the report should address:

- 401 • Literature, including practice description, on performance and test data;
- 402 • A comparison of the function and effectiveness of the proposed alternative practice with the  
403 petitioned substance; and,
- 404 • Frequency or prevalence of use of alternatives, if known.  
405

### Report Authorship

407  
408 The following individuals were involved in research, data collection, writing, editing, and/or final  
409 approval of this report:

- 410 • Name, Title, Organization
- 411 • Name, Title, Organization
- 412 • Name, Title, Organization
- 413 • Name, Title, Organization
- 414

415 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing  
416 Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.  
417

### References

# Name of Material

## Crops or Livestock

1 **Identification of Petitioned Substance**

2

3 <b>Chemical Names:</b>	<b>CAS Numbers:</b>
4 List all chemical names	List CAS numbers
5	
6 <b>Other Name:</b>	<b>Other Codes:</b>
7 List other names	List other codes
8	
9 <b>Trade Names:</b>	
10 List Trade Names	

12 **Summary of Petitioned Use**

13

14 For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently  
 15 on the National List, summarize the allowed uses under the USDA organic regulations.  
 16

17 **Characterization of Petitioned Substance**

18

19 **Composition of the Substance:**  
 20 Describe Composition of the Substance  
 21

22 **Source or Origin of the Substance:**  
 23 Briefly describe the source or origin of the substance (to be addressed in more detail below under  
 24 Evaluation Questions 2 and 3).  
 25

26 **Properties of the Substance:**  
 27 Describe Physical and Chemical Properties of the Substance  
 28

29 **Specific Uses of the Substance:**  
 30 Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of  
 31 the substance; secondary focus should be given to providing general information on other uses of the  
 32 petitioned substance in agricultural crop or livestock production.  
 33

34 **Approved Legal Uses of the Substance:**  
 35 Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA,  
 36 USDA (including APHIS or FSIS), NIEHS, etc.)  
 37

38 **Action of the Substance:**  
 39 Describe the Mode Action of the Substance - focus should be given to describing the mode of action of the  
 40 substance, when used as petitioned.  
 41

42 **Combinations of the Substance:**  
 43 Describe Combinations of the Substance - focus should be given to describing whether the petitioned  
 44 substance is a precursor to, component of, or commonly used in combination with a substance(s) identified  
 45 on the National List.  
 46

47 In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients,  
 48 stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to  
 49 commercially available forms of the petitioned substance.  
 50

**Status****Historic Use:**

Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

**Organic Foods Production Act, USDA Final Rule:**

Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

**International**

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

**Canada -**

CAN/CGSB-32.310- Organic production systems-General principles and management standards

CAN/CGSB-32.311 – Organic production systems - Permitted substances lists

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

Note: For Codex, the reference should be cited as “guidelines,” rather than as “standards”.

**European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008****Japan Agricultural Standard (JAS) for Organic Production –****IFOAM - Organics International****Evaluation Questions for Substances to be used in Organic Crop or Livestock Production****Classification of the substance**

**Evaluation Question #1: (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Based on the manufacturing process description, discuss if the substance is classified as synthetic or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033-1. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Is the substance created using Excluded Methods?**



**Data Required:**

- (A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

- (B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

- (C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic. Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.

- (D) **Nano Particles:** Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

- (E) **Excluded Methods:**

- i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed using invitro nucleic acid techniques, induced mutagenesis developed through in vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).
- ii. If the substance is manufactured from agricultural raw materials, are those materials derived from genetically engineered crop, or crops resulting from excluded methods?

158                   iii. If the substance is manufactured from other biological raw materials – such as  
159                   those produced by fermentation or enzymatic action – are those biological  
160                   materials derived from genetically engineered organisms, or crops organisms  
161                   resulting from excluded methods?

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165 **Evaluation Question #2:** For substances classified as synthetic: Is the substance used in production, and  
166 **does it contain an active synthetic ingredient in the following categories:** [§6517(c)(1)(B)(i)]; copper and  
167 **sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions,**  
168 **treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids**  
169 **including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment**  
170 **cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by**  
171 **the Administrator of the Environmental Protection Agency as inerts of toxicological concern?**

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174 **Evaluation Question #3:** Describe any known chemical interactions between the petitioned substance  
175 **and other substances used in organic crop or livestock production or handling. (7 U.S.C. § 6518(m)(1)).**

176

177 **Data Required:** The response to this request for development of technical information must describe any  
178 known chemical interactions between the petitioned substance and other substances allowed for use in  
179 organic production or handling as applicable. Describe any common combinations of materials used with  
180 the petitioned substance. Describe any substances resulting from these interactions.

181

182 **Evaluation Question #4:** Discuss (A) the toxicity and mode of action of the substance; (B) the toxicity  
183 **and mode of action of its breakdown products or any contaminants; and (C) their persistence and areas**  
184 **of concentration in the environment (7 U.S.C. §6518(m)(2)).**

185 **Data Required:**

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188 (A) Describe whether the petitioned substance has been reported to have toxic effects and if its mode of  
189 action can cause adverse health and/or environmental effects.

190 (B) Describe whether the petitioned substance contaminants, or any of its breakdown products have  
191 been reported to have toxic effects and are capable of causing adverse health and/or  
192 environmental effects either present in the substance or arising from the degradation of the  
193 substance over time.

194 (C) Describe whether and how the petitioned substance and/or the breakdown products are persistent  
195 or cumulative when used in organic crop or livestock production as petitioned.

196

197 **Evaluation Question #5:** Discuss the probability of environmental contamination during manufacture,  
198 **use, misuse or disposal of the substance (7 U.S.C. §6518(m)(3)).**

199

200 **Data Required:** The response must describe the occurrence and severity of environmental contamination  
201 during the manufacture, use, misuse, or disposal of the petitioned substance. Data or reports from U.S. or  
202 International universities, agencies, independent groups, or other news reports should be included in this  
203 response when available. This data may also be available through review of assessments performed per  
204 EPA, FDA, and/or NIEHS review.

205

206

207 **Evaluation Question #6:** Discuss the effects of the substance on biological and chemical interactions in  
208 **the agroecosystem. Include the physiological effects of the substance on soil, crops, livestock or other**  
209 **organisms (such as aquatic) that could be affected by the substance when used as petitioned. (7 U.S.C.**  
210 **§6518(m)(5))**

211 **Data Required:** The response must describe the substances (the petitioned substance and/or its  
212 byproducts in combination with naturally occurring substances over time) that are capable of affecting the  
213 agro-ecosystem.

214  
215 The response should describe whether and how the petitioned substance affects the survival and/ or  
216 function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae,  
217 and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt  
218 concentration, solubility or other parameter. For crops, the response should also describe whether and  
219 how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization,  
220 or other parameters when used as petitioned. For livestock production, the response should also describe  
221 whether and how the substance affects animal physiology by creating changes in behavior, fertility,  
222 metabolism or other parameters.

223  
224 In addition, the response should describe the potential or actual impacts of the substances upon  
225 endangered species, population, viability or reproduction of non-target organisms and the potential for  
226 measurable reductions in genetic, species or eco-system biodiversity, if possible.

227  
228  
229 **Evaluation Question #7:** Discuss and summarize findings on whether the use of the petitioned  
230 substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A)  
231 (i)).

232  
233 **Data Required:** Considering the information described in questions #1-6 and any other relevant  
234 information, discuss if the petitioned substance and/ or its breakdown products can cause harmful effects  
235 on the environment. Describe the biological, chemical and physical factors that may be affected by the use  
236 of the substance and/ or its breakdown products.

237  
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239 **Harm to Human Health**  
240 **Evaluation Question #8:** Describe and summarize any reported effects upon human health from use of  
241 the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518  
242 (m) (4)).

243  
244 **Data Required:** Drawing upon responses to above questions #1-7 and any other relevant information,  
245 describe the reported health effects that may be attributed to the petitioned substance and/or its  
246 breakdown products.

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250 **Necessity and Alternatives**

251  
252 **Evaluation Question #9:** Describe all natural (non-synthetic) substances or products which may be used  
253 in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances  
254 that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

255 **Data Required:** The response must describe the availability of non-synthetic or natural substance(s),  
256 including organic agricultural products, which could be substituted for petitioned substance. The  
257 examination should address:

- 258 • a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or  
259 natural product with the petitioned substance;
- 260 • literature, including product or practice description, on performance and test data;
- 261 • name and address of the manufacturer(s), if applicable; and
- 262 • For livestock (and pet food) feed substances, information on technical barriers to production of  
263 organic agricultural products that may serve as alternatives.

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266 **Evaluation Question #10: Describe any alternative practices that would make the use of the petitioned**  
267 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

268  
269 **Data Required:** The response to this request for development of technical information must describe the  
270 availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use  
271 of the petitioned substance.

272  
273 When assessing alternative practices, the report should address:

- 274 • Literature, including specific practice description, on performance and test data;
- 275 • A comparison of the function and effectiveness of the proposed alternative practice with the
- 276 petitioned substance; and,
- 277 • Frequency or prevalence of use of alternatives, if known.

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### Report Authorship

283  
284 The following individuals were involved in research, data collection, writing, editing, and/or final  
285 approval of this report:

- 286 • Name, Title, Organization
- 287 • Name, Title, Organization
- 288 • Name, Title, Organization
- 289 • Name, Title, Organization

290  
291 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing  
292 Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

293  
294

### References

**National Organic Standards Board  
Materials Subcommittee  
2024 Research Priorities Discussion Document  
Spring 2024  
Executive Summary**

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture, a [process originally established by the Board in 2012](#). The NOSB requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals. As part of this year's process, the Livestock, Crops, and Handling Subcommittee have made an effort to categorize and differentiate highest priority topics from ongoing topics.

## **LIVESTOCK**

### *Top priorities for organic livestock research*

Elucidate the barriers to increased organic pork production and markets.

Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to complement corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation.

### *Ongoing organic livestock research topics*

Evaluate ways to prevent and manage parasites in all species of livestock, in each region. This includes determining the efficacy of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, diatomaceous earth, pasture rotation, pasture species, mixed species grazing, and utilizing the genetic pool within and between breeds.

Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.

Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.

## **CROPS**

### *Top priorities for organic crop research*

The extent and impact of plastic use in organic crop production, and how organic producers can lead in reducing it and aligning with consumer concerns.

Side-by-side trials of approved organic pesticide products, both synthetic and natural, and cultural methods, in multiple regions, with a request for collaboration with the IR4 project.

Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas for Per- and Polyfluoroalkyl (PFAS) substances.

Assessing the economic impact of GMO contamination and prohibited pesticide drift, such as from Dicamba, on organic crops.

#### *Ongoing organic crop research topics*

#### Inputs

Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.

Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.

Holistic soil research to quantify soil biology

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock

Comprehensive review of positive and negative impacts of copper product use in pest management.

#### Contaminants

Investigate contaminated inputs from non-organic sources, including from compost approved for use on organic farms.

#### Systems

Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.

Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems' resilience in the face of climate change.

Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.

Organic no-till and low-till practices for diverse climates, crops, and soil types.

Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.

More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.

Strategies for the prevention, management, and control of problem insects, diseases, and weeds in light of a changing climate, and how to anticipate or predict new pest problems. Systems-based approaches are emphasized.

## **FOOD HANDLING AND PROCESSING**

*(prioritized order within categories; categories not ordered by priority)*

### Improving methods and practices for organic handling and processing

Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the National List.

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

Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.

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

Evaluation of the essentiality of § 205.605(a), § 205.605(b), and § 205.606 substances and the suitability of organic alternatives in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.

Alternatives to conventional celery powder for curing organic meat.

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

### Complete (or full) materials review

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

## **MATERIALS/GMO**

Outcome of genetically engineered (GMO/GE) material in organic compost.

Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.

Develop, then implement, methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed.

Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.

Testing for fraud by developing and implementing new technologies and practices.

## **GENERAL**

Examination of the factors influencing access to organically produced foods.

Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.



**National Organic Standards Board  
Materials Subcommittee  
2024 Research Priorities Discussion Document  
February 13, 2024**

## **INTRODUCTION**

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture based on a [process originally established by the Board in 2012](#). The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2023 Board meeting. The Board requests input from stakeholders on the 2024 research priorities and will review those comments for the Fall 2024 proposal. As part of this year's process, the Livestock, Crops, and Handling Subcommittee have made an effort to categorize and differentiate highest priority topics from ongoing topics.

## **BACKGROUND**

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

The NOSB encourages collaboration with and between laboratories, federal agencies, universities, foundations and organizations, business interests, organic farmers, and the entire organic community to seek solutions to pressing issues in organic agriculture and processing/handling.

The NOSB encourages integrated, whole farm research into the following areas:

## **LIVESTOCK**

*Top priorities for organic livestock research*

**Elucidate the barriers to increased organic pork production and markets.** Production of organic pork has lagged behind chickens, eggs, and dairy. We request holistic investigations into what the barriers are, including, but not limited to markets, pricing, input costs, processing facilities, and production constraints such as lack of hardy breeds and housing/humane standards. Competition from non-organic pasture-raised, local, and other production claims should be included, as should evaluation of methods to avoid the need for farrowing crates.

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

## *Ongoing organic livestock research topics*

**Prevention and Management of Parasites** - Livestock production places large numbers of cattle, sheep, goats, poultry etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner which approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical.

The research question on prevention and management of parasites must be systems-based. What farm systems, bird and animal breeds, herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, diatomaceous earth, or other treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds? An area of particular concern is control of *A. galli* and *H. gallinarum* in laying and replacement chickens.

## **Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production -**

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

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution<sup>1</sup> passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for:

- A. Evaluation of the merits and safety of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials including insect protein in organic poultry production systems. Additional research on the more promising alternatives to bring them into commercial production is also encouraged;
- B. Evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine;
- C. Management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management; and

D. With the European Union as a case study, assess how it is that EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable.

The fruition of these types of research topics could take years to achieve; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand.

**Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.**

To further acknowledge the central role the certified organic industry will play in the fight against climate change, an opportunity exists to both empower the economic resilience of organic dairy farmers while harnessing the soil building potential of diverse perennial and annual forages, we encourage the research community to dedicate resources to the following need:

A. Identify an index of dairy cattle genetics to which producers could breed their existing herds and achieve a minimum of 12,000 lbs. of milk production per year on 100% forage diets. In considering the genetics selected, also identify animals bred for longevity as the more lactations on a cow, the more spread out the fixed costs of raising her as a heifer becomes.

B. To assist dairy farmers in having the tools to consider a forage-based rotation for their herds, research and identify crop rotations that have three functions: produce high quality forage, maximize soil building, and result in the most profitable outcome for the dairy producer.

*<sup>1</sup>The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.*

## **CROPS**

*Top priorities for organic crop research*

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

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

- Statistics on current use (acreage and quantity) of crop production plastics, including mulches, drip tape, containers, row covers, tarps, high tunnels, greenhouses, etc.
- What is the turnover and fate of these plastics? This information is needed for the US and major production areas such as Mexico, Spain, Chile, Holland, Canada, etc.
- What are the effects of breakdown products, airborne releases, and microplastics on soil organisms and crop plants?

- What are the economics of alternatives?
- If approved biodegradable biobased mulch films are developed, how many organic farmers would switch to them, and what would impact overall plastic usage?
- Can longer-term mulches such as landscape fabric reduce overall plastic use if allowed to remain in place over several years?
- What are the best first steps to reduce plastic use in organic production?

### **Efficacy Comparisons of Inputs and Practices for Organic Production**

Organic farmers need to have information from side-by-side trials between allowed and petitioned synthetic inputs versus non-synthetic alternative inputs or practices. During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions. The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

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

Background: There is a need for increased research examining PFAS substances. PFAS is a broad term that contains thousands of chemicals used in consumer, commercial, and industrial products. There is evidence that PFAS substances, also known as “forever chemicals,” contaminate farmland, water, food, consumer goods, and more. PFAS substances can negatively impact human health and animal health in direct and indirect ways over time. Many researchers and scientists are looking into matters related to PFAS substances.

The NOSB is requesting additional research on the following:

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

## Assessing the economic impact of GMO contamination on organic crops

Background: Genetically Engineered Crops and Organic Crops can exist in adjacent fields. There are many risks, including cross-pollination, that are mitigated as best as possible by the growers involved, but much to the expense of the organic producer. Organic growers use borders, at a minimum of thirty feet, off-set planting timeframes to avoid cross-pollination (causing organic crops to be planted sometimes at undesirable times) and change cropping rotations, all to mitigate risk.

Research is needed on the following:

- The total cost of GMO contamination on organic farms for the full range of crops with GMO varieties (including lesser-studied crops like apples, canola, summer squash, sweet corn, etc.). This would include recommended buffer requirements, recommended planting delays windows, testing costs, a variety of pollen receptivity restrictions, loss of sales, etc.
- Are USDA coexistence provisions adequate?
- Drifting chemicals can be considered “chemical trespassing.” Could pollen contamination be considered trespassing as well?

*Ongoing organic crop research topics*

### Inputs

#### **Biodegradable Bio-based Mulch Film**

Biodegradable mulch film was recommended in 2012 for addition to the National List by the NOSB but it did not specify a required percentage of biologically derived (i.e., bio-based) content. The NOP regulations require that all (100%) of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers because petroleum-based polymers are present in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions are important to develop more clarity on mulch films and possibly develop an additional annotation to address producer needs for biodegradable mulch films even if petroleum-based polymers are used. Data from Europe, where BBMF mulches are allowed for organic production, may be particularly useful.

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

- Are the testing protocols in place to insure decomposition standards?

### **Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments**

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

### **Holistic Soil Research to Quantify Soil Biology**

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

### **Identify Barriers and Develop Protocols for Organic Nursery Stock Production**

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap?

Research centered on development of practical organic methods for the nursery industry to implement is needed, including:

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

### **Comprehensive Review of Copper**

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

- Develop alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Develop biological agents that work on diseases that copper is now used on.
- Research on tadpole shrimp and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable copper alternatives in an aquatic environment.
- Research on movement and fate of applied copper in aquatic and field environments.

- Establish available and total copper threshold levels above which soil organisms are harmed, for different regions and soil types.
- Breeding plants that are resistant to the diseases that copper controls.

## Contaminants

### **Investigate contaminated inputs from non-organic sources**

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

## Systems

### **Ecosystem service provisioning and biodiversity of organic systems**

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

### **Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon)**

A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although several researchers are examining this issue, additional work is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security. Life cycle analysis of organic inputs and practices is critical. In particular, work is needed on comparing soil-based and soil-less systems, as well as the effects of farm scale on greenhouse emissions.

### **Nutritional Value of Organic Crops**

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

## Organic No-Till and Minimum Tillage

Organic no-till can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. Farmers are employing several different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.

Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices.

Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
- How does organic no-till influence pest, weed, and disease management?
- What potential pest problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Do these systems affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?

Finally, organic farmers use whole-farm planning when deciding what will be done in each of their fields. Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to “inform” where reduced tillage practices are likely to have their greatest impact.



## **Managing Cover Crops for On-Farm Fertility**

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

## **Pathogen Prevention**

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

## **Management of Problem Insects, Diseases, and Weeds**

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

Examples are:

- spotted wing drosophila
- brown marmorated stinkbug
- Spotted lanternfly
- Swede midge
- Leek moth
- Corn rootworm beetle (northern and western)
- Cutworms (army, western bean, etc.)
- and others

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

Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops.

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

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control, particularly in pears and apples.
- Evaluate plant nutritional strategies to lessen disease impacts.

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

Weed management is one of the greatest challenges to successful organic crop production. Development of integrated organic management strategies that effectively control weeds in specific cropping systems without excessive tillage continues to be a top research priority for organic producers. For instance, Canadian thistle, pigweed (including invasive palmer amaranth and water hemp), wild sunflower, giant ragweed, cocklebur, and other perennial weeds can be very difficult to control in reduced tillage systems.

Research into new technologies such as electroshock weeders, interrow mowers, camera-guided cultivators, laser-weeders incorporating AI (artificial intelligence) and robotics, propane flamers, etc. is critical to success in field crops, whereas tarping, solarization, and a new generation of hand tools have great potential in small- to medium-scale vegetable crops. For large scale vegetables as well as row-crop producers, strip tillage and compatible weed management tools including row cleaners, finger weeders, and high residue cultivators can combine reduced tillage and cover crops into one practice set.

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

## **FOOD HANDLING AND PROCESSING**

*(prioritized order within categories (underlined); categories not ordered by priority)*

### Improving methods and practices for organic handling and processing

Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the NL

- Can research projects that emphasize and reinforce collaboration between researchers, agencies that regulate sanitizers and food safety, and NOP be designed with the goal of developing an alternative process for evaluating sanitizers and sanitation practices for use by organic operations?
- Is there a measurable transfer of sanitizer residue to organic food following the sanitization of food contact surfaces? If residues are not found, is it even necessary for the National List to

regulate surface/environmental sanitizers? (This topic should not be limited to only National List materials and should also include sanitizers such as quaternary ammonia compounds, or QACs.)

- What amount of sanitizer/disinfectant remains on the surface of various organic products after a processing or packing step that includes direct treatment with a sanitizer? That includes a water bath containing water treated with a sanitizer?
- Could the development of robust, post-harvest handling standards better identify which sanitation, disinfectant, or treatment practices have an impact on organic integrity? Could expanded handling standards assist in regulating and enforcing the use of sanitizers instead of, or in addition to, the National List?
- Could restructuring the National List to separate sanitizers from ingredients and processing aids create a pathway to development of an alternative set of evaluation criteria for sanitizers?
- What would the impact on handlers and processors be if any one of the sanitizers were removed from the National List?

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

- *[intentionally does not include further detail]*

Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.

- *[intentionally does not include further detail]*

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

Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations and/or analysis of the barriers to organic production via laboratory testing, sensory evaluation, and/or market analysis

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

Alternatives to conventional celery powder for curing organic meat.

- Celery powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (note: products must still be labeled “uncured”). Celery powder is naturally

high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

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

- *[intentionally does not include further detail]*

#### Complete (or full) materials review

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

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

#### **MATERIALS/GMO**

In previous years, the Materials Subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014), issues which are currently being addressed through a comprehensive stream of work on Excluded Methods. The following research priorities are among the areas that the Excluded Methods work continues to elevate:

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

**Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material** - Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or

they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

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

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

**Testing for Fraud: Developing and implementing new technologies and practices** - new technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

**Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods.** First, identify the set of potential threats the use of excluded methods presents to organic businesses (farms and handlers). The potential threats include crop damage and cross contamination, but we recognize there might be others not yet identified. Second, estimate the costs the threats present to organic farms and organic handlers.

## **GENERAL**

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

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

**Subcommittee Vote:**

Motion to accept the discussion document on the 2024 NOSB Research Priorities

Motion by: Wood Turner

Seconded by: Brian Caldwell

Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 0

**Approved by Franklin Quarcoo, Materials Subcommittee Chair, to transmit to NOSB, February 15, 2024**

**National Organic Standards Board**  
**Materials Subcommittee**  
**Inert Ingredients in Organic Pesticide Products**  
**February 13, 2024**

**Introduction:**

NOP issued a memo to NOSB on June 23, 2023 requesting NOSB provide a recommendation related to inert ingredients used in pesticide products allowed in organic production. This memo provides a history of the inerts issue, describes four options NOP is considering for the future regulation of inert ingredients and provides a synthesis of the public comments received regarding these options in its Advanced Notice of Proposed Rulemaking published September 2, 2022. The four options as described by NOP in its memo are as follows:

- Allow inert ingredients in EPA-registered pesticides without further review. This would be the easiest to implement and an effective way to evaluate products for compliance. This option would require stakeholders to actively engage in EPA rulemaking and may delegate some control of inert ingredients in organic production to the EPA.
- Reference a subset of EPA regulations (e.g., inerts exempt from the requirement of a tolerance) for allowed inert ingredients. This could be combined with an initial list of prohibited inert ingredients. Further prohibitions or allowances may be added through the petition process. This option maintains much of the simplicity of allowing all EPA registered pesticides while allowing more control. Specifically, it allows stakeholders to submit petitions to prohibit or allow certain inert ingredients as more research is published.
- Develop a single, external list of allowed inert ingredients. The National List would reference this list for allowed inert ingredients. This would function similarly to the current system of referencing EPA List 3 and List 4. This option reduces the sunset burden but is inflexible, like the current reliance on EPA List 3 and List 4. The initial list could be developed from EPA List 3 and List 4, but it is unclear how and by whom this list would be maintained or updated, and how it would fit within the regulatory framework of the National List.
- List allowed inert ingredients individually on the National List in the organic regulations. While the NOSB may be able to initially review these inert ingredients in groups to recommend adding them to the National List, they would need individual sunset reviews every five years. This could nearly double the Board's sunset workload.

NOSB received this memo without adequate time to bring forward a discussion document for the Fall 2023 meeting. However, the topic was referred to the Materials Subcommittee (MS) who formed a workgroup to focus on this agenda item. The Subcommittee submitted the following questions into the public docket for stakeholders to consider and to ensure there would be multiple opportunities for stakeholders to provide comments on the topic of inert ingredient review and approval:

1. Capacity - NOSB members devote a considerable amount of time and energy in the sunset review of the materials that make up the National List. Adding significant numbers of individual listings will increase this workload. To what extent should NOSB consider current and potential future workload when evaluating the options for modernizing the approval of inert ingredients in pesticide products?

2. Authority - Congress granted the Environmental Protection Agency the authority to determine efficacy and safety of pesticide products and the NOP and NOSB the authority to determine which pesticide products aligned with the Organic Foods Production Act and National List Criteria. When should NOSB rely on EPA's evaluations of safety, necessity, and efficacy in evaluating inert ingredients used in pesticide products? And when should NOP and NOSB assert its additional statutory constraints and regulatory criteria in the evaluation of inert ingredients in pesticide products?

3. Flexibility - A stable list of approved inert ingredients can provide assurance to manufacturers and producers that the tools they need to control pests and disease will be there when preventive measures have failed. These manufacturers will continue to innovate and develop tools, and scientific research will emerge regarding safety and necessity that may require additions and removals from the list of inert ingredients approved for use in pesticide products. How rigid or flexible should the approved list of inert ingredients be to balance competing concerns? What mechanisms provide stakeholders the ability to simultaneously raise concerns, advance innovation, and maintain confidentiality in amending the approved list of inert ingredients used in pesticide products?

NOSB received numerous comments on the topic of inert ingredients at our Fall meeting, and the general themes of the comments are summarized below:

- There are two options which garner the most support: 1. To list each inert ingredient allowed for use in organic pesticide formulations on the National List individually; and 2. To reference a subset of EPA regulations in combination with an initial list of prohibited inert ingredients.
- There is consensus that inert ingredients allowed in minimum risk ("25(b)") pesticides and inert ingredients allowed in pheromone type pesticides should be allowed in organic production.
- There is little interest from stakeholders in allowing all inert ingredients permitted in EPA pesticides in organic pesticide formulations, as this would delegate too much of the regulatory authority away from NOSB and NOP.
- Several stakeholders pointed out that the number of inert ingredients currently in use is a relatively small subset of those permitted and should be the starting point for handling this issue. MRO's can disclose the inerts in formulations they approve, without revealing confidential information about specific products.

**Subcommittee Next Steps:**

The Materials Subcommittee focused on ensuring the various options are fairly considered and in order to do so, requested NOP provide NOSB with a way to evaluate; which substances are currently allowed as a



List 4 or List 3 inert, which would be allowed under the various options, which are nonsynthetic and therefore categorically allowed in organic pesticide products, and which are currently in use according to Material Review Organizations who review pesticide formulas for compliance to the organic regulations. The data for this last category of substances was drawn from comments received in response to the 2022 Advance Notice of Proposed Rulemaking (ANPR). NOP staff have delivered a draft of this analysis in the form of a spreadsheet, and the MS has included it in this discussion document as Appendix A (See Regulations.gov Docket # [AMS-NOP-23-0075](#): Supporting and Related Materials).

The MS also intends to invite experts on the topic of inert ingredients to its meetings in preparation for a proposal for the Fall 2024 meeting in Portland, OR. We hope the additional information received at the Spring 2024 meeting and through discourse with experts will lay a foundation of understanding for the entire board on this complicated topic, so that a recommendation can be reached advising the NOP on its intention to move forward with rulemaking related to inert ingredients.

#### **Questions for Stakeholders:**

The MS has the following specific questions for stakeholders and, as always, welcomes any additional perspectives, solutions, and information related to inert ingredients used in organic pesticides.

1. Please provide feedback on the format and analysis of Appendix A. The Board will use this to comprehend the practical impact the various options will have on the number of substances that would need to be added to the National List based on the corresponding option (e.g. if all inerts are listed individually or that would be allowed under various subsets of EPA regulations depending on the option)?
2. What areas of expertise should the MS consider when inviting speakers to subcommittee meetings in order to obtain the fullest and most accurate understanding of this topic?
3. Please provide feedback on whether the list of inert ingredients currently in use (see Appendix A), is accurate.
4. Does the potential reduction in the number of substances the Board must review outweigh the inflexibility associated with the option to develop a single, external list of allowed inert ingredients?
5. Would designation of a specific entity responsible for maintaining the single external list of allowed inert ingredients change stakeholder's opinions of this option?

#### **Subcommittee Vote:**

Motion to accept the discussion document on Inert Ingredients used in Organic Pesticide Products

Motion by: Nate Lewis

Seconded by: Brian Caldwell

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

**Appendix A** (See Regulations.gov Docket # [AMS-NOP-23-0075](#): Supporting and Related Materials).



**National Organic Standards Board  
Policy Development Subcommittee Proposal  
Policy and Procedures Manual (PPM) Revision  
February 13th, 2024**

**Introduction and Background**

The [Policy and Procedures Manual \(PPM\)](#) was established to assist the National Organic Standards Board (NOSB) in the implementation of its duties under the [Organic Foods Production Act \(OFPA\)](#), and the [USDA Organic Regulations \(7 CFR Part 205\)](#). It contains operating procedures and policies for the NOSB. During the period since the last revision (April 2022), the Policy Development Subcommittee (PDS) has been compiling a list of minor revisions and suggested changes. The PDS has reviewed these suggested changes and proposes the following as listed in the table below.

**Summary Table of Changes**

Section/Page	Changes <b>(red highlight indicates additions, strikethrough indicates deletions)</b>
III. A Page 5	Updated membership (seat names) per OFPA, as revised 6501 et seq. 2018.
III. D Page 8	Updated Executive “Subcommittee” to Executive “Committee” beginning on page 8, and throughout document.
III. D Page 8	Updated Administrative Team duties.
III. E Page 9	Proofreading and technical edits for clarity.
III. G Page 11	Proofreading edits.
III. J(1) Page 14	Minor clerical correction to Advisory Committee Specialist title.
III. J(3) Page 15	Proofreading and technical edits for clarity.
III. K Page 15	<b>DECLARATION OF INTERESTS/Conflict of Interest:</b> Updated to reflect new designation of 4 seats as Special Government Employees, and clarification that all Board members function as equals regardless of classification. Proofreading and technical edits for clarity.
IV. A Pages 17 - 18	Updated section title and committee names.
IV. E Page 20	<b>Subcommittee Chair duties:</b> Minor update to Subcommittee Chair duties regarding minority opinions.
IV. E Page 20	<b>Subcommittee Vice Chair duties:</b> Removed duty to serve as liaisons for Materials Subcommittee as this is clarified under the Subcommittee Chair duties.
IV. F, F(4), F(5) Pages 20–21	<b>TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING):</b> Updated subcommittee term start date.
IV. G(1) Page 21 -22	Technical corrections to add “discussion documents” and distinguish between proposals and recommendations.
IV. G(2) Page 22	Changed “material” to “substances.” Wordsmithing for clarification and parallel construction.
IV. G(3) Page 22	Wordsmithing for clarification.
IV. G(3) Step 4. Page 23	<b>Subcommittee Vote:</b> Added clarifying language.

IV. H Page 23	Minor clerical corrections.
IV. H Step 3 Page 25	Minor clerical correction.
IV. H Steps 6 - 7 Page 27	Clerical updates.
IV. H Step 8 Page 27	Updated possible public comment formats.
IV. H Pages 28–29	Misc. clerical corrections.
VII. A Page 30	Misc. clerical corrections.
VIII. B Pages 31 - 32	Minor clerical correction. <b>CONDUCTING BUSINESS:</b> Updated section on quorum.
VIII. D Page 33	Technical correction: Deleted “sign and date.”
VIII. E Pages 33 - 34	<b>Written comments:</b> Updated language to reflect actual procedures. Replaced impugn with malign (as suggested in public comment) in two places. <b>Oral Comments:</b> Updated language regarding oral comments. Updated language regarding “electronic meetings.” Updated language regarding recording to say transcripts. Updated language about “paper copies of comments.” General wordsmithing.
VIII. F Page 35	Suggestion: Added contingency plan in case the Chair and/or Secretary is also running for office. Clerical corrections at last bullet.
VIII. G. Page 36	Minor wordsmithing.
IX. Page 36	Updated language about PPM revisions.
Appendix B. Page 41	Minor wordsmithing and clarification.

**Subcommittee Vote:**

Motion to accept the proposal on the PPM updates

Motion by: Nate Lewis

Seconded by: Amy Bruch

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

# NATIONAL ORGANIC STANDARDS BOARD

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## POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002  
Revised August 18, 2005  
Revised March 29, 2007  
Revised November 30, 2007  
Revised May 22, 2008  
Revised November 19, 2008  
Revised May 6, 2009  
Revised November 9, 2009  
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Revised April 29, 2011  
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Revised April 26, 2016  
Revised November 18, 2016  
Revised October 25, 2019  
Revised April 28, 2022  
DRAFT May 1, 2024

**NATIONAL ORGANIC STANDARDS BOARD (NOSB)  
POLICY AND PROCEDURES MANUAL**

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## I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the [Organic Foods Production Act \(OFPA\)](#), NOSB members are encouraged to review this manual in depth as well as to become familiar with the OFPA, the USDA organic regulations at [7 CFR Part 205](#), and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

### A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

### B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title. (OFPA, Sec 2119 (a))

### C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).

To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations
- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List
- Communicating with the organic community, including conducting public meetings, soliciting and reviewing public comments
- Communicating, supporting and coordinating with the NOP staff



## II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

### A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

### B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

### C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The [NOSB charter](#) is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

## III. NOSB ADMINISTRATION

### A. NOSB Membership

OFPA as amended (7 U.S.C. ~~6501XXXX~~ *et. seq.* 2018) specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation, **or employees of such individuals**;
- Two shall be individuals who own or operate an organic handling operation, **or employees of such individuals**;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products, **or employees of such individuals**;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;
- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

### B. Nomination and appointment process

(NOSB Recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five-year term. The terms are

staggered, and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities. The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

### C. Responsibilities of the NOSB

(OFPA, 7 USC 6518(k)):

- (1) **In General.** The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.
- (2) **National List.** The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this title.
- (3) **Technical Advisory Panels.** The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.
- (4) **Special Review of Botanical Pesticides.** The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.
- (5) **Product Residue Testing.** The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.
- (6) **Emergency Spray Programs.** The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of

this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

**Requirements.** (OFPA 6518(l)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

- (1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;
- (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and
- (3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

**Evaluation.** (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. the effect of the substance on human health;
5. the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. the alternatives to using the substance in terms of practices or other available materials; and
7. compatibility with a system of sustainable agriculture.

**Petitions.** (7 USC 6518(n))

The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

**Sunset Provision.** (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

#### **D. NOSB OFFICERS**

Three principal officers, Chair, Vice Chair, and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

## CHAIR

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings, and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings
- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

## VICE CHAIR

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

## SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval
- Assists with the annual election of NOSB officers
- Monitors and notifies Subcommittee Chairs periodically of public comments posted to the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted.
- May delegate tasks to others, but retains responsibility for the official record

## ADMINISTRATIVE TEAM

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. This group is responsible for ~~coordinating~~ **facilitating** logistics and operations of the Board, **including working with USDA staff for onboarding new members and providing outgoing board members with the opportunity to share experiences and feedback.** The Administrative team meets via teleconference on an as-needed basis, to be determined by the Administrative Team. This team is not a subcommittee and makes no decisions. All items needing further

discussion or action are placed on the Executive Committee agenda and are recorded in the Executive Subcommittee notes.

#### **E. NOSB-NOP COLLABORATION**

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to “establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation” of the Act. Section 6503 (a) of the OFPA requires that the Secretary “shall establish an organic certification program ... and shall consult with the NOSB” (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as “Government in the Sunshine Act” (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly, the NOP, as required through OFPA, must consult and collaborate with the NOSB.

Team-work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance, and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all **Executive Committee** calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

~~The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above.~~ **The work of the NOP and NOSB requires a high level of collaboration, and therefore** NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics, and maintain organic integrity. –Every aspect of this work must take place in a manner ~~which~~ **that** clearly demonstrates mutual respect and positive intent.

#### **F. NOSB WORK AGENDAS**

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and

are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope:** Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions to or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.
- **USDA and NOP Priority:** Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.
- **Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Committee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List**  
The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.
- **Changes to annotation or classification of materials**  
The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process,

or as new information is provided in a Technical Review, or from public comment.

- **Recommendation for modification of existing standards or new standards**

The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards**

The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

- **Compliance and Enforcement**

The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review**

The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

## **G. Designated Federal Officer**

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling the meetings of the NOSB
- Approving the semi-annual meeting agenda
- Attending the semi-annual meetings
- Adjourning the meetings when such adjournment is in the public interest

## H. **Advisory Committee Specialist**

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented.
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities.
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls.
- Ensuring NOSB members have all necessary materials and information to provide informed, structured, and timely recommendations to the NOP.
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments.
- Coordinating the NOSB nomination and chartering process.
- Facilitating training of NOSB members.
- Managing information reporting and communication between the NOSB and NOP.

## I. **ADDITIONAL ADMINISTRATIVE ITEMS**

- **Official to whom the Committee Reports**  
The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer; the Agricultural Marketing Service's NOP Deputy Administrator.
- **Staff Support**  
The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.
- **Estimated Number and Frequency of Meetings**  
The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.
- **Recordkeeping**  
Records of the NOSB shall be defined and handled in accordance with General Records Schedule 6.2 or other approved agency records disposition schedule. This schedule is available online at: <https://www.archives.gov/records-mgmt/grs/grs06-2.pdf>. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Requests for records should be handled in accordance with the GSA March 14, 2000 memo that is available online here: <http://www.gsa.gov/portal/content/100785>. Information about the NOSB is available online at:



<http://www.ams.usda.gov/rules-regulations/organic/nosb>

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, documents provided to the board, a complete and accurate description of matters discussed and conclusions, and the outcome of voting. If not included in the minutes, a voting summary will be published that contains votes by member.

**FACA** requires (5 U.S.C. App. Section 10 (b)): “Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.”  
Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- **Freedom of Information Act (FOIA; 5 U.S.C. 552).** Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

## **J. PROFESSIONAL AND ETHICAL STANDARDS**

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

### **1) NOSB Member Professional Conduct Standards**

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust.
- Put forth an honest effort in the performance of their NOSB duties.
- Make no commitments or promises of any kind purporting to bind the Government.
- Act impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings

- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any “specific party matters” (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP’s Advisory Board Committee Specialist any specific party matter in which the member’s immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board’s recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB’s advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

## 2) Additional Standards of Conduct

NOSB members should adhere to the following basic “standards of conduct” while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.
- Do not engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.
- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the

public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

### 3) Failure to participate

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fails to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that they cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or ~~cannot~~ attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary, encourage the Board member to resign.

## K. DECLARATION OF INTERESTS/Conflict of Interest

The Organic Foods Production Act (OFPA) prescribes ~~these seven interest groups/~~seats, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumer and public interest groups, and retailers.

~~NOSB members are classified as representatives under the Federal Advisory Committee Act (FACA). Each Representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe..."). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.~~

In 2022, USDA determined that eleven of the fifteen seats are classified as **representatives** under the Federal Advisory Committee Act (FACA), and four are classified as Special Government Employees (SGEs). Representatives are appointed to articulate the viewpoints and interests of a particular interest group, while SGEs are appointed to provide expert advice. Regardless of classification, all board members function as equals in providing advice to the Secretary in the development of standards for substances to be used in organic production and on any other aspects of the implementation of OFPA.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionately benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

### **Declarations of Interest/Conflicts of Interest Procedures**

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

#### **At the Subcommittee Level**

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are “self-dealing” to benefit yourself or someone close to you, you should refrain from leading.
- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the Subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the Subcommittee.
- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

#### **At the Full Board Level**

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.

2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).
3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP, working with the USDA office of ethics, as needed, will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.
4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.
5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the Board chair, the DFO will state: “the following Board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etc.)”
6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: “if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time.” This is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.
7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state “recuse” when it is his or her time to vote.

#### **IV. SUBCOMMITTEES**

Subcommittees play an important role in administering the NOSB’s responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc.

##### **A. STANDING COMMITTEES AND SUBCOMMITTEES**

The current standing Subcommittees are:

- Executive (ECS)
- Certification, Accreditation, and Compliance (CACCS)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

### **Executive Subcommittee (ECS)**

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Subcommittee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

### **Certification, Accreditation, and Compliance Subcommittee (CACS)**

The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

### **Crops Subcommittee (CS)**

The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

### **Handling Subcommittee (HS)**

The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

### **Livestock Subcommittee (including Aquaculture) (LS)**

The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

### **Materials Subcommittee (including Genetically Modified Organisms) (MS)**

The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS.

In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling

Subcommittees.

**Policy Development Subcommittee (PDS)**

The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

**B. AD HOC SUBCOMMITTEES**

At the discretion of the NOSB Chair, and with approval of the Executive Committee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a “joint” Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the Executive Committee.

**C. SUBCOMMITTEE MEETINGS**

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

**D. TASK FORCES**

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

**E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS**

**Subcommittee Chair duties:**

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed

- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- **Ensure minority opinions are given opportunity to be represented in meetings and in discussion documents and proposals.**
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Committee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

**Subcommittee Vice Chair duties:**

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair’s absence
- ~~The Vice Chairs of the Crops, Livestock, and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.~~

**F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)**

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (~~beginning on January 24 and ending the following January 23~~). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

**After the election of NOSB Officers at the Fall Meeting:**

**1. The new NOSB Chair takes Office**

At the close of the meeting at which the election occurred, the newly elected Chair takes office.

**2. Appointment of Subcommittee Chairs**

The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience.

**3. Appointment of Subcommittee Vice Chair**

Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

**Timeframe for Appointments**

Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a



reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

#### **4. Review of Subcommittee Files**

New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work.

#### **Mentorship Period**

The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair. ~~of their Subcommittee until seated in their positions at the beginning of the new term on January 24.~~ The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

#### **5. Appointment of New NOSB Members:**

The Board Chair will appoint each new NOSB member to appropriate Subcommittees as soon as possible, so that ~~on January 24~~ all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

#### **6. Changing Subcommittee Appointments**

Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Committee.

#### **7. Filling a Subcommittee Chair and/or Vice Chair vacancy**

If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

### **G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS**

#### **1. Development of proposals/discussion documents**

Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

- A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
- By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty-five (45) days prior to a scheduled NOSB meeting.
- When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/~~recommendation~~ as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.

A minority view should:

- Be short and concise, and include reasons for opposing the Subcommittee's recommendation;
- Should not include any data or information not introduced on a Subcommittee call;
- Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its **proposal recommendation**;
- Will be included as a separate section at the end of the **proposal/recommendation**.
- The NOP will post the proposal or discussion document for public comment.
- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.
- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

## 2. **Types of Proposals/Discussion Documents**

(See Member Guide for examples)

There are several formats for writing proposals and discussion documents, based on the subject under review:

- Proposals related to ~~material~~ substances: petitioned **substances**, sunset reviews, annotation changes, or classification changes.
- Proposals for policy or procedure changes
- Discussion documents
- Petitioned material discussion documents

## 3. ~~Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings~~

**The following information should be included in proposals and discussion documents:**  
~~NOSB Subcommittees and task forces should follow the outline below when presenting proposals or discussion documents for consideration by the Board:~~

1. **Introduction:** A brief summary of the issue, or statement of the problem.
2. **Background:** An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.

3. **Proposal:** A concise explanation of the recommended action.
4. **Subcommittee Vote:** The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, or agricultural/non-agricultural, and the other a motion to add to the National List.
5. **Public Comment:** A brief summary of the public comments
6. **Minority View:** If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

## H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is “to assist in the development of standards for substances to be used in organic production” (OFPA 6518 (a)). “The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary ...” (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year “sunset” review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions and [NOP Guidance 3011 Procedure](#)— National List Petition Guidelines, effective March 11, 2016.

In lieu of a formal petition, a Subcommittee (Livestock, Crops, Handling) of the NOSB may propose to add, remove, or amend a material substance from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518(m) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H. [Step 2](#) in this PPM.

### Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines sufficiency of the petition. If found insufficient, the subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.
3. Subcommittee (SC) determines if a technical review (TR) is needed.
4. SC may develop a discussion document based on the petition and forward that document to the full board for posting, and to solicit public discussion.
5. Technical report is completed and sent to the subcommittee for review.

6. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
7. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting ~45 days prior to public meeting.
8. The NOSB members analyze comments and vote on the proposal at the public meeting.
9. The NOSB chair delivers the final recommendations to NOP.

### **Step 1: Receipt of Petition**

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
  - OFPA Checklist, NOP 3005-1
  - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and a petitioner

### **Step 2: Subcommittee (SC) determines sufficiency of the petition**

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine if the petition is sufficient for SC review. This decision may be based on the following:

- Is there sufficient information in the petition for the SC to determine why or

for what purpose the material is being petitioned?

- what is the petitioners proposed wording for listing the material?
- Is the information presented in the petition clear and consistent so that a proposal may easily be developed?

If the petition is found insufficient, the Subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

### **Step 3: Subcommittee determines whether a Third-Party Technical Review is required**

During this phase, which may occur simultaneously with the determination of petition sufficiency, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third-party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition that makes a technical review unnecessary?
- Do any previous technical reviews of other materials provide sufficient information?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides a Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

#### Option for a Technical Advisory Panel (TAP)

OFPA states: “The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List.”(7 USC 6518 (k)(3))

The NOSB has not convened independent Technical Advisory Panels since 2005.

Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations. In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

**Step 4: Subcommittee may develop a discussion document based on the petition and forward that document to the full board and post it for public discussion**

At the discretion of the Subcommittee (SC), the SC may develop a discussion document to:

- Solicit public comment about the material prior to a proposal being developed
- Provide opportunity for full board discussion prior to a proposal being written
- Allow the petitioner to hear public and board comments, and give them an opportunity to submit petition addendums prior to a Subcommittee proposal and vote.

A petition discussion document is optional, but if used, could allow for full board discussion of a material while a technical review is in process or if the SC determines a full board discussion would benefit the writing of the SC proposal on the material.

**Step 5: Third Party Technical Review**

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third-party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

**Step 6: Technical Review Sufficiency Determination**

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail, and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving ~~the~~ a TR, that ~~the TR~~ it is sufficient. If ~~the~~ a TR is ~~not~~ found insufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor. Once ~~the~~ a Technical Reports ~~are~~ is deemed sufficient, the NOP will post it on the NOP website.

### **Step 7: Review by the Subcommittee (Crops, Livestock or Handling)**

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Report Review, personal knowledge, public or board comments from the optional petition discussion document, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review of the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural, non-agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend).
- The review, including a record of the Subcommittee vote, will be finalized as a proposal for the next meeting.
- All proposals must be submitted to NOP for posting ~45 days before the public meeting date.

### **Step 8: Action by Full NOSB**

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, consider ~~listen to~~ public comments (written, virtual, and in-person), and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the Subcommittee, and the Chair will open the motion for discussion. After discussion, board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.

- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

**Step 9:** The NOSB Chair will review all final recommendations and submit them to the NOP

### **Changes to annotations, classification of materials, or proposal to remove.**

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation, a reclassification of the substance, or removal of a substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The Executive Committee ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

### **Additional considerations concerning Technical Reviews**

Basic principles that should be considered when consulting with a third-party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health, and its compatibility with organic principles.
- The decision to request a ~~third-party expert~~ **Technical Report** needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee determines the completeness of the petition and whether a Technical Review is needed.
- The decision to define **specific** the expertise of the third-party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.

The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered



employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.

Link: <https://www.acquisition.gov/far/current/pdf/FAR.pdf>

## Definitions

**Technical Report Review** - A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

**Technical Advisory Panel (TAP)** - Group of third-party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

## V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

**Priority 1:** A petition or proposal to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1**, above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

**Priority 2:** A petition or proposal to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2**, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

**Priority 3:** A petition to **add** a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as **Priority 3**.

**Priority 4:** A petition to **reconsider** adding a material that had previously been rejected by a Board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

## VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and

recommendation procedure. Withdrawals will not be accepted after the Subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

## VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition.”

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

### A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

**Step 1:** The NOSB Subcommittees submit the initial **Sunset Summaries** ~~List Summary~~ for posting, which may include requests for specific information. The NOP posts the ~~list summaries~~ as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

**Step 2:** The public submits written comments, which are analyzed by Subcommittees.

**Step 3 (Public Meeting #1):** Subcommittees summarize background and public comment & receive oral comment.

**Step 4:** Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews**, which are posted on the NOP website.

**Step 5:** Written public comments submitted and analyzed by Subcommittees

**Step 6 (Public Meeting #2):** Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

**Step 7:** AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

**Step 8:** AMS issues Federal Register Notice announcing renewal of applicable substances

Note: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation or re-classifying a material, a Subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

## VIII. NOSB PROCEDURES

### A. BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training, or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

### B. CONDUCTING BUSINESS

#### **NOSB public meetings in brief:**

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

**Quorum:** As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). ~~In cases of a medical situation~~

~~preventing attendance in person, a virtual presence is permitted.~~ In cases when extenuating circumstances prevent in-person participation, a virtual presence is permitted.

**Decisive votes:** As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

**Calculation of Decisive Votes**

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

**C. PARLIAMENTARY PROCEDURES**

No procedures or business of the NOSB shall be taken in conflict with OFPA, FACA, or other pertinent laws (herein referred to as governing legislation). For parliamentary procedure, all motions and votes not covered under the governing legislation shall be governed by this Policy and Procedures Manual, if directly addressed. If procedures, motions, and votes are not directly addressed in the Policy and Procedures Manual, they shall be governed by Robert’s Rules of Order Newly Revised. The NOSB adopted the use of Robert’s Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA, and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

**D. NOSB DELIBERATIONS AND RECOMMENDATIONS**

Board actions include, but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments\* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

**\* Substantive vs. non-substantive amendments.**

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is

substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests.
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal.
- The extent to which the effects of the recommendation differ from the effects of the proposal.

#### **Procedure for submitting final recommendations to NOP**

Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

##### **Each proposal lead prepares the following documents:**

- A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
- The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, ~~sign and date them~~, and then forward them to the Board Chair and the DFO/ACS.

#### **E. PUBLIC COMMENT**

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals are encouraged to submit written comments and may also present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

##### **Comments Before Public Meetings:**

###### **Written comment:**

All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to ~~read~~ **consider** comments in advance, ~~eliminate or decrease the need for paper copies to be distributed during the meeting, and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.~~

Commenters shall refrain from including personal attacks or remarks that might ~~impugn~~ **malign** the character of any individual.

###### **Oral Comments**

Individuals may **have the opportunity to** present oral comment at either a pre-meeting webinar or at the in-person NOSB meeting. Public notice of ~~such electronic meetings~~ **pre-meeting webinars** will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give

the NOSB more time to absorb the information. ~~Transcripts of such electronic webinar meetings shall be recorded and made available to the public and to NOSB members.~~

#### **Comments at In-Person Public Meetings:**

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice. ~~for the meeting.~~ Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to ~~consider~~ read comments in advance ~~electronically, and decreases the need for paper copies to be distributed during the meeting.~~
- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.
- Persons must give their name and affiliation for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comments may be scheduled according to topic.
- Individuals providing public comment shall refrain from making any personal attacks or remarks that might ~~impugn~~ ~~malign~~ the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

#### **Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)**

- The NOSB and NOP seek public communication outside of ~~biannual~~ Board ~~biannual~~ meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.
- The NOSB may post draft discussion documents and proposals between public meetings for review and public comment. Timely submission of comments will assist the NOSB and its Subcommittees in revising such documents for subsequent NOSB review.

## **F. ELECTION OF OFFICERS**

### **Nominations**

- Any NOSB member is eligible for consideration for any officer position
- An NOSB member may self-nominate or may be nominated by another member of the NOSB
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Committee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term
- Members may serve more than one term in any officer position.

#### **Voting schedule**

- Officers shall be elected for one-year terms by majority vote at the fall NOSB meeting.
- Newly elected officers will assume their positions at the conclusion of the Fall NOSB meeting, and assume the responsibilities thereof at that time
- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

#### **Counting of Votes**

- Voting will be by secret ballot immediately following nominations for each office.
- Ballots for officers will be cast in the following order:
  1. Chair
  2. Vice Chair
  3. Secretary
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations.
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote.
- The Secretary will tally the votes and the Chair will verify the results-, **unless the Secretary and/or Chair is running for an executive position, in which case, the Chair will delegate this responsibility.**
- The first nominee to receive a majority of votes will be elected. If no nominee receives the majority of votes, the nominee with the least votes will be eliminated and a revote will occur with the remaining candidates. This process will be repeated until a nominee obtains a majority.
- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote.
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.
- A nominee may withdraw at their discretion at any time.
- In the event of **there is** only one nominee for office, the vote may be by acclamation.

### **G. MISCELLANEOUS PROCEDURES**

#### **1. Invited Speakers**

- Subcommittees, the NOSB, or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.
- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.
- Speakers must be approved and invited by the NOP.

If approved by the NOP, the purpose for the presentation, the subject area and the

bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.

Speakers are expected to disclose any financial interests ~~that he or she has~~ that can be reasonably assumed to influence his or her presentation content.

## **2. Surveys Conducted on Behalf of NOSB Subcommittees**

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Committee before they are submitted for approval to USDA, and
- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

## **IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL**

- The PDS will review the PPM **as needed** ~~each year~~ and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.



## **X. APPENDICES**

### **A. Appendix 1: FOUNDATIONS**

#### **1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING**

(NOSB Recommendation Adopted October 17, 2001)

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

1.2 An organic production system is designed to:

- 1.2.1 Optimize soil biological activity;
- 1.2.2 Maintain long-term fertility;
- 1.2.3 Minimize soil erosion;
- 1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
- 1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
- 1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
- 1.2.7 Minimize pollution of soil, water, and air; and
- 1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

- 1.3.1 Providing good quality organically grown feed;
- 1.3.2 Maintaining appropriate stocking rates;
- 1.3.3 Designing husbandry systems adapted to the species' needs;
- 1.3.4 Promoting animal health and welfare while minimizing stress; and
- 1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

- 1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
- 1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
- 1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;

- 1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and
- 1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.
- 1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
- 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
- 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
- 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
- 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
- 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.
- 1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

## **2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING** (NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

### 3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

#### **Duty of Care**

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

#### **Duty of Loyalty**

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In discharging their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.
- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

#### **Duty of Obedience**

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

## B. Appendix 2: FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years, or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Committee Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
  - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin.
  - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin.
  - ~~The NOP will strive to p~~ublish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" **in which the NOSB and NOP can receive** public comment ~~can be received by the NOP and NOSB~~. Notwithstanding the above, the NOP will publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage: [www.gsa.gov/faca](http://www.gsa.gov/faca)



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Carbon Dioxide  
February 6, 2023**

**Summary of [Petition](#):**

Carbon dioxide (CO<sub>2</sub>) was petitioned in 2020 to be added on the National List of Allowed and Prohibited Substances, for use as a plant or soil amendment at §205.601(j). The same petition requested the addition of carbon dioxide at §205.601(a) of the National List for use as an algicide, disinfectant, and sanitizer, including uses in irrigation systems, to acidify irrigation water. (The petition heavily focused on the use as an algicide, disinfectant and sanitizer in irrigation systems, and did not provide enough information about the material as a plant or soil amendment. Under “the intended use or current use of the substance” the petitioner stated “Carbon dioxide is used in a water pH adjustment process. Dissolved carbon dioxide in water makes carbonic acid, which reduces water pH, therefore increasing H<sup>+</sup> concentration and neutralizing bicarbonates. Water pH adjustment is common practice in agriculture. Irrigation water sources are usually alkaline and with bicarbonates above the maximum desired levels for proper irrigation water quality.”

In 2022, the NOSB recommended the National Organic Program add carbon dioxide at §205.601(a) but requested a full-scope technical report (TR) to address the sections of the petition requesting the addition of carbon dioxide at §205.601(j), as a plant or soil amendment, before making a second recommendation).

The 2023 Technical Report outlined the specific use of the petitioned material as an atmospheric adjustment in indoor production. In the report, we find that ambient air contains 350-450 ppm CO<sub>2</sub>, while the optimal concentration of CO<sub>2</sub> for plant growth in a greenhouse environment is 800-1000 ppm (Poudel & Dunn, 2017; Thomson et al., 2022; Wang et al., 2022). As plants grow, they metabolize CO<sub>2</sub> in the air of the greenhouse, depleting it to 100-250 ppm during peak CO<sub>2</sub> consumption. Venting the greenhouses to allow more atmospheric CO<sub>2</sub> in disrupts the controlled temperature. Ventilation alone cannot maintain constant CO<sub>2</sub> concentrations within the greenhouse at a level comparable to that outside the greenhouse. Natural turnover of air by venting may help to moderate CO<sub>2</sub> levels during warm months, but venting is usually not practical during colder periods or in colder regions, and supplementation is needed.

**Subcommittee Review:**

Because there was a lack of information in the petition about the importance or need for the substance to be listed as a crop or soil amendment, the Subcommittee has been hesitant to recommend its listing. The TR only listed its use as a plant or soil amendment in indoor production. The Subcommittee recognizes that this petition highlights the lack of clear standards pertaining to indoor and container production, and prevents the NOSB from fully evaluating petitions for substances used in this type of production.

One member stated experience with the substance and its noticeable increase in production potential, while another questioned its necessity ;i.e., Is this material truly necessary to organic production or is it used as a booster like synthetic fertilizers or substance of high solubility . The Crops Subcommittee contacted organic greenhouse producers and found that CO<sub>2</sub> was not needed nor supported for use. These producers were in the Southeast where average temperatures are warmer, and venting is less limited compared to colder climates. The Crops Subcommittee requested a greater explanation of the greenhouse gas effects of this material in its manufacture and use and how it ties to climate change.

## Category 1: Classification

1. For CROP use: Is the substance \_\_\_\_\_ **Non-synthetic** or \_\_\_X\_\_\_ **Synthetic**?  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using [NOP 5033-1](#) as a guide.

Carbon dioxide is the byproduct of many chemical and biological processes with fuel combustion and fermentation being the most prominent. The combustion of natural gas results in CO<sub>2</sub> and water vapor and CO<sub>2</sub> may be produced as a by-product of carbohydrate fermentation by yeast in the production of ethanol or alcoholic beverages (TR, 2023).

2. Reference to appropriate [OFPA](#) category:  
Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

CO<sub>2</sub> does not contain an active ingredient in any of the categories listed above. However, it is listed on 2004 EPA List 4A and was not revoked under NOP 5008, Guidance: Reassessed Inert Ingredients. As an insecticide, “carbon dioxide is exempted from the requirement of a tolerance when used after harvest in modified atmospheres for stored insect control on food commodities” per 40 CFR 180.1049 (TR, 2023).

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

At normal temperatures, CO<sub>2</sub> does not break down into simpler compounds, and it is not very reactive. While unlikely to be an issue in organic crop production, CO<sub>2</sub> can react with hydrogen gas to form carbon monoxide (CO). It can also react with ammonia to form ammonium carbamate, which when dehydrated then forms urea (TR, 2023).

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

According to the TR, higher concentrations of CO<sub>2</sub> can benefit plants, but soil composition, nutrient availability, plant species, and plant genetics all influence the response. The technical review referenced a study finding that plants in growth chambers showed symptoms of toxicity when subjected to 2000 ppm CO<sub>2</sub>. It can also be toxic to microorganisms, and animals at significantly elevated levels. No information that specifically indicated that carbonate (CO<sub>3</sub><sup>2-</sup>) or bicarbonate (HCO<sub>3</sub><sup>-</sup>) ions, formed from the dissolution of CO<sub>2</sub> in water, are toxic to plants.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]



CO<sub>2</sub> used in agriculture will largely be derived from fossil fuels, previously stored in the lithosphere, and will re-enter the carbon cycle temporarily persisting or concentrating in one of the three other major reservoirs: the terrestrial biosphere, the hydrosphere (oceanic reservoir), or atmosphere. Gaseous CO<sub>2</sub> is relatively stable in the atmosphere.

CO<sub>2</sub> plays an essential role in soil pH and aquatic environments because of the carbonic-acid system. In contact with water, a proportion of CO<sub>2</sub> dissolves until equilibrium is reached between CO<sub>2</sub>, bicarbonate (HCO<sub>3</sub><sup>-</sup>), carbonate (CO<sub>3</sub><sup>2-</sup>), and carbonic acid (H<sub>2</sub>CO<sub>3</sub>). A greater proportion of CO<sub>2</sub> shifts the equilibrium to the formation of carbonic acid resulting in lower pH (TR, 2023).

In the atmosphere, CO<sub>2</sub> absorbs longwave radiation coming from the earth's surface, causing warming known as "the greenhouse effect." Greenhouses usually have a CO<sub>2</sub>-use efficiency of less than 60%, meaning that over 40% of the CO<sub>2</sub> that is added is released into the atmosphere without being ever incorporated into plant biomass.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

According to the TR, CO<sub>2</sub> can be defined as a toxicant since it induces unconsciousness, respiratory failure, inflammation, and sensory impairment. Instances of CO<sub>2</sub> poisoning are exceedingly rare events. The concentrations found in nature, in typical industrial settings, or used in greenhouses, are far lower than any of the concern levels listed above and are not a threat to human health. Adverse effects generally begin following exposure to 1% or greater CO<sub>2</sub>, while background atmospheric levels are approximately 0.04% and enriched greenhouse atmospheres are approximately 0.1%. Confined areas like mines, silos, or fermentation chambers, for example, may be environments where CO<sub>2</sub> concentrations can surpass 1%, sometimes significantly. The current OSHA Permissible Exposure Limit (PEL) for 8-hour exposure to gaseous CO<sub>2</sub> is 5,000 ppm, or 0.5%.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Lowering the pH to 6.0-6.8 can improve the bioavailability of some nutrients, such as iron, zinc, boron, and manganese. Cation availability can also increase due to increased weathering of parent material and minerals, therefore affecting soil chemistry. In wet environments or where large amounts of irrigation are used, these effects can leach these available cations (TR, 2023).

At low concentrations (up to about 1200 ppm), CO<sub>2</sub> is generally safe and has low toxicity, and can have substantial beneficial effects to plants. However, at moderate concentrations (1200 ppm to several percent, depending on duration and tolerance of a given species, CO<sub>2</sub> can cause toxic effects in plants and animals. At high levels (>~50%), it can be toxic to microorganisms as well.

Decreasing water pH can increase the toxicity of copper for *Arenicola marina*, an aquatic segmented worm.

6. Are there any adverse impacts on biodiversity? (§205.200)

Applying CO<sub>2</sub> at higher than optimum levels could cause toxicity to a wide variety of organisms. This situation is unlikely, however, because it would also begin to exert negative growth effects on crops, thus defeating the purpose of its use.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There is no substitute for gaseous CO<sub>2</sub> in plant biology. It is an essential component of the photosynthesis process.

It is possible to produce CO<sub>2</sub> nonsynthetically using fermentation processes or extraction from natural CO<sub>2</sub> wells but the prevalence and availability of different CO<sub>2</sub> production streams is difficult to define, is determined by regional industry and transport infrastructure, and by the nature of the commodified raw chemical material market because many streams may be combined. Previous written comments have indicated that inadequate infrastructure and costly transport restricts the source of nonsynthetic carbon dioxide. The commentor also stated fermentation businesses were often using the CO<sub>2</sub> for carbonating fermented beverages.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

CO<sub>2</sub> can be used for agriculture without adding harm to the environment. Because it is a byproduct of multiple manufacturing processes, the "production" of CO<sub>2</sub> is occurring regardless of its use in organic agriculture. If it weren't used, it would be released into the atmosphere. Although its use does not reduce emissions because the CO<sub>2</sub> is only temporarily stored in the plant and then re-enters the carbon cycle, the Crops subcommittee did have questions regarding the greater explanation of the overall greenhouse gas effects of this material in its manufacturing and use, especially how it ties into climate change for this particular petitioned usage. The Crops Subcommittee is not recommending adding Carbon Dioxide to the National List due to it not being necessary for organic crop production."

#### **Stakeholders Question:**

How should NOSB evaluate necessity and compatibility with sustainable production for CO<sub>2</sub> without clear production standards for greenhouse and indoor production?

#### **Classification Motion:**

Motion to classify carbon dioxide as synthetic.

Motion by: Logan Petrey

Seconded by: Nate Lewis

Yes: 6 No: 0 Abstain: 1 Recuse: 0 Absent: 2

#### **National List Motion:**

**Motion to add carbon dioxide at §205.601(j).**

Motion by: Logan Petrey

Seconded by: Nate Lewis

Yes: 0 No: 6 Abstain: 1 Recuse: 0 Absent: 2

**National Organic Standards Board  
Crops Subcommittee  
Discussion Document: Compost  
February 13, 2024**

**Introduction:**

Compost and the process by which it is produced are defined in the organic regulations at §205.2 Terms Defined. Additionally, §205.203(c) of the soil fertility and crop nutrient management practice standard outlines further requirements for processing and applying plant and animal materials under the organic regulations. The section emphasizes that an organic producer “must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances”. The National List § 205.601 provides for one synthetic exception to plant and animal material composition of organic compost, with a listing for newspaper as a compost feedstock.

Certain types of compost and manure-based inputs commonly used in organic farming were not directly addressed in the rule, such that additional information and rule clarification was needed. Two different task forces were commissioned to make recommendations on compost, vermicompost, processed manures, and compost tea. In April 2002 the Compost Task Force Recommendation was presented to the NOSB and subsequently accepted as a recommendation to the NOP. In October 2004, a separate report and recommendation was presented to the NOSB by the Compost Tea Task Force. That document was also accepted by the NOSB, and the Crops Committee was directed by the Board to determine the necessary work that needed to be done to clarify these documents to the public. In October 2006, the Crops Subcommittee produced a document titled: Crops Subcommittee Recommendation for Guidance Use of Compost, Vermicompost, Processed Manure, and Compost teas, which was accepted by the NOSB. The NOP responded to those recommendations with Guidance document NOP 5021 with the stated purpose of clarifying “allowed practices for composition, production, and use of compost and vermicompost in organic crop production”. In December of 2016, the NOP published information regarding alternative compost methods in NOP 5034-1 Materials for Crop Production.

Given the efforts to address climate change through waste reduction and recycling, and to continuously improve and provide clarity of the organic standards and rules, the NOSB and NOP have been discussing ways to update organic definitions and regulations regarding organic compost production. These discussions led to an official work agenda request to the NOP in September of 2023. Concurrently, in August of 2023, the Biodegradable Product Institute (BPI) submitted a petition for rulemaking directly to the United States Department of Agriculture (USDA), requesting that AMS change the definition of compost and add a definition of “compost feedstock” to the federal organic regulations at § 205.2. Further, the petition seeks amendments to § 205.203, see Appendix A. In October of 2023, the NOP issued a [Memorandum to the National Organic Standards Board](#) requesting a recommendation on the topic of compost in organic agriculture.

This discussion document intends to provide a forum for the NOSB, NOP, and the stakeholder community to gain insight into the current state of organic compost production, towards updating the regulations and addressing the issues raised by the petition via the public process of stakeholder engagement through oral and written comments.

## Background

1. Compost is defined in the regulations at §205.2:

*Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.*

2. Compost appears at §205.203 the Soil Fertility and Crop Nutrient Management Practice Standard

*(2) Composted plant and animal materials produced through a process that:*

*(i) Established an initial C:N ratio of between 25:1 and 40:1; and*

*(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or*

*(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.*

3. Compost Feedstocks are referenced on the National List § 205.601 “Synthetic substances allowed for use in organic crop production” [Bold emphasis added below]

*In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: **Provided, That, use of such substances do not contribute to contamination of crops, soil, or water.** Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in [paragraphs \(c\), \(j\), \(k\), \(l\), and \(o\)](#) of this section, may only be used when the provisions set forth in [§ 205.206\(a\)](#) through [\(d\)](#) prove insufficient to prevent or control the target pest.*

*(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.*

4. Nonsynthetic (natural) is defined in the regulations at §205.2

*Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act ([7 U.S.C. 6502\(21\)](#)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.*

5. (UREC) is defined in the regulations at §205.2

*Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.*

6. [NOP Program Handbook](#) related Guidance:

NOP 5006: Processed Animal Manure in Organic Crop Production

NOP 5021: Compost and Vermicompost in Organic Crop Production

NOP 5034-1: Materials for Organic Crop Production

\*\*\*Note: 5034-1 lists Compost: nonsynthetic (natural) material for Organic Crop Production

NOP 2602: Recordkeeping of Certified Operations

NOP 2610: Sampling Procedures for Residue Testing PM 11-4: Evaluation of Materials Used in Organic Crop, Livestock, and Handling Operations

\*NOP 5016: Allowance of Green Waste in Organic Production Systems (\*removed in 2016\*)

7. Information regarding “Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic” or “made with organic (specified ingredients or found group(s))” can be found at [§205.670](#)

8. [NOP Preamble on Residue Testing](#) [*Bold emphasis added*]

*In addition, we intend to establish levels of unavoidable residual environmental contamination (UREC) for crop-and site-specific agricultural commodities to be sold, labeled, or represented as "100 percent organic," "organic," or "made with..." These levels will represent limits at which USDA may take compliance action to suspend the use of a contaminated area for organic agricultural production. Currently, USDA is seeking scientifically sound principles and measures by which it can establish UREC levels to most effectively address issues of unavoidable residual environmental contamination with respect to this rule. However, in the interim, UREC will be defined as the Food and Drug Administration's (FDA) action levels for poisonous or deleterious substances in human food or animal feed. UREC levels will be initially set for persistent prohibited substances (aldrin, dieldrin, chlordane, DDE, etc.) in the environment. They may become more inclusive of prohibited residues as additional information becomes available. Unavoidable residual environmental contamination levels will be based on the unavoidability of the chemical substances and **do not represent permissible levels of contamination where it is avoidable.***

**Relationship to other regulations:**

1. EPA indicates where Compost is regulated and establishes a Process to Further reduce Pathogens (PFRP)
  - a. [EPA](#): “Composting policies and regulations are set at the state and local government level.”
  - b. [Process to Further Reduce Pathogens \(PFRP\) is based on USEPA 40 CFR Part 503](#)

**Appendix B to Part 503—Pathogen Treatment Processes**

## A. Processes To Significantly Reduce Pathogens (PSRP)

[excerpted]

“4. Composting—Using either the within-vessel, static aerated pile, or windrow composting methods, the temperature of the sewage sludge is raised to 40 degrees Celsius or higher and remains at 40 degrees Celsius or higher for five days. For four hours during the five days, the temperature in the compost pile exceeds 55 degrees Celsius.”

[.....]

## B. Processes to Further Reduce Pathogens (PFRP)

1. Composting—Using either the within-vessel composting method or the static aerated pile composting method, the temperature of the sewage sludge is maintained at 55 degrees Celsius or higher for three days. Using the windrow composting method, the temperature of the sewage sludge is maintained at 55 degrees or higher for 15 days or longer. During the period when the compost is maintained at 55 degrees or higher, there shall be a minimum of five turnings of the windrow.

[.....]

2. [FDA’s regulations](#) in response to the Food Safety Modernization Act (FSMA) place requirements on producers of fresh produce who use composted biological soil amendments of animal origin.
3. [The Leafy Greens Marketing Agreement](#), a private industry verification of the requirements in the FSMA for compost, aimed at reducing foodborne illnesses.
4. [National Resources Conservation Service](#) provides farmers with technical assistance and cost-sharing of infrastructure investments related to composting of manure, livestock mortalities, and processing offal (317) – establishing a compost site/facility
  - a. Makes general recommendations on time and temperature, etc.
  - b. “C:N Ratio. – Developing a composting recipe is a balancing act as both the C:N ratio and the moisture content of the individual materials need to be within acceptable ranges. The recommended initial C:N ratio of 20:1 to 40:1 for rapid composting is consistent with the nutrient needs of the bacteria and fungi in the compost pile. The composting process relies on the balance of carbon- and nitrogen-containing materials. If carbon is present in excessive amounts relative to nitrogen so that the C:N ratio is above the optimal range, the composting process slows. For composting animal mortalities, C:N ratios as low as 14:1 may be effective and practical. Lower C:N ratios may lead to increased odor and ammonia loss.”
  - c. “For processing compost in either a static aerated pile or in-vessel compost system, the temperature of the compost is required to be maintained between 131°F and 170°F for 3 days”
  - d. “For windrow system the temperature of the compost is required to be between 131°F and 170°F for 15 days with a minimum of 5 turnings of the compost to ensure the windrow is mixed and evenly composted”

5. Federal Trade Commission – [Green Guides](#) provides guidelines for ensuring the accuracy of product claims of “Compostable” and “Degradable”:
  - a. Green Guide is not a regulation, indicates when FTC may find labelling claims to be deceptive
  - b. Can take action to prohibit deceptive claims if the FTC chooses
  - c. Compostable:
    1. “Marketers who claim a product is compostable need competent and reliable scientific evidence that all materials in the product or package will break down into — or become part of — usable compost safely and in about the same time as the materials with which it is composted.”
    2. “Marketers should qualify compostable claims if the product can’t be composted at home safely or in a timely way. Marketers also should qualify a claim that a product can be composted in a municipal or institutional facility if the facilities aren’t available to a substantial majority of consumers.”
  - d. Degradable:
    1. “Marketers may make an unqualified degradable claim only if they can prove that the “entire product or package will completely break down and return to nature within a reasonably short period of time after customary disposal.” The “reasonably short period of time” for complete decomposition of solid waste products? One year.”
    2. “Items destined for landfills, incinerators, or recycling facilities will not degrade within a year, so unqualified biodegradable claims for them shouldn’t be made.”

#### **Subcommittee Review:**

The Crops Subcommittee is seeking information in all areas of regulations surrounding compost making. This discussion document seeks to lay a foundation for future NOSB recommendations to update the organic definitions and regulations, taking into consideration the changes in the compost industry, regulatory emphasis on food safety, and the Petition to the USDA by BPI.

The Subcommittee discussed possible avenues for managing the National List, when considering the implications of classifying materials as synthetic in the context of naturally occurring biological processes for compost feedstocks.

In general, the CS sees the presence of newspaper as a compost feedstock on the National List as an indicator that when synthetic inputs enter into naturally occurring biological processes like composting and fermentation, the product does not automatically result in an allowed substance.

By that logic, the path for making determinations about allowed compost feedstocks beyond plant and animal material is through the National List process for making synthetic allowances is the common practice in organic.

Currently it is the view of the Subcommittee that any synthetic feedstocks must be included on the National List, or it is assumed that it is not allowed. This has been practiced in compost as demonstrated by the investment in depackaging and sorting by the industry and the evaluation by Material Review Organizations (MROs) or during OSP review for certification.

However, the Subcommittee also recognizes that myriad traces of synthetic substances do enter the waste stream and end up as components of otherwise allowed feedstocks to compost (e.g. fruit stickers, pesticide residues in yard waste, antibiotics in livestock manure, etc.). Composters, in general, work

diligently to remove these contaminants from their process at the point of collection, mixing, and screening of the final product, but their systems cannot remove 100% of the contaminants every time. In the current evaluation of compost used in organic production, the presence of these ‘contaminants’ does not automatically render the compost prohibited for use, and there is lack of clarity around what level of contamination is acceptable in compost used in organic production.

The Subcommittee is currently in discovery mode. This discussion document is an opportunity to engage the expertise of the community towards the goal of updating the regulations while addressing the issues raised by BPI in its petition.

### **Questions/Information Requests:**

#### **1. Time and Temperatures at § 205.203(c)**

*(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or*

*(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.*

- a. Comment on this suggested language update and additional method for **§ 205.21(c)**:
  - ii) forced aeration compost/aerated static pile construction*
  - iii) windrow/passively aerated composting systems*
  - iv) contained and in-vessel composting method*
- b. Are there other alternative methods in composting that should be specifically outlined?
- c. Recommend specific language updates to temperature and turn intervals for each.
- d. Provide perspective on the “15 days” requirement for windrows. Should the regulations reflect a window of time to complete PFRP? i.e. should the language stipulate the completion of windrow turnings in 15 days or should organic establish a time range or a time limit for the completion of PFRP?

#### **2. Carbon to Nitrogen Ratios** at § 205.2 and § 205.203 refer to a *C:N ratio of between 25:1 and 40:1*.

Please suggest an update to the range of C:N ratios allowed in organic compost; include a rationale for how it complies with organic principles. Should this range be stipulated as formulated in the recipe stage (via testing or generally available information about feedstocks?) or final composition via a testing requirement?

**3.** How should the Subcommittee weigh the distinction between UREC and ‘Contamination’, as described in the NOP Preamble and testing requirements, against the current realities of contamination inherent in the rapidly growing organic compost industry? How should compliance verification for organic compost orient around the requirements at [§ 205.670](#)?

**4. Contamination.** Currently, organic compost operations, MROs, and inspectors are treating all material that is not of plant or animal origin as contamination. Every effort is made by composters to remove contamination from feedstocks before the composting process.

- a. Describe the effort to remove contamination from compost feedstock; i.e. Education to public? Desorting/depackaging machines?
- b. It is widely acknowledged that some level of pesticides, heavy metals, PFAS, glass, plastic, etc. enters the composting process. When and how should organic draw the line on contamination?



5. The BPI petition requests amending the definition of ‘compost’ eliminating the reference to “plant and animal materials,” replacing the phrase with “compost feedstocks” and adding a definition for “compost feedstocks” which includes synthetic substances that meet certain [ASTM International](#) standards. What do organic stakeholders think of this approach to compost feedstock evaluation? Should a definition for “compost feedstocks” rely on ASTM standards for allowance determinations?
6. The BPI petition also introduces the concept of ‘de minimus’ into final compost product evaluation. Should the organic system embrace the concept of ‘de minimis’ traces of prohibited substances as a platform to acknowledge where and when the organic system cannot control/eliminate contamination?
7. Should the National List include broad classes of substances (e.g. newspaper and other recycled paper) or individual substances (e.g. specific compostable polymers) or both?
- Compostable paper
  - Compostable plastic
  - Stickers
  - Food waste bags
- 8. Testing/Research**
- a. [The Organic Materials Review](#) Institute (OMRI) requires organic compost producers to provide lab analyses that report certain heavy metal content (As, Cd and Pb) and pathogen levels (fecal coliform and salmonella). Are there other testing requirements by MROs and certifiers?
  - b. Should inspections be required for all compost operations producing organic compost?
  - c. Given that compost labs are routinely performing a wide variety of tests on both feedstocks to develop recipes for compost and tests to establish the constituents of finished compost, how should organic regulations use residue testing to ensure final product quality? Should we prioritize the tests which are most pressing from a contamination perspective and representative of issues concerning organic systems of agriculture? What are those most pressing issues?
  - d. Certifiers have the authority to test compost for contamination at 205.670. How can this testing authority be used to address contamination concerns in compost?
  - e. Provide data on practical experience, research and testing on the following:
    - i. Persistence of contaminants (pesticides, antibiotics, heavy metals, plastic, pathogens, etc.) through composting process, expense of testing, broad based testing, availability/accessibility of testing laboratories for smaller producers;
    - ii. Breakdown of paper products in compost;
    - iii. Breakdown of “compostable” plastic products in compost
    - iv. Operations who have succeeded at accepting food waste with compostable packaging, or discussions that have occurred around diversifying food waste collections systems that could allow food waste to be collected with compostable packaging.
9. Organic regulations often rely on external agencies to determine the framework for its authority. Please describe the path for regulatory authority in the packaging industry and whether organic regulations should or can establish an authority over compostability/biodegradable packaging claims.

Motion to accept the discussion document on Compost

Motion by: Nate Lewis

Seconded by: Jerry D’Amore

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 2





## Sunset 2026

### Meeting 1 - Request for Public Comment

### Crops Substances § 205.601 & § 205.602

April 2024

#### Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's [Petitioned Substances Index](#).

#### Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2024 public meeting. Written comments should be submitted via Regulations.gov at [www.regulations.gov](http://www.regulations.gov) 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 Support 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 Do Not Support 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 new information since its last NOSB review to demonstrate that the substance is:

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

**For Comments that Support the Continued Prohibition of 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 Do Not Support 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 new information since its last NOSB review to demonstrate that the substance is:

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

**For Comments Addressing the Availability of Alternatives:**

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

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

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

Written public comments will be accepted through April 3, 2024 [www.regulations.gov](http://www.regulations.gov). 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 H<sub>2</sub>O<sub>2</sub>. 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 (H<sub>2</sub>) and oxygen (O<sub>2</sub>): H<sub>2</sub>+ O<sub>2</sub>→H<sub>2</sub>O<sub>2</sub>

#### 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)

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

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 specify 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 repellent only, no contact with soil or edible portion of crop.

**Technical Report:** [1996 TAP](#); [2019 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB 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

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/demosers ((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)

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

Not explicitly mentioned

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

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:** [1995 TAP](#); [2019 TR](#)

**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 ([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

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 stilet 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)

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

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).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

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 granulosus 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:** [1995 TAP](#); [2019 TR](#)

**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 ([77 FR 33290](#)); Renewed 03/15/2017 ([82 FR 14420](#)); Renewed 8/3/2021 ([86 FR 41699](#))

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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)

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

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:** [1995 TAP](#); [2012 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB 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

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**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

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)

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

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 aurally 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 ([71 FR 53299](#)); Renewed 08/03/2011 ([76 FR 46595](#)); Renewed 09/12/16 ([81 FR 8821](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**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)

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

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  $KHCO_3$ . 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)

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

Allowed for the production and conservation of organic grapevine products (Annex V, Part D, 2021/1165)

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

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 amyliquisfaciens* strain D747, *Bacillus subtilis*, *Bacillus pumilis*, gibberellic acid and *Streptomyces griseoviridis* 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:** [1995 TAP](#); [2011 TR](#)

**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 joint 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)

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

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](#))

**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**

[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 for crop production. Allowed in the preparation of foodstuffs of animal origin for gelatine production (Annex V, Section A2, 2021/1165)

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

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).

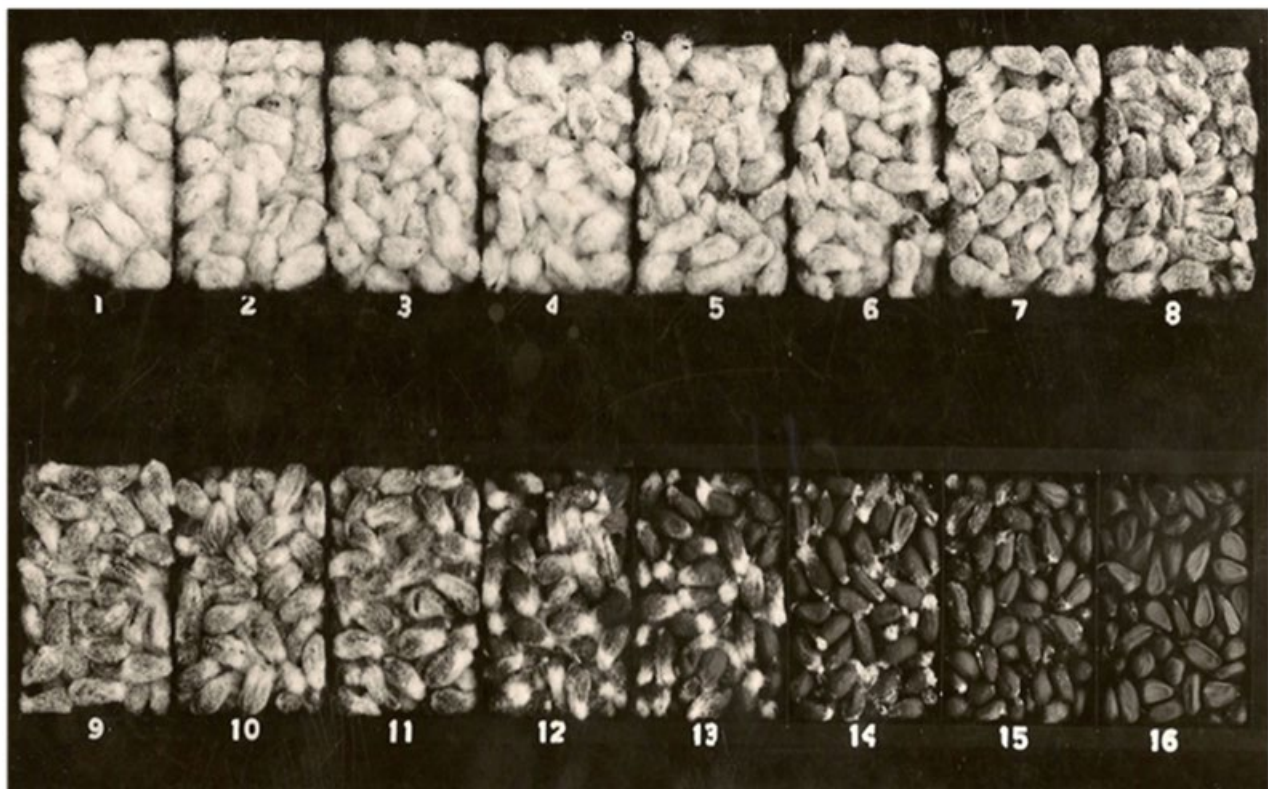
The TR also provided insight into alternative practices that could be used to delint cotton outside of chemical means involving acid, which includes mechanical delinting, flaming, or breeding fuzzless seed.

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](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 re-feeding 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 bark, organic waste, animal bedding, livestock manure, poultry litter, sewage sludge, paper sludge, and municipal waste

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

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

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

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 high-temperature 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, its 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.”<sup>1</sup>

Sodium fluoaluminate (Na<sub>3</sub>AlF<sub>6</sub>)—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

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<sup>1</sup> [https://www3.epa.gov/pesticides/chem\\_search/reg\\_actions/reregistration/fs\\_PC-075101\\_1-Aug-96.pdf](https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-075101_1-Aug-96.pdf)

[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”<sup>2</sup> 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?

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<sup>2</sup>[https://www.fluoridealert.org/wp-content/uploads/cryolite.summary.epa\\_.2011.pdf](https://www.fluoridealert.org/wp-content/uploads/cryolite.summary.epa_.2011.pdf)





**National Organic Standards Board**  
**Certification, Accreditation, Compliance Subcommittee (CACS)**  
**Oversight to Deter Fraud: Residue Testing for a Global Supply Chain**  
**Discussion Document**  
**February 6, 2024**

**Introduction:**

The Certification, Accreditation, & Compliance Subcommittee (CACS) presented a [discussion document](#) at the Fall 2023 NOSB meeting on Residue Testing for a Global Supply Chain (RTGSC). Many commenters supported continuous improvement in testing to ensure integrity, considering the size of the organic marketplace and the program's global reach.

The RTGSC series aims to work with the community to provide a recommendation that ensures testing remains a relevant and effective tool for compliance verification in the organic global supply. A fall public commenter in support wrote, "An updated and more rigorous testing program will augment the ability for both ACAs and certified operations to verify compliance, deter fraud, and prevent contaminated/fraudulent products from entering organic supply chains."

**Foundational Focus and Timing:**

Foundational work is needed first to accomplish the goals. Therefore, this document will focus on working with the organic stakeholder community to update the foundational elements found in the respective related guidance and instruction documents. As one commenter stated, "...ensure there can be clarity and consistency in the testing and response practices."

**Next Steps:**

CACS is open to general feedback about the importance of residue testing, suggestions for incorporating residue testing more thoroughly in the organic compliance verification process, and barriers to implementing residue testing programs in the organic supply chain. Additionally, CACS has several questions about residue testing document instructions in the [NOP Handbook](#).

CACS will consider all general and specific comments in developing recommendations to NOP.

**Stakeholder Questions:**

[NOP 2610: Instruction Sampling Procedures for Residue Testing](#)

1. Does this document instruction provide adequate information for certifiers and inspectors to collect samples in the field?
2. Are there areas pertaining to sample collection (sample size, when to collect samples, sample selection, etc.) that need to be developed or improved? Please provide suggestions.
3. How can additional instruction or guidance on sample collection support the veracity of testing results so that adverse actions are more defensible?

[NOP 2611: Instruction Laboratory Selection Criteria for Pesticide Residue Testing](#)

1. Section 4.1 describes one type of residue screen that can be used for testing. What additional tests should be included in this section (e.g., heavy metals, synthetic solvents, fumigants,

herbicides, etc.)? What should be the threshold for validating additional testing methodologies in this section to ensure results are actionable?

2. Sections 4.2 and 4.3 describe laboratory selection criteria and suggested laboratory practices. Do either of these sections need to be updated to align with current best practices?
3. How can additional instruction or guidance on laboratory selection criteria and testing methodology support the voracity of testing results so that adverse actions are more defensible?

#### [NOP 2611-1: Prohibited Pesticides for NOP Residue Testing](#)

1. Does this list of prohibited substances provide value to certifiers in evaluating organic compliance?
2. How can this document be improved?
3. Would certifiers find value in developing a decision tree to determine which tests should be conducted depending on the commodity, geographical location, and position within the supply chain? Please describe how a decision tree could assist certifiers with testing and compliance verification.

#### [NOP 2613: Instruction Responding to Results from Pesticide Residue Testing](#)

1. Section 5.3.3 describes how to respond to positive results when there is no EPA tolerance or FDA action level. Please describe experiences attempting to respond to results in this type of situation. How can this section be improved to facilitate and support sampling and testing for prohibited substances that do not have EPA tolerances or FDA action levels (e.g., synthetic solvents)?
2. Are additional sections within this instruction needing updating or improvement? Please provide suggestions.

#### **Subcommittee Vote:**

Motion to accept the discussion document on Residue Testing for a Global Supply Chain

Motion by: Nate Lewis

Seconded by: Kim Huseman

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

**National Organic Standards Board**  
**Certification, Accreditation, Compliance Subcommittee (CACS)**  
**Climate-Induced Farming Risk and Crop Insurance**  
**Discussion Document**  
**February 6, 2024**

**Intro & Background:**

As USDA has recognized Organic farming as climate-smart, the NOSB has worked to identify barriers to farmers' transition to organic and the further retention of existing organic producers. Through robust rounds of public comment, we have heard repeatedly that crop insurance is one program that has an outsized potential to help farmers mitigate the risk of both transitioning to organic and staying organic once they've been certified.

The Director of the Product Administration & Standards Division of the USDA's Risk Management Agency (RMA) gave a presentation on crop insurance at the Fall 2023 meeting in Providence, RI. Her presentation described the crop insurance landscape across the United States and how the agency works diligently to make better insurance products available to more producers.

**Progress:**

The CACS celebrates the progress RMA has made to improve access to crop insurance for organic producers. RMA has attempted to understand how organic farming works and to build better programs for organic farmers. Indeed, several CACS members remarked on how much progress has been made in the past ten years. Some of this progress includes:

1. RMA introduced a contract price addendum that allows transitioning and organic producers to submit their contracts in advance to obtain a higher price for crop coverage.
2. [RMA has launched its 2024 handbook](#), with updated good farming practices (GFP) definitions – making it clear the use of NRCS Conservation Practice Standards will be considered GFP
3. RMA allows enterprise units by organic farming practice.
4. RMA allows enterprise units for specialty and perennial crops
5. The [RMA Agent Finder Web Page](#) connects farmers interested in the Whole Farm Revenue Program/Microfarm Program with agents experienced in writing those policies.
6. Pasture, Forage, Rangeland (PRF) now has organic forage as an option allowing for more suitable organic coverage.

**Continuous Improvement Still Needed:**

Through public comments and various farmer and crop insurance agent interviews, we have heard that while significant progress has been made, there is still work to be done to level the playing field for organic producers. At a minimum, by offering risk management options that do not *disincentivize* the transition from conventional production to organic, the opportunity to participate in the organic marketplace will expand to more producers. Additionally, those certified producers will benefit from more robust, equitable risk management options.

Because the organic marketplace is unique, organic farmers frequently face different risks than their conventional counterparts. The following list includes over-arching opportunities that producers and agents mentioned through public comments and various interviews on how to improve crop insurance to better help organic producers mitigate risk.

*Please note, opportunities 1 and 3, while specific examples, also fall into the greater theme that we heard: organic is unique and would benefit from having a distinct section in the loss adjustment manual.*

**Opportunities for Improvement:**

1. **Quality Factor Consideration During Loss Adjustment:** because of the dynamic food market that corresponds to a more diverse cropping rotation, organic producers raise crops that, to meet the market demand, must meet high-quality specifications. Because they are unique and not readily substitutable into the conventional commodity supply chain, these crops may only have a secondary market, like feed, if they meet the specifications. For this reason, if a farmer does not experience a yield loss but rather a quality loss due to a climatic event, it can be as economically devastating as a complete yield wipeout. For example, when raising blue corn, if a farmer does not have a yield loss but does have a quality loss, they will not be able to sell into the food market. They also cannot sell into the organic feed market as their blue corn may discolor chicken eggs. Their corn cannot be sold into the conventional market because of the colors. Therefore, with no quality coverage, the farmer raising this otherwise in-demand-for-food crop will be left with only the option to compost it—a complete loss with no coverage even though yields were “fine.” \*Note: specific loss adjusting standards for quality are available for some specialty crops, including produce crops.
2. Organic crop insurance requires additional expertise to help farmers maximally. Modeled after the newly created [agent finder for Whole Farm Revenue Protection/Micro Farm Landing Page hosted by RMA](#), it would be an excellent service to organic producers for RMA to create a similar landing page for adjusters and insurance agents who have specific knowledge of organic policies and are interested in working with organic farmers. There are many excellent crop insurance agents and crop adjusters around the country. Still, a farmer's ability to find them is relative to their network in the organic farming world. It is a distinct disadvantage to producers new to organic or farmers outside of organic agricultural hot spots.
3. The time frame for adjusters to review a loss and visit a crop in-field can be the difference between an organic farmer saving the crop after weather damage (currently, adjusters are to visit a field 7-13 days after a climatic event). For example, if a producer has a hail event before organic crops have time to canopy, the producer will experience a burst of weed pressure within one day of the hail event. Because of the potential delay in receiving a visit from an adjuster, the farmer is not allowed to get in the field and address the weeds mechanically without risking losing coverage for the crop. All organic crops need specific “in-field” adjusting standards specific to organic producers.

**Other challenges that producers and agents mentioned include:**

1. By resetting T-yield at the start of transition, producers' coverage is generally decreased compared to conventional counterparts. Note: T-yield, coverage level, and price are the three main factors determining loss payout.
2. There is not a clear path to provide feedback for the Launch of the Good Farming Practices Updated Handbook.
3. Whole Farm Revenue Program (WFRP) – agents cite the complexity (a 50-75 page application) of the program and the lower agent compensation as compared to other insurance as a disincentive for writing those policies.
4. The time required to develop yield history on new crops insured under written agreements can slow their adoption which in turn disincentives producers to diversify their rotation.
5. Producer awareness and understanding of RMA's current policies and programs is inconsistent across the country.
6. The "Transition System Plan" or "Transition Producer Plan" is new and producers transitioning to organic may not have sufficient help to understand the role of the Transition plan in obtaining coverage.
7. Required planting dates can conflict with diverse crop rotations including the incorporation of cover crops.

**Questions for Stakeholders:**

In addition to the summary above, CACS is interested in hearing how T-yields affect transition and organic farmers around the country and what possible solutions we could offer to address them. In addition, CACS is eager to receive more examples and personal stories about how crop insurance can be improved for organic producers.

1. **T-yields (Assigned yields when a producer doesn't have production history):**
  - a. Would organic producers be open to using transitional yield history to accelerate t-yield replacement to build organic yield history faster?
  - b. Would "buy up" coverage above 85%, which is the current limit, to 120% be of interest to obtain more coverage?
  - c. Suppose you have a currently approved production history (APH) for organic production. Would you be interested in having a percentage of that APH carried over to your transition or organic t-yields?
2. What other concerns remain?

**Subcommittee Vote**

Motion to accept the discussion document on Climate-Induced Farming Risk and Crop Insurance

Motion by: Amy Bruch

Seconded by: Nate Lewis

Yes: 6 No: 0 Abstain: 1 Recuse: 0 Absent: 1



**National Organic Standards Board**  
**Certification, Accreditation, Compliance Subcommittee (CACs)**  
**Organic Food System Capacity and Constraints**  
**Discussion Document**  
**February 7, 2024**

**Introduction:**

The organic market continues to be a bright spot in agriculture. With near double-digit growth since 2020, and historic investments by stakeholders, including the USDA, organic holds the promise of being an opportunity for everyone in the supply chain.

The historic investment by USDA in the Transition to Organic Partnership Program (TOPP) represents an unmatched opportunity to help bring new producers into organic certification. While growth in new organic operations is essential, the NOSB heard from public commenters at both the spring and fall 2023 public meetings that current producers around the United States are at risk of exiting certification or refraining from growing their operations due to price instability due to limited market opportunities.

**Background and Comments:**

To encourage farmers to transition there needs to be a consistent market on the other side of that transition. Additionally, several existing organic producers from Montana, Iowa, South Dakota, Nebraska, Texas, and Oregon producers commented that crops such as corn, fruits, vegetables, produce, and soybeans, peanuts, as well as beef, lamb, and dairy said that more robust markets are needed for producers to maintain organic certification. In summary, to retain organic producers who have already transitioned and to allow for more producers that are interested in transitioning, markets must be stable and fair.

Several commenters highlighted the necessity of matching growth in production to demand.

1. A produce wholesaler, “is concerned about the possibility of repercussions in the marketplace if programs encouraging transition are not balanced with an equal, or greater, emphasis on market growth and development.” “...asserts that the organic community must ensure that we are not setting up transitioning farmers for failure or unintended hardship through unrealistic promises of premium pricing and markets for their goods.”
2. A certifier commented, “In the Northwest region there are producers who would grow more certified organic crops if there was a clear market opportunity. Several buyers of organic products in the region have reported a saturation of the organic produce market in specific crop categories, for example. Market data is needed to clearly identify crop categories where demand still exceeds supply or where market expansion opportunities exist. With such insights, pinpointed market development efforts can fill supply gaps and respond to opportunities for growth.
3. An Advocacy group mentioned that we “need a conversation about oversupplied organic markets and where there is a need for more products”
4. An organic consultant stated, “USDA has chosen to launch this program without actually having a goal, and I think that’s problematic...maybe the NOSB could be a factor in getting the department to do that.... creating a dialogue that would help the industry or the community create a goal.....there’s important economic analysis that could be done. ERS should be part of this process to establish.... realistic but ambitious goal that’s differentiated in different segments of the supply chain. And the emphasis absolutely needs to be on domestic production.... we’re relying on imports.”

Part of NOSB's role is to advise the Secretary on implementing the Organic Foods Production Act, and, by extension, the programs the agency develops to support organic. Therefore, the Board believes that examination of current and future markets, gaps in supply chain infrastructure, and market-related risk management tools will support the agency's efforts in transitioning additional producers into organics, retaining current organic producers, and helping to ensure the ongoing success of the organic marketplace.

The CAC Subcommittee's goal is to build on our previous work on climate change that focused on addressing managing on-farm risk. In this phase, we propose examining market development as a risk management tool, where the key risks organic farmers face include price and market access risks.

**Questions to Stakeholders:**

1. Are we retaining our existing organic acres and producers or are we experiencing overall loss of current organic producers?
2. Are existing organic producers expanding or contracting acres of organic production?
3. What additional infrastructure is needed to make organic supply chains more lean and more efficient?
4. What organic processing capability do we need to establish?

**Subcommittee Vote:**

Motion to accept the discussion document on Organic Food System Capacity and Constraints

Motion by: Nate Powell-Palm

Seconded by: Amy Bruch

Yes: 6 No: 0 Abstain: 1 Recuse: 0 Absent: 1



**National Organic Standards Board**  
**Certification, Accreditation, Compliance Subcommittee (CACS)**  
**Improving Support for Organic Transition Proposal**  
**February 13, 2024**

**Introduction:**

The NOSB has gathered information about stakeholder experiences with organic transition programs generally, and USDA’s Organic Transition Initiative (OTI) specifically, to inform this proposal to maximize the benefits of public investments in organic transition and ensure that organic is relevant to a more diverse population – as an environmental stewardship strategy, a career path, and a source of sustenance.

**Background:**

Organic agriculture offers significant climate, health, and economic benefits, for producers and consumers. Organic market growth has been strong for decades, with domestic organic food sales surpassing [\\$60 billion in 2022](#). But still [less than 1%](#) of U.S. agricultural land is managed organically and the U.S. remains a net importer of organic products.

Numerous barriers may deter producers from pursuing organic certification, including – but certainly not limited to: certification costs, challenges with the process, and proximity to certification services and inspection capacity; limited access to land and capital; insufficient regionally-relevant technical assistance for organic management systems; lack of economic opportunities and benefits, including lack of access to regional markets and organic supply chain infrastructure; agricultural training that does not present organic as an option; and inadequate access to organic mentorship and peer networks.

Producers who may be interested in transitioning to organic come from diverse backgrounds and career paths – from farmworkers seeking to become organic farm owners to seasoned producers considering a different approach to farming. This diversity means that the most successful approaches to overcoming barriers may vary significantly. In addition, many beginning producers and producers of color face heightened challenges related to language, cultural competency, and discrimination that must be addressed. Increasing diversity among organic producers and handlers could contribute to a stronger sense of inclusion and opportunities in organic.

More programs to support organic transition are becoming available, and USDA and the NOSB have a shared interest in ensuring that these resources are used effectively and efficiently to expand organic production and markets in the long-term. In addition, there is a need for deeper understanding of how improvements in diversity, equity, and inclusion in the organic sector could expand the relevance of organic – to producers and consumers alike.

In 2022, USDA announced the unprecedented \$300 million Organic Transition Initiative (OTI), with three main elements designed to address many of these barriers: funding to build a transition support network, with organic certifiers in the lead; an organic practice standard for conservation programs and a crop insurance discount; and market development grants. Each of these elements is currently in process.

**Relevant areas in the Regulation or OFPA:**

One of the three primary purposes of the Organic Foods Production Act of 1990 (OFPA) is “to assure consumers that organically produced products meet a consistent standard,” and the NOSB is charged with advising USDA on implementing this purpose.<sup>1</sup> Organic producers do not believe that consumers

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<sup>1</sup> 7 U.S.C. §§ 6501(2), 6518(a).

are receiving that assurance, and consumer confidence is essential to organic market growth. The NOSB gathered stakeholder input and feedback during the Fall 2023 NOSB meeting to advise the Secretary on continuing to improve implementation of OFPA and ensure consumer access to and confidence in the organic label.

**Discussion:**

The proposal is organized into four categories that stood out in public comments, with the following rationales:

**1. Support economically viable opportunities in organic.**

- a. Organic producers do not believe that consumers are receiving assurance about consistent standards, and consumer confidence is essential to organic market growth.
- b. Several cost and pricing issues impact the potential for organic growth. Where the primary consumer base cannot afford to pay more for food, producers may have less incentive to pursue organic certification, but can still enhance their operations and reduce costs with support and technical assistance with organic management systems.
- c. Lack of access to land and capital remain significant barriers to organic transition because unstable land tenure prevents farmers from making the long-term investments necessary for successful organic farming systems; historic and continuing racial discrimination exacerbate these barriers for farmers of color.
- d. Existing organic producers also have concerns about increased organic supply depressing prices – although organic consumers could stand to benefit in that scenario, including consumers who face perceived or actual cost barriers to buying organic.
- e. Public investments are a tool for bridging cost/price gaps, and stronger integration and commitments to organic at USDA and other agencies could help ensure that organic producers maximize use of existing resources and funding sources.
- f. Retailers may also contribute to pricing challenges for both producers and consumers; USDA and other federal and state agencies could play a stronger role in ensuring that organic producers have access to a fair and competitive marketplace.

**2. Reduce costs of certification by offsetting costs that organic producers bear.**

- a. The costs of certification remain a significant barrier to organic certification, especially for producers serving low-income communities and communities of color where price premiums for organic are less prevalent.
- b. Implementation of new management systems may be costly.
- c. Immigrant farmers and farmers with limited experience navigating regulatory systems and/or or distrust of government agencies must invest significant time and resources to translate and comprehend certification materials and processes.
- d. Organic producers are not receiving a fair share of public investments in agriculture, so they are competing in a skewed marketplace.

**3. Invest in relationship and trust building.**

- a. Support for transition requires a significant time investment from support systems – organizations, farmer mentors, etc. Producers are more likely to successfully achieve certification after participating in a training session or receiving one-on-one technical assistance.
- b. Money is time: a significant success of the TOPP program to date is the use of funding to pay staff and farmer mentors to be available and to proactively conduct outreach – building capacity and extending the reach of support organizations. However, conversely, the structure of cooperative agreements with the NOP has resulted in lack of adequate funding

- for early stages of project work for TOPP partners, which has limited the type of hiring and program growth that is needed to maximize success. Organizations supporting organic transition need multi-year support to build and maintain capacity.
- c. Organic producers cannot always access relevant advice – programmatic or agronomic – at their local USDA office.

#### **4. Diversify and expand the organic community.**

- a. The first year of TOPP has focused on low-hanging fruit – stitching together existing capacity, encouraging more systematic and proactive outreach, and helping producers who are already interested in organic farming achieve certification.
- b. To achieve transformational change in agriculture and reach organic’s full potential, transition resources also need to reach producers and supply chains that are not already aware of opportunities in organic.
- c. Many farmers hold misconceptions about organic farming and certification. Education and farmer outreach help farmers make fact-based decisions and spread accurate information through word of mouth.
- d. Relationship and trust-building take time and require reciprocity.

#### **Public Comment:**

Public comments on the Fall 2023 discussion document called for more resources to support organic transition, provided that those resources are coupled with market development efforts. One-on-one mentorship and relationship-based support stood out as an essential theme – farmers are more likely to survive and thrive after the transition to organic when they receive support early in the process and from trusted sources. Commenters also noted the need for reaching producers who are not adequately represented in the organic sector yet.

#### **Summary:**

USDA agencies, including the National Organic Program (NOP), Natural Resources Conservation Service (NRCS), Transportation and Marketing (T&M), Farm Service Agency (FSA), Risk Management Agency (RMA), Economic Research Service (ERS), and Food and Nutrition Service (FNS), should work closely together to provide flexible and coordinated support to organic and transitioning producers, including taking actions in the four main areas identified by organic stakeholders:

#### **1. Support economically viable opportunities in organic.**

- a. Ensure strong integration of all elements of USDA’s Organic Transition Initiative (OTI) and other federal and state resources to support organic, so opportunities and deadlines are communicated to all agencies and partners involved with OTI. For example, participants in the Transition to Organic Partnerships Program (TOPP) should receive and disseminate information about market grant and conservation program deadlines and the NOP Climate-Smart Agriculture Crosswalk. (NOP, NRCS, T&M, USDA)
- b. Identify and address barriers to organic transition, including assisting farmers with long-term access to land and capital. (NOP, ERS, USDA)
- c. Build consumer demand for organic by educating the public about what organic is and why it matters. Campaigns run through check-off programs (e.g., Got Milk?) are the type of promotion that organic producers would like to see. (NOP, USDA)
- d. Create stable markets for organic through public procurement (i.e. government food purchasing). (FNS, USDA)

#### **2. Reduce costs of certification by offsetting costs that organic producers bear.**

- a. Ensure the Organic Certification Cost-Share Program is administered consistently and predictably. (FSA)
  - b. Pay producers for participation in training programs (both presenters/mentors and participants/mentees). (NOP)
  - c. Ensure the benefits of organic are acknowledged and compensated in programs that pay producers for public benefits they provide, like building healthy soil and ecosystem services. (NRCS)
  - d. Provide culturally appropriate, inclusive, and supportive certification services; adapt certification culture to the people and communities that certifiers serve. (NOP)
- 3. Invest in relationship and trust building.**
- a. Continue to work through organizations that producers already trust. (NOP, USDA)
  - b. Provide funding early in processes to both resource organizations with demonstrated experience and capacity and build capacity at additional organizations. (NOP)
  - c. Build organic-relevant capacity at all USDA agencies, and particularly those that directly interface with producers. (NRCS, FSA, RMA, USDA)
- 4. Diversify and expand the organic community.**
- a. Resource organizations that serve producers of color for a multi-year timeframe, including to support activities that are not directed specifically toward organic certification. (NOP, USDA)
  - b. Actively educate farming communities on opportunities in and benefits of organic agriculture. (NOP, NRCS, USDA)
  - c. Target outreach to organizations that work on succession planning, to leverage organic as a way to keep land in agriculture. (USDA)

**Subcommittee Vote:**

Motion to accept the proposal on Improving Support for Organic Transition

Motion by: Allison Johnson

Seconded by: Jerry D'Amore

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

**National Organic Standards Board**  
**Handling Subcommittee**  
**Petitioned Material Proposal**  
**Magnesium Carbonate and Magnesium Carbonate Hydroxide**  
**January 23, 2024**

**Summary of Petitions** [[Magnesium carbonate petition](#); [Magnesium carbonate hydroxide](#)]:

This document reviews the petitioned use and inclusion of magnesium carbonate and magnesium carbonate hydroxide as processing aids to the National List at §205.605(b): Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” as the reviews for these materials are essentially the same. As in the TR when referring to magnesium carbonate, “MC” (singular) will be used or when referring to multiple magnesium carbonates (both magnesium carbonate and magnesium carbonate hydroxide) “MCs” will be used.

**Introduction:**

In December 2022, Leroux petitioned the United States Department of Agriculture (USDA) National Organic Program (NOP) to add both magnesium carbonate and magnesium carbonate hydroxide as processing aids to the National List at §205.605(b).

**Relevant Background:**

Magnesium carbonate was previously listed on the National List at §205.605(b) with the following annotation: “for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic.” ([65 FR 80547, page 1708](#))

In 2005, MC was petitioned for inclusion to the National List as a filtering aid at §205.606. The petition was rejected by the NOP because the petition was incomplete, and this substance was ineligible to be added to §205.606 as it is not agricultural.

During the sunset review process in 2015, the NOSB voted to remove MC from the National List stating, “the material does not appear to be essential to organic handling.” MC was removed from the National List effective August 7, 2017. The final rule stated, “AMS received no public comments concerning the proposed removal of...magnesium carbonate from the National List.” ([82 FR 31241, page 14](#))

Magnesium carbonate hydroxide has never been petitioned or included on the National List.

**Use:**

MCs are used as drying agents / anti-caking agents. The petitioned use is focused on organic chicory production, specifically organic instant chicory powder. The petitioner notes that during the final steps of atomization and packing, the instant chicory powder sticks to the walls of the installations, requiring several steps for cleaning which reduces the rate of production.

The petition states, “The use of magnesium carbonate (or magnesium carbonate hydroxide) as a processing aid is intended for the manufacture of the instant extract of chicory obtained by atomization. The incorporation of E504(i) (or E504(ii)) is done in the crown of air at the bottom of the tower feeding the dryer in order to obtain re-aeration and very good homogeneity of the product (figures 1 and 2). The maximum amount used would be 0.05%.” The petition includes several diagrams to pictorially represent the use of MCs in the production of organic instant chicory powder.

### Summary of Review:

The Handling Subcommittee's (HS) discussion focused on whether the potential presence of nanoparticles in the alternatives -calcium carbonate, tricalcium phosphate, and silicon dioxide - makes the case for the essentiality of MCs. The HS discussed the current prohibition of nanotechnology (NOP PM 15-2) and if this is sufficient in certifiers' material review processes to keep engineered nanomaterials out of organic products and if there is a true concern here that perhaps petitioning removal of those materials in question is the better approach.

The HS also discussed the environmental impact that any substance that is mined or uses a precursor that is mined has on the environment due to the adverse effect the mining industry has on the environment.

Lastly, MCs are generally allowed in all the international schemes included in the TR (Canada, CODEX, EU, JAS, IFOAM). There are some restrictions made by CODEX, EU and JAS allowing MCs only in processed products of plant origin (or alternatively not allowed in food of animal origin). Canada restricts its allowance in meat products with 70-95% organic content. JAS only allows magnesium carbonate but not magnesium carbonate hydroxide. Based on this allowance there could be products imported into the US through an equivalency arrangement that have been produced using MCs as a processing aid.

### Category 1: Classification

1. Substance is for:  **Handling**  **Livestock**
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance  **Agricultural** or  **Non-Agricultural**?  
Describe reasoning for this decision using [NOP 5033-2](#) as a guide:

MCs are mineral salts. Magnesium carbonate hydroxide is the mixture of magnesium carbonate and magnesium hydroxide rather than a specific chemical compound.

- b. If the substance is **Non-agricultural**, is the substance  **Non-synthetic** or  **Synthetic**?  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using [NOP 5033-1](#) as a guide:

Evaluation of MCs against Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016) is discussed below. The following is from lines 507-540 in the TR.

1. *Is the substance manufactured, produced, or extracted from a natural source?*

The substance, MC, is manufactured by chemical reaction of precursors, which themselves may be nonsynthetic, as is the case with some magnesium salts and sodium carbonates, or else synthetic, such as magnesium hydroxide and carbon dioxide. Carbonation of magnesium hydroxide involves the reaction of two synthetic substances. Thus, the answer to whether the substance is manufactured from a natural source in this case would be no, and the end-product is considered

synthetic. The determination for MC manufactured by the reaction of a magnesium salt with an alkaline carbonate is more complex.

Assuming a magnesium chloride or magnesium sulfate is from a nonsynthetic source, and the sodium carbonate with which it is reacted is also nonsynthetic, gives the following result when evaluated using the decision tree:

1. *Is the substance manufactured, produced, or extracted from a natural source?*

One could answer yes because the magnesium and carbonate sources are natural.

2. *Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?*

The answer to this question would be yes if we consider the source materials to be the reactants, because their ions exchange during the process: in solution magnesium is in ionic form ( $Mg^{2+}$ ), separate from the salt ions ( $Cl^-$  or  $SO_4^{2-}$ ), but combines with carbonate ions ( $CO_3^{2-}$ ) from a different source in a crystalline structure, yielding the final MC. The next question is:

3. *Is the chemical change created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter?*

The answer to this question is no. The chemical change is the result of a chemical reaction. No biological processes are involved, and while temperature can affect the form of the final MC, the reaction is not driven by heating. Thus, the material is synthetic according to the decision tree.

3. For **LIVESTOCK**: Reference to appropriate OFPA category  
Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

N/A

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

None, as both magnesium and carbonates are naturally occurring.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

MCs are non-toxic. The petition states that magnesium carbonate will dissociate into magnesium and carbonate ions. The petition and the TR discuss the ubiquitous presence of these ions in nature.

3. Describe the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance? [§6518(m)(3)]

MANUFACTURE: The main environmental concern regarding MCs pertains to the manufacturing process of magnesium, which is a precursor used in MCs manufacturing. Magnesium itself can be obtained through several different extraction routes and from various magnesium-containing brines and mineral ores. [TR 458-488]

Additionally, the TR, noted that MC is naturally occurring in rock known as magnesite. The TR stated that no commercial sources of food-grade MC produced directly from magnesite were identified. That said, magnesite is one of the mineral ores described above as a precursor to synthetically processed MCs.

USE/MISUSE: Using magnesium carbonate in the manufacturing of chicory extract is unlikely to harm the environment or biodiversity. [TR 649]

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Magnesium and MCs are not toxic to humans at doses that fall close to the maximum daily intake. High doses of magnesium (from dietary supplements or medications) can result in stomach issues (e.g. diarrhea, nausea, abdominal cramping) as well as magnesium toxicity. Too much magnesium from food does not pose a health risk in healthy individuals because the kidneys eliminate excess amounts in the urine. [TR 753-780]

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

The TR doesn't indicate any negative impact by MCs on soil organisms, crops, and livestock. Again, magnesium and carbonates are both found ubiquitously in nature.

However, the magnesium oxide industry impacts soil and groundwater by magnesite dust. Median levels of magnesium content induced toxicity to plants resulting in a gradual necrosis and loss of soil vegetation cover and causing an extremely low vegetation diversity.

6. Are there any adverse impacts on biodiversity? (§205.200)

Using MCs in the manufacturing of chicory extract is unlikely to harm the environment or biodiversity. [TR 649]

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]



The TR stated that there was no indication of nonsynthetic MCs being commercially available for applications of food processing.

The TR indicates several alternative practices that help but do not resolve the problems entirely or may not be suitable for all production types. These practices include cooling the chamber wall and scraping the dryer. Sun drying can be used but is limited to locations with favorable climates.

The TR also identified other National List materials including calcium carbonate, tricalcium phosphate, and silicon dioxide. However, the TR did state that as food additives, all three of these substances are under increasing scrutiny in France as sources of nanoparticles.

Lastly, the TR identified corn starch, potato starch, rice hulls, and cane sugar as alternative anti-caking agents available as organic agricultural products. However, it was noted that the TR did not find literature that indicated that these have been studied for use in chicory root powder production and therefore may or may not be suitable alternatives to MCs.

**Category 4: Additional criteria for synthetic substances used in Handling** (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

MCs are not agricultural products and therefore can't be produced as organic. The TR states that there was no indication that nonsynthetic MCs are commercially available for application in food processing. [TR 545-550]

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

Using MCs in the manufacturing of organic chicory extract is unlikely to harm the environment or biodiversity.

Again, the main environmental concern regarding MCs pertains to the manufacturing process of magnesium, which is a precursor used in MCs manufacturing. Magnesium itself can be obtained through several different extraction routes and from various magnesium-containing brines and mineral ores. The impacts of mining and use of brines are not unique to these substances. There are other substances on the National List whose main environmental concern is due to the adverse effects of mining. [TR 649-709]

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

Regarding nutritional qualities, the addition of MCs into instant chicory would slightly increase the amount of elemental magnesium in the powder. However, this increment is unlikely to significantly boost the nutritional profile of the product in terms of the elemental magnesium content.

As for the impact on human health, the TR states that magnesium and MCs are not toxic to humans at doses that fall close to the maximum daily intake. High doses of magnesium (from dietary supplements or medications) can result in stomach issues (e.g. diarrhea, nausea, abdominal cramping) as well as magnesium toxicity. Too much magnesium from food does not pose a health risk in healthy individuals because the kidneys eliminate excess amounts in the urine. [TR 753-780]

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

According to the TR, the petitioned use of MCs does not fit the FDA's definition of chemical preservative. [TR 564-574]

Additionally, the TR states that MCs can improve the texture of chicory extract by improving the flowability, which reduces fouling in production and packaging. [TR 594-598]

The TR indicates that no studies were found that show that MCs primary use contributes to improving flavors, colors, or nutritive value lost during processing. That said the TR does state that while not a primary function, MCs are an excellent carrier and retainer of perfumes due to their fine texture. Therefore, if added to chicory extract powder it could improve flavor by retaining some of the volatile compounds that characterize the beverage. [TR 607-610]

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

As described in *Approved Legal Uses of the Substance*, above, MCs (CAS RN 39409-82-0) are categorized by the FDA as GRAS at 21 CFR 582.1425. The conditions of use are that it be used in accordance with good manufacturing or feeding practice. [TR 556-558]

The TR found no reports of heavy metal or other contaminants in excess of FDA tolerances in MCs [TR 636-637]

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

MCs do not appear essential for organic chicory powder production. There are 12 operations currently listed in the Organic Integrity Database (OID).

There are many alternative organic agricultural substances as well as other anti-caking agents that are already listed on the National List.

In 2015, the NOSB recommended that magnesium carbonate be removed from the National List, because it was not essential to organic handling (NOSB, 2015). The NOP removed it from the National List in 2017 (82 FR 31241).

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

Magnesium carbonate and magnesium carbonate hydroxide are not compatible with organic handling due to the existence of several alternatives on the National List.

#### **Questions to stakeholders:**

1. Essentiality:
  - a. Have we misunderstood the scope of essentiality since organic chicory powders are being produced currently?
  - b. What has changed since 2017 when magnesium carbonate was removed from the National List due to lack of essentiality?
  - c. Why are the other substances (e.g. calcium carbonate, tricalcium phosphate, and silicon dioxide) listed on the National List as drying agents / anti-caking agents not sufficient for organic chicory powder production?
2. CERTIFIERS: Given NOP's prohibition (PM 15-2) of engineered nanoparticles, is there truly a risk that nanoparticles are ending up in organic food from calcium carbonate, tricalcium phosphate, and/or silicon dioxide or are current materials review criteria sufficient to review and prohibit materials manufactured using nanotechnology?
3. Are there challenges for producers that are importing and/or exporting organic chicory powder? If so, explain the challenges you are facing.

#### **Subcommittee Votes:**

##### **Classification Motion:**

Motion to classify magnesium carbonate as nonagricultural, synthetic

Motion by: Nate Lewis

Seconded by: Kyla Smith

Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

##### **National List Motion:**

Motion to add magnesium carbonate – for use only as an anti-caking agent in chicory powder – at § 205.605(b)

Motion by: Kyla Smith

Seconded by: Nate Lewis

Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

**Classification Motion:**

Motion to classify magnesium carbonate hydroxide as nonagricultural, synthetic

Motion by: Nate Lewis

Seconded by: Kyla Smith

Yes: 8 No: 0 Abstain: Recuse: 0 Absent: 1

**National List Motion:**

Motion to add magnesium carbonate hydroxide – for use only as an anti-caking agent in chicory powder – at § 205.605(b)

Motion by: Kyla Smith

Seconded by: Nate Lewis

Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Rye Pollen Extract  
January 16, 2024**

**Summary of Petition [\[link\]](#):**

The petition for rye pollen extract (RPE) was made by the Graminex company. Rye pollen extracts are an agricultural ingredient from *Secale cereale* pollen and are produced separately extracting the water and the lipid portions of rye (*Secale cereale*) pollen. The primary use of RPE is for vegan sweetener syrup, replacing honey from bees.

**Summary of Review:**

The Subcommittee discussed the petition and the Technical Report (TR) thoroughly. The Subcommittee paid particular attention the following section of the TR, line 330-335, page 7:

*Section 7 CFR 205.301(b) permits nonorganically produced ingredients at less than 5% of a product's formulation when not available in organic form. The petitioner states that the specific high-pollen-producing rye breeder seed is unavailable in organic form. However, § 205.204(a) allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available. Certification of the petitioner's rye farm and processing facility may be possible, even if the specific seed used is not available in organic form.*

The Subcommittee agreed that the petitioner has the option of obtaining rye pollen extract by using nonorganic seed raised on farmland under organic management.

**Category 1: Classification**

1. Substance is for:  **Handling**  **Livestock**
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance  **Agricultural** or  **Non-Agricultural?**

Describe reasoning for this decision using [NOP 5033-2](#) as a guide: Following the decision tree: the product is not a mineral or bacterial culture, is not a microorganism, is derived from a crop, is not processed to the extent that its chemical substance has been changed, and thus meets the definition of an agricultural product.

**Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The TR does not discuss the impact of rye pollen extract on other materials used in organic farming systems.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

As petitioned, RPE adds pollen to vegan honey substitutes (sweeteners). The vast majority of the available literature on grass pollen extracts focuses on phytotherapy, or the use of plants to relieve symptoms related to disease. These studies typically do not describe the physical properties of the substance. The TR authors found no explicit physical descriptions of RPE raw material used in food products except that discussed in the petition.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The TR cites research that indicates fertile rye produces a large volume of pollen with the ability to travel long distances. Consequently, extreme care is required in breeding programs since any genetic contamination leading to sterility can render an entire crop useless for future seed production.

The TR states there is little research examining the manufacturing process of pollen extracts.

Extraction of the water-soluble and lipid-soluble fractions of RPE are carried out via water extraction and supercritical CO<sub>2</sub> extraction, according to the petition. The TR indicates that both methods offer non-toxic alternatives with less environmental concerns compared to conventional organic solvent extraction methods.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The TR found no documented evidence of specific health risks or benefits related to the consumption of RPE as an ingredient in processed foods. Discussion of the reported effects on human health of the related materials bee pollen, raw rye pollen, and pollen extracts as therapeutic agents were included in the TR for broader consideration of strictly theoretical health implications related to consumption of the petitioned material.

The TR found no literature suggesting there is any clear toxicity risk associated directly with RPE. Several studies identified varying levels of lead, cadmium, and arsenic in bee pollen (see TR for specific citations).

The TR found no literature that indicated any clear allergen risk associated directly with RPE.

Rye, rye pollen, and rye pollen extract do not appear in any FDA Generally Recognized as Safe (GRAS) listings for human or animal uses, nor do they appear in the GRAS Notice Inventory. This does not necessarily mean that RPE is not permitted in food. The TR indicates that user of RPE would have to contact FDA about its use in food since it is not included in the *Substances Added to Food* inventory. The TR authors attempted to contact FDA but received no reply.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

The TR indicates that Impact studies on rye are limited. Farm level studies (see TR for specific details) compared the carbon and water dynamics of perennial rye and annual rye. The perennial rye demonstrated greater atmospheric carbon uptake compared to the annual rye. The terrestrial water balance was similar between both rye crops. The manufacturing process described in the petition suggests the use of annual rye.

Studies comparing conventional cereal crops for livestock feed indicate that among barley, rye, and sorghum, rye had the lowest environmental impact (see TR for specific citation). Rye is a common cover crop often planted to control soil erosion but can become a weed, particularly when planted before winter wheat (see citations in TR).

6. Are there any adverse impacts on biodiversity? (§205.200)

Conventional agriculture, through its reliance on synthetic chemicals, is thought to have a negative impact on biodiversity. The TR authors did not find research that examined rye crops as nesting sites or food sources for insects or other forms of biodiversity. Similarly, the authors did not find literature that indicated there was a negative impact on the environment or biodiversity resulting from the use of RPE in food.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The TR offers several alternatives to the petitioned use:

- Continue to omit the ingredient in vegan honey alternatives.
- Obtain organic certification for this agricultural ingredient. § 205.204(a) allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available, the lack of available breeder stock should not pose a barrier to organic certification.
- Instead of RPE, vegan honey substitutes may be able to use extracts of bioactive compounds from plants and plant parts other than pollen.

2. **For Livestock substances, and Nonsynthetic substances used in Handling:** In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

The TR does not directly address this, but since RPE as petitioned would come from rye that is not grown organically, nonorganic farm production of rye is incompatible with a system of sustainable agriculture.

### **Category 4: Additional criteria for synthetic substances used in Handling** (does not apply to nonsynthetic or agricultural substances used in organic handling):

**N/A** – The questions in Category 4 are not relevant because this is an agricultural product.

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))
2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))
3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))
4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))
5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))
6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))
7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

**Category 5: Additional criteria for agricultural substances used in Handling** (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

The petitioner states that organic breeding stock with high pollen-producing potential is commercially unavailable, despite the availability of organic rye. The TR suggests the lack of high pollen producing organic rye seed may be the result of the fact that most rye breeding emphasizes grain yield rather than pollen production.

That said, the TR indicates that rye produced under conventional management is not necessary for organic handling; buying conventional seed and raising it under organic management is possible.

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?

The petition indicates that organic rye seed with high pollen-producing ability is unavailable. That said, as specified in the TR, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill



an essential function in a system of organic handling?

The petition indicates that organic rye seed with high pollen-producing ability is unavailable. That said, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?

The petition indicates that organic rye seed with high pollen-producing ability is unavailable. That said, there is no evidence supporting the need for RPE as petitioned in terms of form, quality, or quantity.

5. Does the industry information about unavailability include (but is not limited to) the following?:

There is no industry information about unavailability for reasons specified in this question. The challenge for the petitioner is lack of organic breeding stock of high pollen producing rye; conventional breeding stock with the necessary qualities does exist.

Regions of production (including factors such as climate and number of regions);

- a. Number of suppliers and amount produced;
  - b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;
  - c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or
  - d. Other issues which may present a challenge to a consistent supply?
6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?

- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

The Handling Subcommittee finds that the use of RPE, as petitioned, is incompatible with Organic Handling and suggests that the petitioner pursue section § 205.204(a), which allows nonorganic, untreated seed to be used for the production of an organic crop when an organically produced variety is not commercially available.

**Subcommittee Vote:**

**Classification Motion:**

Motion to classify rye pollen extract as agricultural

Motion by: Carolyn Dimitri

Seconded by: Kyla Smith

Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

**National List Motion:**

Motion to add rye pollen extract [as petitioned] at § 205.606

Motion by: Carolyn Dimitri

Seconded by: Jerry D'Amore

Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0



**Sunset 2026**  
**Meeting 1 - Request for Public Comment**  
**Handling Substances § 205.605(a), § 205.605(b), § 205.606**  
**April 2024**

### Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's [Petitioned Substances Index](#).

### Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2024 public meeting. Written comments should be submitted via Regulations.gov at [www.regulations.gov](http://www.regulations.gov) 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 **Support** the Continued Use of Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:

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

### For Comments that **Do Not Support** the Continued Use of Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

If you provide comments that do not support a substance on § 205.605(a), § 205.605(b), and/or § 205.606, you should provide reasons why the use of the substance should no longer be allowed in organic

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

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

**For Comments Addressing the Availability of Alternatives:**

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

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

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.

**For Comments on Nonorganic Agricultural Substances at § 205.606:**

For nonorganic agricultural substances at § 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e., is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 3, 2024 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

**§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:**

[Acids - Citric](#)

[Acids - Lactic](#)

[Calcium chloride](#)

[Enzymes](#)

[L-Malic acid](#)

[Magnesium sulfate](#)

[Microorganisms](#)

[Perlite](#)

[Potassium iodide](#)

[Pullulan](#)

[Yeast](#)

**§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:**

[Activated charcoal](#)

[Ascorbic acid](#)

[Calcium citrate](#)

[Collagen gel](#)

[Ferrous sulfate](#)

[Hydrogen peroxide](#)

[Nutrient vitamins and minerals](#)

[Peracetic acid/Peroxyacetic acid](#)

[Potassium citrate](#)

[Potassium phosphate](#)

[Sodium acid pyrophosphate](#)

[Sodium citrate](#)

[Tocopherols](#)

**§205.606 Sunsets: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”:**

[Celery powder](#)

[Fish oil](#)

[Gelatin](#)

[Orange pulp, dried](#)

[Seaweed, Pacific kombu](#)

[Wakame seaweed \(Undaria pinnatifida\)](#)

## Acids Citric

**Reference:** § 205.605(a) Nonsynthetics allowed

(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

**Technical Report:** [1995 TAP - Citric](#); [2015 TR - Citric](#); [1995 TAP - Lactic](#); [2015 TR - Lactic](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 recommendation](#); [11/2005 sunset recommendation](#); [03/2010 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

Citric acid is widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. It is also an ingredient in dietary supplements and a nutrient, sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), raising agent, and emulsifying salt for many other products. It is also used to improve baking properties of flours, and as a stabilizer, and to inhibit color and flavor deterioration in fruits. Roughly 75% of all citric acid commercially produced is used by the food industry including baby food, breakfast cereals, frozen desserts, frozen entrees and certified organic personal care products. The remainder is used in cleaning agents, or in the cosmetics and pharmaceutical industries.

#### Manufacture

First isolated from lemons, it was extracted from lemons and limes until 1919 when production shifted to fermentation (a biological process by which sugars are metabolized to acids, gases, and/or alcohol). Today, the mold *Aspergillus niger* is cultured with low pH values and high levels of sugars and mineral salts to economically produce high yields through fermentation. Various chemical synthesis of citric acid appeared but none have reached the economics derived from the fermentation process. The fermentation process has been refined over the years to produce high levels of citric acid instead of high levels of the by-product oxalic acid. Some public commenters expressed a concern that the fermentation process involves the use of synthetic chemical reactions that were not considered in the original 1995 classification.

NOSB requested a limited scope TR for citric acid in preparation for this sunset review. The limited scope TR focused on the microorganisms used in the fermentation process to manufacture citric acid and what potential there is for these microorganisms to have been produced through excluded methods as defined by the NOP regulations. Based on available information, most citric acid manufacturers use wild type fungal strains or strains that are products of classical induced mutagenesis. The use of microorganisms developed using excluded methods appears to remain at an experimental phase and is not commercially available.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

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

Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

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

Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.

Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

### **Ancillary Substances**

Citric acid is commercially supplied as a pure compound and otherwise does not contain ancillary substances.

### **Human Health and Environmental Issues**

Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will degrade

to produce non-toxic and non-persistent environmental products. The potential health hazard of citric acid is moderate based on systemic toxicity (EPA 2007). EPA listed citric acid as List 4A (minimal risk inert) in their 2004 list and currently list citric acid at 40 CFR 180.950(e) as a tolerance exempt inert ingredient.

### Discussion

Citric acid remains an essential ingredient for organic food processors, and NOSB does not have any new information to suggest that citric acid should be removed from the National List at 7 CFR 205.605(a). NOSB requested a limited scope TR to evaluate the potential for microorganisms used in the fermentation process of citric acid manufacturing to be products of excluded methods. The TR indicated that the use of genetically modified microorganisms remains only in experimental phase in the production of citric acid, and it listed numerous suppliers of citric acid that utilize either wild type fungal strains or strains that are the product of classical induced mutagenesis. This indicates that there is ample supply of citric acid that complies with the prohibition on excluded methods in organic food.

### Questions to our Stakeholders

There are now numerous suppliers of certified organic citric acid. Should NOSB consider recommending the addition of an annotation to citric acid requiring processors to use an organic version of citric acid when commercially available?

## Acids Lactic

**Reference:** § 205.605(a) Nonsynthetics allowed

(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

**Technical Report:** [1995 TAP - Citric](#); [2015 TR - Citric](#); [1995 TAP – Lactic](#); [2015 TR - Lactic](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2010 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

Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting Transcript 2015 pp. 263). The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008). Other uses include mixing with sodium, potassium, and distilled water to form intravenous fluids commonly used after blood loss. It is sometimes used in the pharmaceutical industry to adjust acidity. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material without further annotation.

Common uses include, but are not limited to:



1. In sugar confectionery, it is used in a continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and NOSB Mesenteric groups of bacteria.
6. Lactic acid can be used as a meat carcass “wash” or in meat products to reduce microbial contamination.
7. It is used in jams, jellies, and frozen fruit desserts.
8. In dairy products such as cottage cheese, the addition of lactic acid is preferred by some manufacturers to fermentation.
9. Used in imitation dairy products such as non-dairy cheese and non-dairy yogurt powder.
10. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.
11. Buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
12. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
13. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
13. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.
14. Lactic acid is used for flavor development and the control of microorganisms in soy cheese.

### **Manufacture**

First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid. A secondary manufacturing process involves chemical synthesis of adding hydrogen cyanide to acetaldehyde, an organic chemical compound found in coffee, bread, ripe fruit, coal, or crude oil. This process only exists today in Japan. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation.

### **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

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

Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

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

Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.

Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

**Ancillary Substances**

None

**Human Health and Environmental Issues**

The fermentation process produces calcium sulfate waste (sometimes sold as fertilizer), but it is not known to create any negative environmental impacts.

**Discussion**

Lactic acid is a “Direct Food Substance Affirmed as Generally Recognized as Safe,” or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061.

Lactic acid is one of the most widely distributed acids and preservatives in nature. It is produced naturally by humans, animals, and microorganisms. Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with sour milk. It occurs naturally in two isomers (D) and (L).

(D) is harmful to humans so (L) is the preferred isomer for food and pharmaceuticals. It functions as a flavor agent, preservative and acidity adjuster in foods.

There is no known organic alternative to lactic acid.

### Questions to our Stakeholders

None

## Calcium chloride

**Reference:** § 205.605(a) Nonsynthetics allowed  
(7) Calcium chloride.

**Technical Report:** [1995 TAP](#), [2023 TR \(pending\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2010 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

Used in a wide variety of food processing applications including the following as listed in the Table 3 in the 2023 draft TR:

- Firming agent (fish, mushrooms, processed whole and cut vegetables)
- Flavor enhancer (beer, canned breadnut seeds, cucumber pickles, processed meat products)
- Nutrient supplement (dairy products, nutrition beverages, tofu)
- pH control agent (beer)
- Processing aid (bakery products, beer, cheese, tofu)
- Stabilizer and thickener (fruit jams and jellies)
- Synergist in combination with sodium alginate (dressings, fruit snacks, sauces, soups)
- Tenderizer/texturizer (beef, chicken, goose, lamb, rabbit)

#### Manufacture

According to the 2023 draft TR, calcium chloride can be produced from three different sources/processes:

- From natural brines
- Reaction of calcium hydroxide with ammonium chloride (Solvay ammonia-soda process)
- Reaction of hydrochloric acid with calcium carbonate

The TR also mentioned a fourth method claimed by TETRA Technologies, as a byproduct of the manufacturing of magnesium oxide. The TR authors couldn't find details on this process or mention of it elsewhere. [2023 TR 487-494]

Calcium chloride derived from brines are nonsynthetic in many cases. However sometimes depending on the brine process, classification becomes more complicated. The starting material is a natural brine solution that is pumped out from underground salt beds and calcium chloride is what is left when other materials are extracted from the brine. When calcium chloride uses evaporation for the extraction, it is effectively

unchanged (more concentrated and some ions are removed). This process is nonsynthetic. However, sometimes other chemicals are added such as calcium hydroxide or slaked dolime. These substances are processing aids added to remove other substances and they may leave residues of calcium and chloride in the final calcium chloride product and would be indistinguishable from their natural counterparts. [2023 TR 496-628]

Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (synthetic). Soda ash can also be produced in other ways, such as through the chlor-alkali process or by utilizing an ore called "trona". According to the TR, trona is rare in the EU, so almost all of the soda ash produced in the EU utilizes the Solvay process. However, trona is plentiful in the US and since that process is cheaper, very little soda ash is produced from the Solvay process in the US. Therefore, when calcium chloride is sourced from the US, the likelihood that it is processed using the Solvay process is quite low. [2023 TR 630-676]

Lastly, calcium carbonate can be produced from the reaction of hydrochloric acid with calcium carbonate, which is a process that renders the calcium chloride synthetic. However, the TR states that it is unclear how relevant this process is for current industrial production. [2023 TR 678-697]

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as food additives in milk products; fat products; soybean products; and fruits and vegetables. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

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

Allowed as a coagulation agent in dairy products. (Annex V, Part A, Section A1, 2021/1165)

Allowed as a coagulation agent in products of plant origin & sausages based on meat. (Annex V, Part A, Section A2, 2021/1165)

Allowed as a processing aid for the production of primary yeast. (Annex V, Part C, 2021/1165)

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

Allowed in the following plant origin products: fruits and vegetables (including mushrooms, seaweeds, and nuts and seeds) and soybean products (excluding seasonings, condiments and fermented soybean products).

Allowed in the following animal origin products: Dairy products and analogues. Not allowed in processed meat, poultry, poultry and game products, edible casings. (Table 3 - page 28). Allowed as a firming/coagulation agent in cheese making. (Table 4 - pages 30-31)

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as an as additive and processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive. Limited to the use as a coagulant in processed products of plant origin/cheesemaking, or in edible oils or fats, processed vegetable products, processed fruit products, products containing beans, dairy products, or processed meat products. (Appended Table 1)

## Ancillary Substances

None

## Human Health and Environmental Issues

Environment: The 2023 draft TR indicated that calcium chloride, at the concentrations used for food commodities, is unlikely to negatively affect the environment when disposed, as it dissociates into calcium and chloride ions that can easily be taken up and metabolized by plants (at low concentrations). However, it was noted that calcium chloride can be toxic to plants and animals at high concentrations.

As with all mined substances on the National List, the biggest impact to the environment is caused by the manufacturing of calcium chloride. Calcium chloride utilizes similar extraction and recovery techniques used by the oil and gas industry. [2023 TR 944-1105]

Human Health: GRAS. When used in concentrations utilized in food products the 2023 draft TR stated that calcium chloride is unlikely to have a negative effect on human health as it readily dissociates into calcium and chloride ions which are both essential body constituents in all animal species.

The 2023 draft TR also stated that although rare, in certain circumstances, calcium chloride may cause soft tissue necrosis. [2023 TR 1110-1133]

## Discussion

The Handling Subcommittee received the draft TR on January 22, 2024. It was reviewed and the Subcommittee had additional questions regarding the manufacturing process when calcium chloride is produced from soda ash derived from trona ore, as well as commercial availability of calcium chloride manufactured by the various processes.

The Subcommittee discussed the wide use of calcium chloride. The TR authors found no evidence of a single substance offering the versatility of calcium chloride that is also non-synthetic. [2023 TR 1166-1290]

The 2023 draft TR mentions the following alternatives by function:

- Anti-microbial agents: carbon dioxide and ozone
- Firming agent: ozone and other sources of calcium such as calcium sulfate, calcium citrate and monocalcium phosphate
- Coagulants: calcium phosphate, calcium sulfate and magnesium sulfate
- Curing/pickling: other salts such as sodium chloride, calcium hydroxide, magnesium chloride and potassium chloride
- Nutrient supplement: calcium carbonate, calcium citrate, calcium hydroxide, and calcium phosphate
- pH control in brewing: calcium sulfate
- Tenderizer/texturizer: sodium chloride, lactic acid

The Subcommittee discussed the various ways to manufacture calcium chloride, some of which are nonsynthetic and some synthetic, as noted in the 2023 draft TR. Calcium chloride is currently listed at §205.605(a), so only the nonsynthetic forms are allowed. The TR noted that some methods used to extract calcium chloride from the natural brine use chemicals as processing aids. According to the TR when evaluating the classification of this manufacturing process using the decision tree, it falls into a gray area. The Subcommittee determined that use of these chemicals as processing aids would result in a nonsynthetic classification as the calcium chloride did not undergo a chemical change (it is still calcium

chloride) and the additional calcium or chloride ions that may still be present were not added with the intent of providing a technical effect. [2023 TR 476-782]

During the previous review most stakeholders were in favor of relisting due to essentiality and lack of negative impact on the environment and human health.

### Questions to our Stakeholders

1. Is the calcium chloride that is commercially used/available produced using non-synthetic processes?
2. CERTIFIERS: What kinds of supporting documentation is obtained to verify the manufacturing process of calcium chloride is non-synthetic?

## Enzymes

**Reference:** § 205.605(a) Nonsynthetics allowed

(11) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

**Technical Report:** [1995 TAP](#) (bacterial); [1996 TAP](#) (plant); [1996 TAP](#) (microbial); [2003 TAP](#) (enzymes: plant, fungal); [2011 TR](#); [2015 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [10/1999 recommendation](#) (plant, fungal); [11/2005 sunset recommendation](#); [04/2011 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

Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. Enzymes are produced by all living organisms; however, the 2023 Limited Scope TR only focuses on enzymes produced by microorganisms (including fungi). In some cases, enzymes are produced by microorganisms that are developed using excluded methods, which was the focus of the 2023 Limited Scope TR.

In the organic food industry, enzymes are used to carry out biological processes that are useful in the processing of food products or ingredients. Commonly used in the production of sweeteners, chocolate syrups, bakery products, alcoholic beverages, precooked cereals, infant foods, fish meal, cheese and dairy products, egg products, fruit juice, soft drinks, vegetable oil and puree, candy, spice and flavor extracts, and liquid coffee, and are used for dough conditioning, chill proofing of beer, flavor development, and meat tenderizing. Enzymes can also be used to help reduce production costs, reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods. (Technical Report 2011 lines 140-148).

## **Manufacture**

According to the 2023 draft TR, “Food-grade enzymes are typically produced in pure culture fermentation using “Current Good Manufacturing Practices” for food. Almost all fermentation processes used to produce enzymes are aerobic. Most industrial producers of food-grade enzymes use aerobic submerged fermentation or liquid fermentation (LF). Fungi produce approximately 50% of the enzymes used globally, bacteria produce 35%, and the remaining 15% are produced from non-fermentation organisms like plants and animals.”

Some examples of different sources of food-grade enzymes include:

Microbial rennet is a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Bromelain is extracted from the pineapple’s fruit, stem, peel and juice. First the fruit is crushed. Bromelain is then further isolated, separated, and purified using chromatography, ultrafiltration, precipitation, freeze drying, and other procedures. (TR 2011 494-496)

Pectinase is produced by the controlled fermentation of nonpathogenic and nontoxicogenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic processing. The 2023 TR takes an intensive look at the excluded methods used to produce enzymes (such as using genetically modified organisms) and found that there is currently no capacity for regulators to determine the origin of an enzyme sample once it has been produced (Draft TR 2023 976-983).

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as food additives. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) derived from animals—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); and c) egg white lysozyme. (Table 6.3, CAN/CGSB-32.311-2020, page 31)

Allowed as processing aids. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) animal-derived—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); c) egg white lysozyme. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

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

Allowed (Annex II, Part IV, 2.2.2 (a), 2018/848)

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

Allowed. Enzymes derived from genetic engineering organisms is prohibited. (Table 3 - 3.4 - page 29 & 31)

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 & 72)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive. (Appended Table 1)

## **Ancillary Substances**

Ancillary substances are explained in the 2015 Technical Report:

“Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014).”

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.

To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

The following additional ancillary substances were identified through public comment during the last sunset review:

Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.

Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.

Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.

Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose. pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate. Public comment submitted during the Spring 2019 NOSB meeting suggest adding several other ancillary substances to this list:

Anti-Caking & Anti-Stick Agents: manganese sulphate, magnesium sulphate, microcrystalline cellulose powder

Carriers and Fillers: corn gluten, corn steep powder, dextrose, lactose, propylene glycol, soya flour, soya oil, soyatone, sucrose.

Preservatives: propyl p-Hydroxybenzoate, sodium metabisulfite, sodium nitrate.

Stabilizers: calcium lactate, ethylene diamine tetra acetic acid, glycerin, sodium alginate.

pH control, Buffers: adipic acid, di potassium phosphate (K<sub>2</sub>HPO<sub>4</sub>), diammonium phosphate, disodium phosphate (Na<sub>2</sub>HPO<sub>4</sub>), hydrochloric acid, mono potassium phosphate (KH<sub>2</sub>PO<sub>4</sub>), tri ammonium citrate.

## **Human Health and Environmental Issues**

The 2011 TR did not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

The 2011 TR did not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any



allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).

The 2023 Limited Scope TR does not add any information about human health or environmental issues, beyond those which would be of concern should excluded methods be used.

### Discussion

During the 2015 sunset review, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change. Public comments received during the Spring and Fall 2019 NOSB meetings widely favored relisting of enzymes and numerous examples of their use in organic handling were listed. One group did object to the review of enzymes as a class noting that this broad review was insufficient to address classification and adherence to all OFPA criteria. They noted that enzymes should be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

The new 2023 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material.

### Questions to our Stakeholders

1. For manufacturers: describe how you ensure no excluded methods are used when including enzymes into your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when enzymes are used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

## L Malic acid

**Reference:** § 205.605(a) Nonsynthetics allowed  
(16) L-Malic acid (CAS # 97-67-6).

**Technical Report:** [2003 TR](#); [2019 TR](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [05/2003 sunset recommendation](#); [11/2009 sunset 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](#))

**Sunset Date:** 9/12/2026

### Subcommittee Review

#### Use

Malic acid exists in D-, L-, and racemic DL-forms, which is a mixture of equal parts of D- and L-. L-malic acid is the form listed at §205.605(a), while the D- and DL-forms are not approved for use in organic production. L-malic acid is used as a flavor enhancer, flavoring agent, adjuvant, and pH control agent in a variety of foods. The 2002 malic acid petition also notes it is used in dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and tea as a flavor enhancer and food acidulant, and that malic acid provides greater tartness and better taste retention than other major food acids. Malic acid has a smooth, persistent sourness and can be blended with other organic acids, sugars,

sweeteners, and flavors. It also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring. U.S. Food and Drug Administration (FDA) lists L-malic acid as a Generally Recognized as Safe (GRAS) food additive as a pH control agent, flavor enhancer, flavoring agent, and adjuvant in all food types except for baby food. The listing also includes maximum good manufacturing practice (GMP) levels for various applications (21 CFR 184.1069; U.S. FDA 2018).

### **Manufacture**

L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries, and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice. In the first round of the Spring 2019 sunset review, a number of commenters questioned whether commercially available L-malic acid comes from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process. Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

1. Production of fumaric acid either synthetically from petroleum or by fermentation of carbohydrates; and
2. Enzymatic conversion of fumaric acid to L-malic acid by immobilized microbes producing the enzyme fumarase.

More detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

There are two options for obtaining the fumaric acid in the first step in this process: 1) The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., *Rhizopus spp.*) or, 2) The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin. Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium viticola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most, if not all, of the L-malic acid on the market will also be synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).[All citations from 2019 TR]

L-malic acid can also be made from ethanol and biodiesel production waste but, again, this is not the production method that commonly supplies the market. Thin stillage is a byproduct of corn fermentation in the production of ethanol from which *Aspergillus niger* ATCC 9142 can produce L-malic acid (West 2017). Another L-malic acid production process is the fermentation of crude glycerol obtained from production of biodiesel. Non-engineered *Ustilago trichophora* can be used for high yield production. *A. niger* MTCC 281 can also produce L-malic acid from crude glycerol (Iyyappan et al. 2018ab).

L-malic acid can also be produced by microbes in a one-step fermentation process fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism. While this production process is possible, it is not clear how much is produced and whether it will be able to produce sufficient quantities to supply handlers currently relying on the L-malic acid produced by the synthetic process.

The production of DL-malic acid is a synthetic process according to [NOP Guidance 5033-1](#); the malic acid undergoes a chemical change that is not the result of a naturally occurring biological process (USDA 2016b). Note this is similar to the method of production for synthetic fumaric acid used as precursor for industrial L-malic production.

Research quantities of D-malic acid and L-malic acid can be obtained by chemically separating the racemic DL-malic acid into its components in a process called chiral resolution. Chiral resolution is an expensive process that is not used to make large commercial quantities. D- or L-malic acid produced by chiral resolution is synthetic according to NOP Guidance 5033-1 because the isomers are isolated by chemical processes (USDA 2016b; West 2017).

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives: listed as malic acid (Table 6.3, CAN/CGSB-32.311-2020, page 33).

#### [European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 & 2021/1165](#)

Malic acid is allowed in products of plant origin (Annex V, Part A, Section A1, 2021/1165).

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

In Table 3 of “Annex 2: “Permitted substances for production of organic foods,” malic acid (INS no. 296) is a permitted food additive listed without conditions (Codex 2013). L-malic acid is not explicitly mentioned; DL-malic acid is allowed.

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

L-malic acid (INS no. 296) is listed on page 79 in Appendix 4, “Table 1: List of approved additives and processing/post-harvest handling aids.” L-malic acid is listed both as a food additive and post-harvest handling aid without restrictions (IFOAM 2014).

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

On page 6, “Appended Table 1-1, Additives,” DL-malic acid (INS no. 296) is an approved food additive limited to use in processed foods of plant origin (JAS 2022). L-malic acid is not explicitly mentioned.

### **Ancillary Substances**

The 2019 TR does not describe any ancillary substances in L-malic acid.

### **Human Health and Environmental Issues**

The manufacture of L-malic acid by fermentation is fairly benign to the environment. Waste products such as spent cells and fermentation media can be composted. Processing chemicals include low toxicity acids and bases; while some of these can be recycled, they may end up in industrial landfills (West 2017; Dai et al. 2018). L-malic acid is found extensively throughout the environment in rotting fruit in agricultural or garden applications. Because it is soluble in water, L-malic acid eventually leaches out into the soil, where it is degraded by microbes. Manufactured malic acid is not deliberately released into the environment, and the amounts released incidentally into the environment through manufacturing processes and spills are likely to be small compared to the amounts already found in nature. The impacts of the manufactured material on beneficial insects, diversity, and other important aspects of environmental quality are negligible compared to natural exposures from rotting vegetation (Baker and Grant 2016).

Animal tests show that malic acid has low acute toxicity. Because it is easily metabolized in the body and occurs naturally in many fruits, there are no known reports of animal or human toxicity (Cornell Cooperative Extension 2016). Malic acid is an eye and skin irritant. The consumption of acidic soft drinks containing malic acid can lead to erosion of tooth enamel and can cause tooth decay.

### Discussion

The ongoing discussion around L-malic acid is not whether it is essential to organic handling or if it has detrimental effects on the environment or human health. In fact, there is broad agreement that it is essential, particularly to juice manufacturers, and there is no evidence to suggest that it does not meet National List criteria. However, as the organic material review process has become more refined and the production methods of L-malic acid has changed, we now see that much of the L-malic acid used in organic processing is “synthetic” while L-malic acid is currently listed at 7 CFR 205.605(a) as a “nonsynthetic” substance.

Previous Handling Subcommittees have suggested relisting L-malic acid on §205.605(b) as a “synthetic” substance to accurately reflect the predominant production method, and to ensure that the classifications inherent to the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” are consistent with NOP material classification guidance.

This Subcommittee agrees with the previous thinking of the Board and would like to suggest adding L-malic acid to §205.605(b) to reflect that most L-malic acid used in organic food processing is synthetic in origin. However, the Subcommittee also questions whether L-malic acid should be removed from §205.605(a), as there may be nonsynthetic forms of L-malic acid in use, and should commercial quantities of nonsynthetic L-malic acid become available, organic processors may show a preference for a nonsynthetic option.

### Questions to our Stakeholders

1. Do any organic products contain nonsynthetic forms of L-malic acid?
2. Do stakeholders think L-malic acid should be reclassified as a synthetic substance and added to §205.605(b)?
3. If L-malic acid is added to §205.605(b), should its nonsynthetic listing be removed from §205.605(a)?

## Magnesium sulfate

**Reference:** § 205.605(a) Nonsynthetics allowed

(18) Magnesium sulfate, nonsynthetic sources only.

**Technical Report:** [1995 TAP](#); [2011 TR](#); [2023 TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 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 is Generally Recognized as Safe (GRAS) and has a wide variety of uses in food processing and personal care products. It is used as a firming agent, and sometimes combined with other coagulators, in the production of tofu. Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks, and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages. In addition, magnesium sulfate has a variety of human medicine applications. Epsom salts are a common form of magnesium sulfate.

## Manufacture

Both nonsynthetic and synthetic forms of magnesium sulfate exist. The nonsynthetic forms are from naturally occurring salt deposits or rocks, with isolation from open-pit mines or salt ponds. Various levels of hydration create different crystalline structures that impact commercial viability, and manufacturers control humidity and temperature to isolate useful forms of magnesium sulfate. Magnesium sulfate can also be manufactured synthetically through the chemical reaction of magnesium containing materials and sulfuric acid.

## International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

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

[European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 & 2021/1165](#)

Not addressed

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

Not addressed

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Not addressed

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not addressed

## Ancillary Substances

None identified.

## Human Health and Environmental Issues

Magnesium sulfate is primarily extracted from salt lakes in the northern part of the Tibet Autonomous Region and Qaidam Basin of the Qinghai Province using large-scale open-pit mining, which results in heavy damage to surface vegetation, as well as water and air pollution from equipment. There is limited information available about mining magnesium sulfate specifically, relative to other magnesium materials.

Use of magnesium sulfate in food processing does not appear to cause significant health or environmental issues, particularly relative to industrial uses.

## Discussion

There are alternatives to magnesium sulfate for at least some applications, including tofu and beer production, but they may change properties of the finished product.

During the last sunset review, there were no comments on this listing, and the vote to relist was unanimous.

### Questions to our Stakeholders

1. What organic products currently include magnesium sulfate?
2. Are there adequate alternatives to magnesium sulfate?
- 3.

## Microorganisms

**Reference:** § 205.605(a) Nonsynthetics allowed

(19) Microorganisms—any food grade bacteria, fungi, and other microorganism.

**Technical Report:** [2003 TAP](#); [2014 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** [2002 petition](#)

**Past NOSB Actions:** [05/2003 minutes and vote](#); [11/2009 sunset recommendation](#); [04/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Added to National List with annotation 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](#))

**Sunset Date** 9/12/2026

### Subcommittee Review

#### Use

Microorganisms are organisms that are so small they can only be viewed with a microscope, broadly encompassing bacteria, fungi, viruses and other single-celled organisms. The microorganisms used in organic handling include bacteria, yeasts and viruses, but yeasts are reviewed separately as their applications are broad. Microorganisms are used as probiotics, for fermentation, and bacteriophages are used for food safety. Microorganisms are used by organic processors to make many well-known products including yogurts, miso, soy sauce and sake. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

#### Manufacture

There are a variety of ways microorganisms can be produced. As noted in the 2014 technical report (TR), generally a medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different products. Depending on the organism desired, different mediums ranging from milk products to rice may be used to create the starter culture. After a culture is generated, the starter culture may be inoculated directly into a product that will be altered by the microorganisms or the culture may be preserved by drying, encapsulating, freezing or other method and used at a later time in the handling process.

The 2023 Limited Scope TR stated that there is no direct evidence that microorganisms other than yeast were produced by excluded methods, but there were cases in which no methods were disclosed. It went on to say that for microorganisms created through solid state fermentation, many are genetically modified using recombinant DNA technology. Any microorganism that is genetically modified is not permitted in organic food.

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed in feed. If organic sources of yeast are not commercially available, non-organic yeast sources shall be used. (Table 5.2, Microorganisms and yeasts listing, CAN/CGSB-32.311-2020, page 24)

Allowed as ingredients not classified as food additives. Microbial preparations may contain substrates derived from agricultural or biological substances such as milk, lactose, soy, agar, etc. May also contain allowed carriers (see Table 6.3 & 6.4 Carriers). Starter and dairy cultures and other preparations of microorganisms normally used in product processing are allowed. (Table 6.4, CAN/CGSB-32.311-2020, page 36)

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

Allowed (Annex I, 3. Micro-organisms, 2021/1165)

Rules for the production of processed feed and food.

For the purpose of Article 19(2)(b) of Regulation (EC) No 834/2007, only the following substances can be used in the processing of organic food, with the exception of wine:

- (a) substances listed in Annex VIII to this Regulation;
- (b) preparations of micro-organisms and enzymes normally used in food processing.

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

Allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - pages 29 & 31)

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - pages 58 & 72)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

JAS does not specifically mention microorganisms as an ingredient or additive to organic food.

## **Ancillary Substances**

Ancillary substances may be present in microorganism cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism, and fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. According to the 2023 Limited Scope TR, "growth media can be as simple as a single feedstock and water, or may be comprised of as many as 40 different components." These components may include corn steep liquor, molasses and horse manure extract. Additional preservatives or anti-caking agents are used with some species.

The 2023 Limited Scope TR includes the following table of allowed ancillary substances in organic microbial preparations.

Functional class	Substance name
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate, potassium phosphate, potassium sulfate, tricalcium phosphate
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol, polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. It is unclear, for example, whether the corn used to make the starches and liquors mentioned above is required to be organic. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated in negative health effects, but are something that should be continually monitored. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

### Human Health and Environmental Issues

Microorganisms have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of many products. They pose minimal health risks, and in many cases can enhance health. As noted in the 2014 TR, the health effects can be expressed directly through the interactions of the ingestion of the live microorganisms (probiotic effect) or indirectly as the result of ingesting the metabolites synthesized by the microbes during fermentation (biogenic effect). Food-grade bacteria may also be used for improved vitamin production, raw food materials are often fortified with food grade bacteria that produce an excess of B vitamins in situ, and bacteriophages (viruses) are utilized as antimicrobials to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing (2014 TR).

The 2023 Limited Scope TR did not bring up additional concerns for human health or the environment, beyond those that would occur through the use of excluded methods.

### Discussion

In general, microorganisms are essential to the production of many organic foods, and they are widely used in the industry. A question could be posed regarding whether yeast should be grouped with other microorganisms, as they certainly fall within the classification of microorganisms. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms.

This discussion could be taken a step further to determine whether the products of microorganisms, substances such as citric acid, malic acid, and others, could also be grouped under the umbrella of



microorganisms. As the primary concern for most of these microbial products is whether the microorganisms used to produce them were genetically modified, the broader guidelines may apply. These comments do not suggest that microorganisms should be delisted, but rather that additional attention needs to be paid to this particular listing and the definitions associated with it.

The new 2023 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material.

### Questions to our Stakeholders

1. For manufacturers: describe how you ensure no excluded methods are used when including microorganisms in your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when microorganisms are used in the formulation.
3. Are there any ancillary substances that should be prohibited due to the potential for excluded methods?

## Perlite

**Reference:** § 205.605(a) Nonsynthetics allowed  
(22) Perlite—for use only as a filter aid in food processing.

**Technical Report:** [1996 TAP](#); [2023 TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [09/1996 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2010 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

Perlite is used as a filter aid in food processing, such as in the filtration of juices, beer, wine, and vegetable oils.

#### Manufacture

Perlite is an amorphous volcanic glass that occurs naturally and is sourced primarily from mines in the U.S., Greece, Turkey and China. The high-water content of the mineral causes it to expand many times its original volume when exposed to temperatures of 850-900°C.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as a filtering aid. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

[European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 & 2021/1165](#)

Perlite is allowed as a processing aid in products of plant origin and gelatine. (Annex V, Part A, Section A2, 2021/1165)

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

Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4, page 30)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as a processing/post-harvest handling aid. (Appendix 4, Table 1, page 81)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Perlite is an approved food additive limited to use in processed products of plant origin. (Appended Table 1-1: Additives, page 8)

### Ancillary Substances

None Identified

### Human Health and Environmental Issues

There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

### Discussion

Subcommittee discussion was brief and overall supportive to relist.

### Questions to our Stakeholders

Have there been any advancements in food processing that would eliminate the need of perlite on the National List?

## Potassium iodide

**Reference:** § 205.605(a) Nonsynthetics allowed  
(24) Potassium iodide.

**Technical Report:** [1995 TAP](#); [2011 TR](#); [2023 TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 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 iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points [2011 TR 356-359]. Iodization of salt eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as a food additive in the following functions:

- A nutrient in table salt as a source of iodine.
- A dietary supplement for human consumption and in animal feeds.

- A sanitizing agent for food processing equipment. [2011 TR 35-38]

### **Manufacture**

Potassium iodide can be refined non-synthetically from sea water and in salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] [2011 TR 200-201].

### **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients not classified as food additives. Use when legally required or allowed. (Table 6.4, CAN/CGSB-32.311-2020, page 36)

[European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 & 2021/1165](#)

Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165). Not explicitly mentioned for use in/on processed products.

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

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**

No identified

### **Human Health and Environmental Issues**

Potassium iodide may be added to food as a nutrient/nutritional supplement for human consumption or to animal feeds. Iodine (in the form of iodide) is a necessary human nutrient that is required for proper functioning of the human endocrine system, specifically synthesis of thyroid hormones—thyroxine (T4) and triiodothyronine (T3) [2011 TR 352-354]. It is well-documented that pre-existing nutritional deficiency of iodine in the diet can perturb levels of thyroid hormones which cause a spectrum of disorders that include in increasing order of severity, goiter and hypothyroidism, mental retardation, and cretinism. There are no indications of special sensitivity of infants or children resulting from exposure to iodine. Therefore, the Food Quality Protection Act (FQPA) Safety Factor has been removed (i.e., reduced to 1x) for iodine [2011 TR 396-397].

Based on a review of the available toxicology data, the U.S. Environmental Protection Agency (EPA) has concluded that iodine and iodophor complexes are of very low toxicity by the oral, dermal, and inhalation routes of exposure. Acute and chronic risks to non-target birds, aquatic invertebrates, and fish are highly unlikely [2011 TR 345-346].

### **Discussion**

Potassium iodide is an important material that helps prevent a range of health issues caused by iodine deficiencies. In previous sunset reviews the NOSB asked questions to stakeholders regarding the use of this

substance as a sanitizer, but no feedback was received. Stakeholders favored keeping this listing in addition to the current Nutrient Vitamin and Mineral listing. The NOSB has unanimously supported relisting potassium iodide at each sunset date.

### Questions to our Stakeholders

None

## Pullulan

**Reference:** § 205.605(a) Nonsynthetics allowed

(25) Pullulan—for use only in tablets and capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).

**Technical Report:** [2018 TR](#)

**Petition:** [2004](#); [2018](#)

**Past NOSB Actions:** [04/2019 recommendation to add](#)

**Recent Regulatory Background:** Added to National List effective 07/26/2021 ([86 FR 33479](#))

**Sunset Date:** 7/26/2026

### Subcommittee Review

#### Use

According to the FDA Center for Drug Evaluation and Research (CDER), pullulan is a “product used for tablet coating, as an excipient to aid tableting processes, in the production of edible films, and as an alternative to gelatin in capsule production” (FDA 2014). The unique film-forming property of pullulan 74 enables the production of clear capsules and coatings for dietary supplements (Farris et al. 2014). [2018 TR 72-75]

In addition to the petitioned use of pullulan as an ingredient in tablets and capsules for dietary supplements, edible pullulan films are used to extend the shelf life of various foods. These films prevent moisture loss and reduce surface exposure to oxygen and spoilage bacteria in intact berries (Krasniewska et al. 2017; Trevino-Garza et al. 2015; Diab et al. 2001), Brussels sprouts (Krasniewska et al. 2016), baby carrots (Gniewosz et al. 2013), nuts (Gounga et al. 2008), fresh eggs (Ozaki, Nomura and Miyake 1996), intact apples (Chlebowska-Śmigiel, Gniewosz and Świńczak 2007), and cut fruits such as apple slices (Wu and Chen 2013). [2018 TR 88-94]

#### Manufacture

All pullulan is created by microbial fermentation. The microorganism is usually the black, yeast-like fungus *A. pullulans*, although other species from this genus of black fungus—such as *A. fermentans* (Ozaki, Nomura and Miyake 1996) and *A. melanogenum* (Jiang et al. 2018)—have also been shown to produce pullulan. Nitrogen is provided in the growth medium in the form of inorganic nitrogen sources such as ammonium salts and nitrates and biological sources such as glutamate, peptone, yeast extract, and corn steep liquor. Essential nutrient minerals are provided as phosphates, magnesium salts, and the sulfates of iron, manganese, and zinc. [2018 TR 219-225]

#### International Acceptance

[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.

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

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

### **Human Health and Environmental Issues**

According to 2018 TR no adverse effect on human health and environmental issues mentioned.

### **Discussion**

Public comments urge NOSB to recommend applying the commercial availability clause to the entirety of the substances on §205.605 including Pullulan.

### **Questions to our Stakeholders**

Does pullulan have the potential to be produced organically, and if so, would a commercial availability requirement help drive commercialization of organic pullulan?

## **Yeast**

**Reference:** § 205.605(a) Nonsynthetics allowed

(30) Yeast—When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

**Technical Report:** [1995 TAP](#) (smoked yeast); [1995 TAP](#) (baker’s yeast); [1995 TAP](#) (autolysate); [1995 TAP](#) (brewers); [2014 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** [2006 Petition](#); [2010 Petition Supplement](#); [2010 Petition memo](#)

**Past NOSB Actions:** [10/1995 sunset recommendation](#); [11/2005 sunset recommendation](#); [3/2007 NOSB committee recommendation](#); [10/2010 NOSB 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**

Yeast is widely used and has been for centuries. Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

In general, yeast species (brewer's yeast) used in anaerobic conditions are for fermentation whereby they convert sugars to ethanol. This process includes ciders, beers, wines, and distilled spirits. Other uses for yeast are generally in aerobic conditions where they may be used as leavening agents (baker's yeast), for the addition of vitamins or minerals (nutritional yeast, chromium yeast, selenium yeast, torula yeast), as probiotics that may prevent or treat pathological conditions (probiotic yeast), and for flavoring (smoked yeast, torula yeast) (2014 TR). As the 2014 TR notes, they may be used synergistically or in conjunction with bacteria or other materials to create specific foods such as when kombucha is fermented with yeast and acetic acid bacteria to create fermented, sweetened tea.

Many organic products rely on the use of yeast for their distinctive features and characteristics. While there has been broad support for the relisting of yeast on the National List in past reviews, significant discussion has been centered on ancillary substances and whether organic forms of yeast are available. Yeast underwent a significant review that led to a 2010 recommendation to change the listing. The 2014 Technical Review added information about the current status of various yeasts and looked at the ancillary substances. There are many types of yeast and yeast is used to produce many substances, so this is a constantly changing playing field. As part of the prior sunset review many commenters noted that organic yeast forms are readily available, but that for certain uses there are some forms that are not yet organically produced in sufficient quantity or quality. These included torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. This led to the extensive annotation for the listing of yeast on the National List.

## **Manufacture**

Many yeasts are ubiquitous in the environment and in some cases, handlers use these wild yeasts to make breads or for fermentation. However, since most handlers prefer more control over the specific type and strain of yeast that is utilized, most yeasts are grown under controlled conditions and then sold to end users. Typically, yeast is grown in a lab environment to prevent contamination from undesirable or pathogenic organisms. The lab grown yeast is then used to inoculate growth media for industrial production (2014 TR). In many cases there are several iterations of inoculation and addition of growth media in order to achieve the desired quantities. The yeast may then be used directly for food production or be concentrated and packaged for future use. Traditionally, smoked yeast is made by passing smoke through dried yeast, but it may also be manufactured using chemical processes. This necessitated the annotation that when smoked yeast is used, documentation that the yeast is smoked by natural processes must be submitted by the user.

The 2023 Limited Scope TR made it clear that yeast may be genetically modified, primarily within brewing and fermentation applications. Yeast manufacturers are increasingly using tools like CRISPR to edit genes and add desirable traits from wild strains [2023 TR 499-504]. These genetically modified yeast would be prohibited under current NOP regulations.

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives. If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke-flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in Tables 6.3, 6.4 or 6.5). (Table 5.2, CAN/CGSB-32.311-2020, page 35)

Allowed as ingredients not classified as food additives: If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in Tables 6.3, 6.4 or 6.5). (page 37)

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

Allowed (Annex II, Part VII, 2021/1165)

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

Not explicitly mentioned; may be considered a micro-organism, which is allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - page 29 and 31)

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Cultures that are prepared or multiplied in house shall comply with the requirements for the organic production of microorganisms. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 and 72)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

JAS does not specifically mention yeast as an additive or ingredient to organic food.

## **Ancillary Substances**

During the 2015 sunset review, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance, BHT, was questioned as problematic for exposure.

According to the 2014 TR, there are a few yeast species that are formulated with no ancillary substances; however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products.

The 2023 Limited Scope TR indicates that for yeast to be certified as organic, the inputs such as molasses or corn steep liquor must also be organic and no synthetic substance that is not on the National List may be included [2023 TR 1255-1261].

## Human Health and Environmental Issues

It should be noted that while yeast itself is often considered of minimal risk to both the environment and in human use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR). The 2023 Limited Scope TR did not provide additional information on the potential impacts to human health or environmental issues, aside from those that could potentially occur through the use of excluded methods.

## Discussion

Public comment from the Spring and Fall 2019 meetings was overwhelmingly in favor of relisting of yeasts as annotated. Commenters noted that since yeast is commonly not available in organic form necessary for certain flavors, yeasts are not always available in the quantities needed, and that organic yeast quality can vary, the annotation and listing should remain as is. It isn't currently clear how to determine whether a non-organic form of yeast may be used in an organic product.

The new 2023 Limited Scope TR brings up a number of new questions relevant to the use of excluded methods in the production of this material.

## Questions to our Stakeholders

1. For manufacturers: describe how you ensure no excluded methods are used when including yeast into your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when yeast is used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

## Activated charcoal

**Reference:** § 205.605(b) Synthetics allowed

(2) Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.

**Technical Report:** [2002 TAP](#); [2023 TR pending](#)

**Petition(s):** [2002 petition](#)

**Past NOSB Actions:** [09/2002 sunset recommendation](#); [11/2009 sunset recommendation](#); [04/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Regulatory Background:** Added to National List with annotation 9/11/06 ([71 FR 53299](#)); Renewed 8/03/2011 ([76 FR 46595](#)); Renewed 09/12/16 ([81 FR 8821](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

## Subcommittee Review

### Use

Activated charcoal is used in processing for mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity.



## **Manufacture**

Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs, and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Canada General Standards Board Permitted Substances List allows the use of activated charcoal as an ingredient classified as a food additive. Shall be of plant origin. Prohibited for use in the production of maple syrup.

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

Lists activated carbon for the preparation of foodstuffs of plant and animal origin.

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

Codex Alimentarius lists activated carbon as a processing aid which may be used for the preparation of products of agricultural origin.

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and postharvest handling aid. Synthetic forms are allowed if organic or natural sources are not commercially available. May be used as a processing or a post-harvest handling aid.

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Appended Table 1-1, Additives (Organic processed foods other than organic alcohol); Appended Table 1-2, Additives (Organic alcohol beverages). Limits the use of active carbon for processed foods of plant origin; also beverages.

## **Ancillary Substances**

None identified.

## **Human Health and Environmental Issues**

Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

## **Discussion**

An updated TR was received during the Subcommittee review. The Subcommittee discussion was brief and in favor of relisting.

## **Questions to our Stakeholders**

Are there any industry changes that would challenge the current listing for activated charcoal?

## Ascorbic acid

**Reference:** § 205.605(b) Synthetics allowed  
(6) Ascorbic acid.

**Technical Report:** [1995 TAP](#); [2019 TR](#)

**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

Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties. Ascorbic acid is often added to processed foods for nutritional purposes and is one of the most common sources of Vitamin C, which provides many important biological functions. Several animals, including humans, a variety of primates and guinea pigs have lost the ability to produce ascorbic acid and must obtain this essential vitamin through their diets. As it is water soluble, and cannot be stored in the body, it must be consumed daily. However, its addition as a nutritional fortifier also provides preservative properties. The preservative nature of the compound is derived from its reducing nature, through which it reacts with oxidized species (including radicals and molecular oxygen) to prevent enzymatic browning and food spoilage. Ascorbic acid is GRAS as a chemical preservative (21 CFR 182.3013), a dietary supplement (21 CFR 182.5013), and nutrient (21 CFR 182.8013) when used in accordance with Good Manufacturing Practices. The FDA has identified ascorbic acid as a required nutrient in infant formula (21 CFR 107.100).

#### Manufacture

For more than 50 years, the predominant industrial production of ascorbic acid involved synthesis using the Reichstein and Grussner process, a six-step process developed in the 1930's. The process begins with D-glucose and involves hydrogenation, oxidizing, and treatment with acetone and then hydrogen chloride to yield L-ascorbic acid. Despite the effectiveness of the purely synthetic production of ascorbic acid with the Reichstein process, most modern industrial production processes use fermentation of glucose with additional biooxidation steps adding a bio-catalyst which eliminates the need for the chemical steps. Despite the use of various microorganisms for the bulk of the synthesis, the use of acid in the final step of the process to convert the 2-keto-L-gluconic acid to ascorbic acid results in the substance's classification as "synthetic," according to the guidelines in NOP 5033-1.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aid, specifically anti-browning agents prior to the extraction or concentration of fruit or vegetable juice. (Table 6.5, CAN/CGSB-32.311-2020, page 38)

[European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 and 2021/1165](#)  
Allowed in products of plant origin & meat products. (Annex V, Part A, Section A1, 2021/1165)

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

Allowed in food of plant origin, provided natural sources are not available. Allowed in the following foods of animal origin, provided natural sources are not available: processed meat, poultry, game products, poultry and edible casings. (Table 3 - page 24)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as an additive. (Appendix 4 - Table 1 - page 79)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive. Limited to the use in processed products of plant origin. (Appended Table 1)

### **Ancillary Substances**

No discussion of ancillary substances in the 2019 TR.

### **Human Health and Environmental Issues**

The 2019 Technical Report found no published studies on the persistence or impacts to biodiversity of ascorbic acid. Given the natural prevalence of the substance in plants and animals, the incorporation of ascorbic acid in the handling/processing of organic food products is unlikely to provide any significant increase to environmental levels of the substance.

### **Discussion**

Ascorbic acid is a vital nutrient necessary for humans and other primates. Humans cannot synthesize Vitamin C and must rely on dietary intake. Modern production techniques rely on fermentation of glucose, but addition of synthetic acids in the process render the final ascorbic acid product a “synthetic” substance according to NOP 5033-1. Previous sunset reviews of the substance asked whether excluded methods are used in the production of ascorbic acid, and the 2019 TR indicates that the microorganisms used in its manufacture are not the product of excluded methods.

Some stakeholders have identified its use as a preservative as incompatible with the requirements in organic handling, however, other stakeholders report it remains essential for numerous functions in food including protein processing in cheese, color stabilization in fruit juice, and as an antioxidant and vitamin C source. The subcommittee notes that evaluation criteria at 7 CFR 205.600(b) restricting a material’s use as a preservative or its use to recreate or improve flavors, colors, textures, or nutritive value lost during processing is limited to processing aids and adjuvants.

The 2019 Technical Report notes alternative acids such as citric and lactic acid, nonsynthetic substances permitted at 7 CFR 205.605(a). These weak acids inhibit food discoloration, however the inability of these acids to provide the reducing power of ascorbic acid prevents preservative action against reactive oxidized species and limits their efficacy against viral contamination. The Technical Report cites the use of controlled atmosphere with little to no oxygen to retard microbial-based spoilage. However, the use of controlled atmospheres in packaging and processing has also been known to affect the color and other organoleptic properties of the foods. Other alternatives include the use of fruit juices to fortify foods. However, this strategy is limited; the relative instability of ascorbic acid and the presence of additional substances present in fruit juices that may result in undesired changes to the organoleptic properties of the processed foods.

## Questions to our Stakeholders

Do stakeholders have any experience with natural or organic alternatives to ascorbic acid for some or all of its uses in organic handling?

### Calcium citrate

**Reference:** § 205.605(b) Synthetics allowed  
(7) Calcium citrate.

**Technical Report:** [1995 TAP](#); [2015 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [4/2010 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

Calcium citrate is used as an ingredient in dietary supplements, where it provides calcium. It is also used as a nutrient; sequestrant; buffer; antioxidant; firming agent; acidity regulator in jams and jellies, soft drinks and wines; raising agent; an emulsifying salt; to improve the baking properties of flours; a stabilizer; to remove scale from boilers, evaporators and other processing equipment; to wash equipment to remove off flavors; in cosmetic and personal care items; and as a water softener.

Calcium citrate may be added to foods to supplement calcium per FDA nutrition guidelines, although there are other calcium sources for supplementation purposes including calcium carbonate, calcium oxide, calcium sulfate, etc., all of which are permitted per a separate listing on §205.605(b) as Nutrient Vitamins and Minerals.

### Manufacture

Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources, but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization. It is most commonly found in the tetrahydrate form.

## International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

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

Allowed as a food additive and processing aid in products of plant origin. (Annex V, Part A, A1, 2021/1165)

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

Calcium citrate is allowed in food of plant origin and dairy products/analogues. Not allowed in fats, oils, and fat emulsions. (page 25)

<https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-norms>  
[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as an additive. (Appendix 4 - Table 1 - page 79)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

## Ancillary Substances

None

## Human Health and Environmental Issues

There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

## Discussion

The bulk of the discussion about this product addresses the production process for citric acid. The Subcommittee supports relisting.

## Questions to our Stakeholders

Is there any information we should consider regarding the sunset of this substance?

## Collagen gel

**Reference:** § 205.605(b) Synthetics allowed

(13) Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.

**Technical Report:** [2019 TR](#)

**Petition(s):** [2018 \(for addition at 205.606\)](#)

**Past NOSB Actions:** [04/2019 Recommendation to add](#)

**Recent Regulatory Background:** Added to NL 07/26/2021 ([86 FR 33479](#))

**Sunset Date:** 7/26/2026

## Subcommittee Review

## Use

Collagen gel acts as an edible film used in meat products (e.g. sausage) as an alternative to casings, which is listed at §205.606(b). Collagen casings protect the meat product from oxidation and discoloration by acting as a semipermeable membrane for gases, moisture, and other solvents. The casing also provides a more desirable bite and texture to meat products as well as aids in additional flavorings to the product [2019 TR 282-284]. Collagen gel is a more affordable, efficient, and sanitary means of manufacturing meat products and increases opportunities to produce a larger variety of organic meat products [2019 TR 27-28]. It allows production of single-species products that can meet the needs and preferences of different consumer populations.

## Manufacture

Collagen is a natural animal protein found in skin, bones, muscle, and connective tissues that is isolated from mostly bovine and porcine sources at USDA-inspected facilities following all pertinent regulations. The animal-based collagen source is partially hydrolyzed through enzymatic, thermal, or acid treatment from meat processing byproducts to cleave the protein. Once cleaved, the collagen extract is decalcified and ground to uniformity within the collagen fibers. The collagen fibers are then swollen with an acid treatment before the extrusion process.

According to the TR, collagen gel is comprised of 3.0–4.5% collagen, <3% cellulose, and 95.5-97% water. Collagen is a naturally occurring protein that is abundant in the connective tissue, bones, blood vessels, skin, and muscles of animals. The unique structural properties of collagen's triple helix provide the desirable qualities of high-tensile strength and flexibility important to edible film casings [2019 TR 43-47].

Cellulose is currently approved for use as a synthetic substance in regenerative casings [extruded collagen casing that is dried prior to use], as an anti-caking agent (non-chlorine bleached) and filtering aid, and for processed products labeled "organic or made with organic," at 7 CFR 205.605.

Marine collagen is rarely used. Dark coloration and odor have been difficult to overcome. Isolating collagen from marine sources are based on processing fish by-products. Sources are not well defined and may vary from bones and skins to include viscera and heads [2019 TR 99-102]. At the time of the technical review, marine sources of collagen remained largely in research state.

## International Acceptance

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Collagen is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 6.4 as allowed for "ingredients not classified as food additives" in the form of "collagen casings." Collagen casings are required to "be derived from animal sources," and "if derived from cattle, shall be guaranteed free of specified risk materials." Moreover, collagen casings are permitted to include "other ingredients (such as, but not limited to cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture, which remain in the collagen casing."

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

Not explicitly mentioned

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

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**

Cellulose powder, derived from plant sources, is an inert substance in collagen gel. Cellulose's functionality is, however, critical once collagen gel has been coextruded into an enrobed extruded sausage. Cellulose adds permeability to the sausage's skin, allowing for the release of the meat emulsion's oil and fats during the sausage's cooking process. In finished collagen gel, cellulose is present in the range of 2 – 5%, depending on targeted product characteristics.

### **Human Health and Environmental Issues**

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional adverse impact on the environment.

### **Discussion**

Collagen gel, added to the National List in 2021, has provided more options for edible films and thus created a bigger market for organically produced meat; it is consistent with current regulations.

Collagen gel is GRAS (Generally Recognized as Safe) for use in meat products.

### **Questions to our Stakeholders**

1. Is there a method of production for nonsynthetic collagen gel?
2. Are organic livestock by-products commercially available for organic collagen gel production?
3. Have advancements been made with testing the viability of marine sourced collagen gel?

## **Ferrous sulfate**

**Reference:** § 205.605(b) Synthetics allowed

(15) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

**Technical Report:** [1995 TAP](#); [2015 TR](#) (Nutrient Vitamins and Minerals)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Renewed 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**

Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.).

## **Manufacture**

Ferrous sulfate is made by reacting sulfuric acid with iron.

## **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Ferrous sulphate is allowed for use if legally required and may be used, on a voluntary basis, if legally allowed. (Table 6.4, Vitamins and mineral nutrients listing, CAN/CGSB-32.311-2020, page 37)

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) & [2021/1165](#)

Not explicitly mentioned.

[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.

## **Ancillary Substances**

The 2015 TR for nutrient vitamins and minerals notes that ferrous sulfate is sometimes encapsulated to prevent the iron from catalyzing oxidation reactions that lead to rancidity, color and taste changes, or other undesirable effects. It is usually encapsulated in hydrogenated vegetable fat, with lecithin as an optional ingredient.

## **Human Health and Environmental Issues**

Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues.

Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function.

However, excess dietary iron can also cause health problems. Accidental overdose of ferrous sulfate drops is the most common cause of poisoning deaths in children in the U.S. Chronic excess consumption can cause constipation, nausea, vomiting, iron accumulation in the liver, higher cancer risk, and hemochromatosis.

Ferrous sulfate may also be hazardous in cases of skin contact (irritant), eye contact (irritant), ingestion, or inhalation. Possibly hazardous short term biodegradation products are not likely. However, long term biodegradation products may arise. The products of biodegradation are less toxic than the product itself.

The 2015 TR does not include information on environmental concerns for ferrous sulfate.

## **Discussion**

There has been past discussion about whether ferrous sulfate is encompassed within the nutrient vitamins and minerals listing or needs to be listed separately. The NOSB recommended identical annotations for



ferrous sulfate and nutrient vitamins and minerals in 1995, but they were ultimately listed with different annotations. The nutrient vitamins and minerals annotation is broader and would encompass ferrous sulfate and potentially allow other uses. However, because of the risks of excess iron consumption, it is unlikely that it would be added to products outside the uses currently allowed under the ferrous sulfate annotation.

The Subcommittee recommends retaining the current listing.

### Questions to our Stakeholders

Should the individual listing for ferrous sulfate be removed from the National List, with continued use of ferrous sulfate allowed under the nutrient vitamins and minerals listing, to eliminate redundancy?

## Hydrogen peroxide

**Reference:** § 205.605(b) Synthetics allowed  
(17) Hydrogen peroxide.

**Technical Report:** [2015 TR \(Crops\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 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

Hydrogen peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H<sub>2</sub>O<sub>2</sub>. 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, sanitizer, and 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 under 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))” under 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 (H<sub>2</sub>) and oxygen (O<sub>2</sub>): H<sub>2</sub>+ O<sub>2</sub> → H<sub>2</sub>O<sub>2</sub>

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Permitted for many uses including as food-grade cleaners, disinfectants and sanitizers that are

allowed without mandatory removal of residues; cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production; and as a food-grade processing aid for bleaching proteins and starches.

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

Allowed as a processing aid for gelatine. (Annex V, Part A, Section A2, 2021/1165)

[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](#)

Allowed as an equipment cleanser and disinfectant. (Appendix 4 - Table 2- page 82).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

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 2015 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 2015 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 with a yellow triangle designation; the yellow triangle means that 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 continues to receive strong support from 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, hydrogen peroxide should not have adverse impacts on human health and the environment.

Most recently, it was supported by the prior Handling Subcommittee without dissent and was relisted by the full NOSB without dissent. Discussion during this sunset cycle at the subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, and whether it has specific value in one sector or another. Questions emerged about the fact that the annotation on this substance differs from that on peracetic acid (another sanitizer) and why that might be.

## Questions to our Stakeholders

1. Is hydrogen peroxide an alternative to other more problematic sanitizers?
2. Do certifiers allow it to be used in direct contact with products?

## Nutrient vitamins and minerals

**Reference:** § 205.605(b) Synthetics allowed

(20) Nutrient vitamins and minerals, in accordance with [21 CFR 104.20](#), Nutritional Quality Guidelines For Foods.

**Technical Report:** [1995 TAP - Minerals](#); [1995 TAP - Vitamins](#); [2015 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2011 Handling Subcommittee Proposal](#); [04/2011 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

This listing allows nutrient vitamins and minerals to be added to organic food in accordance with 21 CFR 104.20, which is the U.S. Food and Drug Administration's (FDA) fortification policy. That policy lays out principles intended to serve as a model for the rational addition of nutrients to food and promote a balanced and nutritious food supply, while avoiding over- or under- fortification of consumer diets. It outlines situations in which it may be appropriate to add nutrients to food, including certain situations where needed to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency; to restore nutrients lost in storage, handling, or processing; to avoid nutritional inferiority of a food that replaces a traditional food; as well as where required by regulation. It states that FDA does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies or carbonated beverages. Manufacturers are urged to use these principles to design fortified foods.

The 2015 TR breaks this umbrella listing into five categories: fat-soluble vitamins (Vitamins A, D, E, K, carotenoids), water-soluble vitamins (Vitamins C, B1, B2, B6, B12, niacin, folate, pantothenic acid, biotin, choline, inositol), trace mineral elements (chromium, copper, iodine, iron, manganese, molybdenum, selenium, zinc), major minerals in bone (calcium, phosphorus, magnesium, fluorine), and major electrolyte minerals (potassium, sodium, chloride).

### **Manufacture**

Because this listing encompasses a wide range of substances with nutritional value, the processes used to create them also vary widely. Vitamins can be extracted from food, synthesized, produced via fermentation, or some combination of these methods. Of note, fermentation methods may involve genetically engineered microorganisms. Minerals are pulled from the environment, including brines, salt deposits, and mineral ores.

### **International Acceptance**

In addition to the categorical listings described below, all international standards also individually list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate).

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Vitamins and mineral nutrients are allowed as ingredients not classified as food additives in three situations:

1. Shall be used if legally required (e.g., fluid milk, white flour, infant formula, meal replacement, etc.).
2. The following non-dairy substitute products may be fortified on a voluntary basis, if legally permitted: plant-based beverages, products that resemble cheese, and butter substitutes.
3. Ferrous sulphate shall be used if legally required and may be used, on a voluntary basis, if legally permitted.

European Economic Community (EEC) Council Regulation, EC No. [2018/848](#) & [2021/1165](#)

Vitamins are allowed in the processing of food if their use is legally required. (Annex II, Part IV, 2.2.2 (f), 2018/848)

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

Vitamins and minerals are allowed if their use is legally required in the food products in which they are incorporated. (3.5, page 29)

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Minerals (including trace elements), vitamins, essential fatty, amino acids, and other isolated nutrients allowed when their use is legally required or strongly recommended in the food products in which they are incorporated. (Processing and Handling, page 19)

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

### **Ancillary Substances**

The 2015 TR states that ancillary substances are used to limit oxidation and promote even distribution of fat-soluble vitamins. Substances used to limit oxidation may include tocopherols, fat-soluble ascorbic acid (ascorbyl palmitate), carotenoids (e.g., beta carotene), and GRAS synthetic chemical antioxidants (BHT, BHA, PG, and TBHQ). Fat-soluble vitamin materials usually can be obtained free of BHT, BHA, PG, and TBHQ. Emulsifiers like lecithin are used to disperse fat-soluble vitamins in baby formula, and microencapsulation in

starch, gums, gelatin, casein, and a wide range of other GRAS substances help with dispersion in other foods. Encapsulation is also used to protect and disperse water-soluble vitamins and minerals in substances including fats, waxes, and cellulose. Many, but not all, of these substances are included on the National List.

### **Human Health and Environmental Issues**

The 2015 TR does not identify significant human or environmental issues connected with this categorical listing.

### **Discussion**

The NOSB's original 1995 recommendation for the nutrient vitamins and minerals listing included this annotation: "Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization," but the final rule published in 2000 (65 FR 13512) included the current annotation, which references FDA's fortification policy.

The Board and NOP have considered various proposals to change this listing to align more closely with the NOSB's original recommendation, to specifically address concerns about fortification of infant formula, and to consider nutrients that may fall in gray areas. According to the Board's 2019 sunset recommendation, in 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting, and the NOSB supported relisting with the existing annotation for the 2012 sunset review.

Several subsequent actions were considered, but nothing further appears to have progressed after the current listing was retained in the 2021 sunset, in alignment with the Board's 2019 recommendation. Specifically, no action has been taken to:

- Act on the [2016 Handling Subcommittee discussion document](#), which outlined several options for annotation changes.
- Finalize or withdraw the January 12, 2012 Proposed Rule (77 FR 1979), which would have changed the listing to: "Vitamins and minerals. For food- vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula-vitamins and minerals as required by 21 CFR 107.100 or §107.10." NOP published an Interim Rule on September 27, 2012 (77 FR 59287), effective October 21, 2012, which renewed the current listing until completion of the Proposed Rule.

It appears that there has not been sufficient public demand or regulatory challenge to carry through with changes to this listing. The current reference to 21 CFR 104.20 in the annotation essentially commits the use of nutrient vitamins and minerals to an organic food manufacturer's discretion, within the principles the FDA has set out.

The subcommittee recommends retaining the current listing.

### **Questions to our Stakeholders**

1. Are you aware of nutrient vitamins and minerals being used in organic products in ways that do not conform to 21 CFR 104.20?
2. Are there any remaining issues with fortification of infant formula that have not been resolved?
3. Do certifiers find the current annotation enforceable? Are there any particular substances in this category that are being allowed or prohibited inconsistently?
4. Are certifiers reviewing ancillary substances for nutrient vitamins and minerals in accordance with the Spring [2016 NOSB recommendation](#)? Are they imposing limits on ancillary substances that may be present?

5. Are there any specific substances included in this categorical listing that pose health or environmental concerns requiring closer review?

## Peracetic acid/Peroxyacetic acid

**Reference:** § 205.605(b) Synthetics allowed

(22) Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

**Technical Report:** [2000 TAP](#); [2016 TR](#)

**Petition(s):** [2008 Petition \(Crops\)](#)

**Past NOSB Actions:** [11/2000 recommendation \(Periacetic \[sic\] acid p. 467\)](#); [04/2004 resolution \(periacetic \[sic\] acid p. 2740\)](#); [11/2009 sunset recommendation](#); [04/2015 sunset recommendation](#); [10/2019 sunset recommendation](#).

**Recent Regulatory Background:** Added to National List with annotation 9/11/2006 ([71 FR 53299](#)); Renewed 8/03/2011 ([76 FR 46595](#)); Renewed 09/12/2016 ([81 FR 8821](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

### Subcommittee Review

#### Use

Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products according to FDA limitations, and to sanitize food contact surfaces, including dairy-processing equipment and food-processing equipment and utensils. It is an important sanitizer used in organic handling. It is widely used as a sanitizer on food contact surfaces and as a disinfectant for fruits and vegetables.

Peracetic acid/Peroxyacetic acid was added to the National List at §205.605(b) on September 12, 2006, with the annotation, “for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.” It is also on the National List at §205.601 and §205.603 for use in crops and livestock, respectively. Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The end products of peracetic acid oxidation are acetic acid and water.

#### Manufacture

According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer “peracetic acid.” Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Commercial grades are available in concentrations ranging from about 0.3 to 40% by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide.

## **International Acceptance**

### [Canadian General Standards Board Permitted Substances List](#)

Not explicitly mentioned for processed products. On food and plants, peracetic acid may be used in wash or rinse water and on food contact surfaces. (Table 7.3, page 42)

### [European Economic Community \(EEC\) Council Regulation, EC No. 2018/848 & 2021/1165](#)

Allowed for cleaning and disinfection. (Annex IV, Part D, 2021/ 1165)

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

Not explicitly mentioned for processed products.

### [International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Allowed as an equipment cleanser and disinfectant. (Appendix 4, Table 2, page 82)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

## **Environmental Issues**

Peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

## **Ancillary Substances**

HEDP (1-hydroxyethylidene-1,1- diphosphonic acid) and dipicolinic acid (2,6- pyridinedicarboxylic (DPA) are added to peracetic acid solutions to chelate metals, especially iron, copper and manganese, because decomposition of peracetic acid and, thus, loss of sanitizing power is accelerated by these impurities. However, in past reviews, stakeholders did not declare the inclusion of ancillary substances (see below).

## **Discussion**

Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has been strong support for continued availability of this material. Oral and written comments submitted for the Spring and Fall 2019 NOSB meetings represent hundreds, if not thousands, of crop and livestock farmers and

processors who uniformly support relisting this essential and relatively safe material. In particular, many processors identified the need for a “no-rinse” material as essential for treating equipment and other food contact surfaces. Overall, this material is considered effective and offers a less toxic profile than several other sanitizing materials, including many chlorine compounds. The TR does not offer new evidence of unacceptable adverse impacts on human health or the environment.

During the last sunset review, use of a synthetic stabilizer such as 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) or 2,6- pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition were judged to be “inerts” for EPA registration as an antimicrobial and not subject to review as an ancillary substance. However, comments submitted for the Spring 2019 meeting that at least “dipicolinic acid is a former List 3 ‘inert’ and not allowed in products used in organic production” and identifies additional

“inert” materials that warrant review. Only products with allowable “inert” ingredients should be used.

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

Discussion during this sunset cycle at the subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, whether it has specific value in one sector or another, and how stakeholders might become more open to using sanitizers like peracetic acid that are less corrosive without losing efficacy. Questions emerged about the fact that the annotation on this substance differs from that on hydrogen peroxide (another sanitizer) and why that might be.

### Questions to Stakeholders

None

## Potassium citrate

**Reference:** § 205.605(b) Synthetics allowed  
(25) Potassium citrate.

**Technical Report:** [1995 TAP](#); [2015 TR](#); [2023 Limited Scope TR pending](#)

**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

Potassium and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. The three citrates are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Potassium citrate is commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat.

#### Manufacture

Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources, but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered ‘classical mutants,’ and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.



The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization. It is most commonly found in the monohydrate form.

#### **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

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

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

Not explicitly mentioned.

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

Not explicitly mentioned

<https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-norms>  
[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as an additive. (Appendix 4 – Table 1 – page 79)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned

#### **Ancillary Substances**

None

#### **Human Health and Environmental Issues**

There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

#### **Discussion**

The bulk of the discussion about this product addresses the production process for citric acid. The Subcommittee supports relisting.

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

Is there any information we should consider regarding the sunset of this substance?

### **Potassium phosphate**

**Reference:** § 205.605(b) Synthetics allowed

(28) Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

**Technical Report:** [1995 TAP](#); [2016 TR](#)

**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

Potassium phosphate can be used as a pH control in milk and dairy products, to make acidified milk products and in milk protein stabilization. Potassium phosphate interacts with milk proteins, such as casein, to function as emulsifiers that prevent the separation of fat and water in cheese that stabilize milk and cheese by chelating (“sequestering”) calcium. [2016 TR, pgs. 4, 6]

Potassium phosphate can also be used as a nutritional additive for a source of potassium and as a nutrient in yeast. It can also be used in prepared meat applications and liquid eggs. The 1995 Technical Advisory Panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled “organic,” but was only approved for use in “made with” products.

### Manufacture

The 1995 TAP noted potassium phosphates are isolated from brines or salt deposits. However, the 2016 TR explained the manufacturing process to be as follows: All of the orthophosphate derivatives of potassium can be generated by neutralization of phosphoric acid with potassium hydroxide (Budavari 1996). Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate (Budavari 1996). Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm. [2016 TR, Table 5]

### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives. For use in products whose contents are  $\geq 70\%$  and  $< 95\%$  organic ingredients. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

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

Not explicitly mentioned

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

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

Not identified

## Human Health and Environmental Issues

During the last sunset review commenters noted a concern with the use of phosphates in production of processed foods and that phosphorus may not appear on the nutritional panel making it difficult to be informed about total phosphorous intake— although they would appear on the ingredient list. There were concerns raised about the cumulative health impacts of phosphorous additives in food and in 2015 the NOSB requested a technical review and work agenda item to study this issue further. According to the 2016 TR, most dairy foods naturally contain substantial amounts of both sodium and phosphorus from the milk, the small incremental amount of sodium and phosphorus contributed by a sodium phosphate stabilizer may exempt sodium phosphate from the requirement to be declared as an ingredient on the label; FDA requires more labeling in hypoallergenic foods and infant foods [2016 TR138-140]). The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long-term cumulative impacts are not fully understood.

## Discussion

Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis, and heart failure. Sodium phosphate was reviewed in 2017 and the NOSB came to the following conclusion: No single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population.

## Questions to our Stakeholders

1. Are there any new studies supporting the link between potassium phosphate and health issues?
2. Are there any new alternatives?

## Sodium acid pyrophosphate

**Reference:** § 205.605(b) Synthetics allowed

(30) Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.

**Technical Report:** [2001 TAP](#) (Sodium Phosphates); [2010 TR](#); [2016 TR](#)

**Petition(s):** [2002](#); [2007 \(Petition for expanded use\)](#)

**Past NOSB Actions:** [05/2003 recommendation](#); [11/2009 sunset recommendation](#); [04/2011 recommendation](#); [10/2019 sunset recommendation](#)

**Regulatory Background:** Added to National List 09/12/06 ([71 FR 53299](#)); Renewed 8/03/2011 ([76 FR 46595](#)); Renewed 09/12/16 ([81 FR 8821](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

## Subcommittee Review

### Use

The 2010 Technical Report (TR) indicates that sodium acid pyrophosphate is used in conventional foods as a chemical leavening agent in baked goods; a sequestrant (chelating agent) to maintain the appearance of cooked and uncooked fruits and vegetables, particularly processed potatoes; an emulsifying agent and stabilizer in cheeses and related products; an inhibitor of struvite formation in canned tuna; and a curing accelerator in processed meat and poultry products [2010 TR 36-40]. . The NOP regulations at 7 CFR 205.605(b) limit the use of sodium acid pyrophosphate in organic foods to use only as a leavening agent. Sodium acid pyrophosphate is used as a component of chemical leavening agents (“baking powder”). In some meat- and poultry-containing processed foods, sodium acid pyrophosphate is used to accelerate color fixing or to preserve color during storage of cured pork and beef cuts, cured poultry, and cured

comminuted poultry and meat food products. However, in organic foods, sodium acid pyrophosphate is permitted solely for leavening, so this color-fixing use is not permitted.

### **Manufacture**

Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220°C to form sodium acid pyrophosphate. It is expressed by the formula  $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$  and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

### **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed in ingredients classified as food additives. For use as a leavening agent. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

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

Not explicitly mentioned

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

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**

The 2016 technical report (TR) on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and completely bioavailable upon consumption whereas “food” phosphorous is much less available. High blood phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

### **Discussion**

Yeast is a natural leavener but results in a different physical texture and requires more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes such as found with muffins, pancakes and cookies.

Many manufacturers made comments during the 2019 sunset review about essentiality of this material because it is the only chemical leavening agent available.

The Subcommittee is interested to know if there has been any more definitive research linking this material to human health issues.

### Questions to our Stakeholders

1. Are there any new health studies regarding phosphorous consumption?
2. Are there any new alternatives to this material?

## Sodium citrate

**Reference:** § 205.605(b) Synthetics allowed  
(31) Sodium citrate.

**Technical Report:** [1995 TAP](#); [2015 TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB 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 and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. These materials are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Sodium citrate is used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy.

Sodium citrate is chiefly used as a food additive, usually for flavoring or as a preservative. Sodium citrate gives club soda both its sour and salty flavors. It is common in lemon-lime soft drinks, and it is partly what causes them to have their sour taste. Additionally, it is used in jams, jellies, meat products, baby foods, and milk powder.

#### Manufacture

Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources, but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization. It is most commonly found in the anhydrous or dihydrate forms.

### **International Acceptance**

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

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

Allowed as a food additive and processing aid in products of plant and animal origin. (Annex V, Part A, A1, 2021/1165)

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

Sodium Dihydrogen Citrate is not allowed in food of plant origin. Allowed in milks/cream, dairy-based drinks, unripened cheese, and yogurt as a stabilizer only. Allowed in processed cheese as an emulsifier only. Allowed in whey and whey products; excluding whey cheeses; processed meat; poultry, and game products; and egg white products. (page 25)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as an additive. (Appendix 4 - Table 1 - page 79)

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.

### **Ancillary Substances**

None

### **Human Health and Environmental Issues**

There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

### **Discussion**

The bulk of the discussion about this product addresses the production process for citric acid. The Subcommittee supports relisting.

### **Questions to our Stakeholders**

Is there any information we should consider regarding the sunset of this substance?

## Tocopherols

**Reference:** § 205.605(b) Synthetics allowed

(36) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

**Technical Report:** [1995 TAP](#); [2015 Limited Scope TR](#); [2023 Limited Scope TR pending](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#); [10/2015 sunset recommendation](#); [09/2016 Handling Subcommittee proposal to add listing](#); [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

Synthetic tocopherols are currently permitted for use in organic agriculture handling/processing as an antioxidant ingredient in foods (2015 TR). Tocopherols are added to foods to help prevent oxidation of the fatty acids present in the lipid components of the food. Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group[s])” when rosemary extracts are not a suitable alternative (7 CFR 205.605[b]).

#### Manufacture

Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables. As described in the 2015 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation. The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives. Tocopherols may be derived from vegetable oil when rosemary extract is not a suitable alternative. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

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

Allowed as an antioxidant in products of plant & animal origin. (Annex V, Part A, Section A1, 2021/1165)

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

Natural tocopherols allowed. (Table 3 - page 24)

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as a processing/post-harvest handling aid if from a natural source. (Appendix 4 - Table 1 - page 79)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed as an additive when used in products of livestock origin. Limited to the use in processed meat. (Appended Table 1)

### **Ancillary Substances**

The following ancillaries were listed in the 2015 TR: sunflower oil, soybean oil, gum acacia, sterols, squalene, monodiglycerides, calcium carbonate, silica, rice maltodextrin, organic sunflower oil, tapioca starch. The 2015 TR also listed “unknown” in the ancillary column for several tocopherol products. [2015 TR, Table 1]

### **Human Health and Environmental Issues**

Environment: Tocopherols are abundant in plant tissues and therefore are naturally abundant in the environment. Potential contamination could result from the manufacturing process of tocopherols if organic solvents and other chemicals are used. If these are released into the environment through waste streams, then environmental contamination could occur. The 2015 TR found no sources that discussed the possible persistence of tocopherols in the environment nor that concentrations of tocopherols or its breakdown products were present in the environment. [2015 TR 476-486]

Human Health: GRAS. It is unlikely that the use of tocopherols as an antioxidant in foods is harmful to human health. Tocopherols are a natural part of the human diet, with a large portion coming from naturally present in vegetable oils [2015 TR 507-509]

### **Discussion**

During previous reviews, the Board has consistently relisted tocopherols due to their wide use in many processed foods even though stakeholders have been divided about relisting.

Those in favor stated that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers.

Those opposed stated that the material’s primary use is as a preservative and therefore inconsistent with organic production, along with the assertion that non-synthetic tocopherols are commercially available and should be used instead of synthetic.

At the Fall 2019 meeting, the 2017 decision by the Handling Subcommittee to not move forward with an annotation change was reiterated, noting that if there were sufficient commercial availability of tocopherols in another form that members of the public were encouraged to submit a petition.

The Handling Subcommittee requested a limited scope TR to address the following: update to evaluation questions 1, 2, 3 and 13 to clarify the different manufacturing process of non-synthetic and synthetic tocopherols, as well as the commercial availability of the different forms (non-synthetic vs. synthetic). The Handling Subcommittee did not receive the TR in time to include into this document. The information in the TR will be discussed during the spring 2024 board meeting and be included in the fall proposal document.

### **Questions to our Stakeholders**

1. Are organic tocopherols commercially available?
2. Is there an adequate and suitable supply of non-synthetic tocopherols to meet commercial needs?



## Celery powder

**Reference:** § 205.606 Nonorganic agriculturals allowed

(c) Celery powder

**Technical Report:** N/A

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** [03/2007 NOSB 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

Celery powder serves a dual purpose in the formulation of meat products. In addition to flavor, its primary function is as a natural source of nitrate which cures meat without relying on synthetic nitrates and nitrites and has been used in this application for millennia. There are other vegetables and minerals which contain natural nitrates including beets, spinach, and sea salt. Although each has its benefits and challenges, none is an ideal substitute for natural celery powder in quality, form, and function.

In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage (as an antioxidant) and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled “uncured.”

#### Manufacture

Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, then heated and vacuum dried. According to the original 2007 petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (<https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf>), “the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load.” Celery powder is typically standardized to a specific nitrite content. See discussion below for more information about source material.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as food additives: Extracts, juice, or cultured powder of celery or chard are allowed. Shall be organic if commercially available. (Table 6.3, Meat curing agents listing, CAN/CGSB-32.311-2020, page 33)

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

Not explicitly mentioned, although sodium nitrate (an alternative to celery powder) is allowed.

[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**

Nonorganic celery is used to produce celery powder, with concomitant use of allowed conventional pesticides and fertilizers. These materials may pose risks to workers, consumers and the environment. Additionally, health concerns have been raised about the use of synthetic nitrates and nitrites in processed meats (allowed in the European Union). For example, the International Association for Research in Cancer (IARC) listed processed meats as carcinogenic to humans due to the formation of nitrosamines, albeit with low potency, and the review committee was not unanimous. In terms of human health risks from nitrates/nitrites in food, there is no difference between celery or other plant-based nitrate sources versus synthetic nitrates and nitrites used on non-organic meats. In summary, nitrates and nitrites from celery powder would pose similar risks. Nitrates in food may provide some health benefits. For example, formation of nitrous oxide may result in lowered blood pressure and better cardiovascular function.

### **Ancillary Substances**

Possibly materials listed in the patent and 2007 petition: “including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates.”

### **Discussion**

In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture.

Concerns were raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to “supercharge” the product used for celery powder manufacture.

In lieu of a technical report, a celery powder expert panel was convened for the April 2019 NOSB meeting. Experts spoke to key questions addressing nitrate safety, organic celery powder production, processing and manufacture of celery powder, progress toward organically sources celery or other substrates that could be used process organic meats, and the scale of the organic processed meat industry.

Overall, trade and industry members of the organic community supported relisting of celery powder at §205.606, with the caveat that more research is needed to produce a viable organic alternative. Given the importance of the organic processed meat industry, public and NOSB comments encouraged the USDA to fund additional research to develop organic alternatives to conventionally produced celery powder. It continues to be included in the Handling Subcommittee’s annual research priorities (most recently on the approved proposal from the Fall 2023 NOSB meeting).

Celery powder was recommended for relisting by the NOSB in 2015 on a split vote (9-5). It was recommended by the Handling Subcommittee for relisting in 2019 with no dissent and relisted by the full Board with one member in dissent.

Discussion during the current sunset cycle has focused on questions of ancillary substance review, fermentation, and an interest in understanding environmental impacts from conventional celery production.

### Questions to our Stakeholders

1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?
2. Is organic supply commercially available for this material? What are the barriers to organic production?
3. Is the organic version of the same caliber as the nonorganic?

## Fish oil

**Reference:** § 205.606 Nonorganic agriculturals allowed

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, [§§ 205.605](#) and [205.606](#)

**Technical Report:** [2015 TR](#)

**Petition(s):** [2007](#)

**Past NOSB Actions:** [03/2007 recommendation](#); [04/2010 sunset recommendation](#); [10/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Added to NL 6/21/2007 ([72 FR 35137](#)); Renewed 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

Fish oil is currently included on the National List as a nonorganically produced ingredient allowed in or on processed products labeled as “organic” when the substance is not commercially available in organic form (7 CFR 205.606). FDA GRAS notices (GRNs) exist for several variations of the term fish oil.

- fish oil concentrate (GRN 105)
- fish oil (GRN 138)
- fish oil (predominantly sardine and anchovy); tuna oil (GRN 193)

Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids—primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes,

inflammation, atherosclerosis. Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat products, cookies, crackers, snack foods, condiments, sauces, and soup mixes. [2015 TR 19-25]

Fish oil is also used in aquaculture as a feed supplement for farmed fish (Naylor et al., 2001). The farmed fish are fed fish oil because their diets are typically deficient in plants and animals that lead to the inherent production of fish oil (Naylor et al., 2001). [2015 TR 148-150]

In addition to aquaculture—estimated to use about 81% of the fish oil produced worldwide—fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture. Historically, fish oil was used as lamp oil, among other uses (Rizliya and Mendis, 2014). [2015 TR 155-158]

### **Manufacture**

Fish oil is produced from fish byproducts or from fish that are caught specifically for the purpose of making fish oil (Kim and Venkatesan, 2014). Between 20 and 80 kilograms of fish oil can be extracted per ton of fish waste (Karadeniz and Kim, 2014). The steps for fish oil extraction are-

Once the raw fish or fish parts are obtained, they are cooked in steam at 100 °C in a process called wet reduction (U.S. EPA, 1995; Kim and Venkatesan, 2014). The cooked material is then strained and sent to a press, where liquid, including the oil, is pressed from the cooked fish (U.S. EPA, 1995). The oil is decanted from the pressing liquid, and separation is accomplished using a centrifuge (U.S. EPA, 1995; Kim and Venkatesan, 2014). The oil may be further washed with hot water in a process called polishing (U.S. EPA, 1995). The oil is stored in tanks until it is used for its commercial purpose as a food ingredient or supplement, and any remaining fish solids or fish solubles from the process are dried and used as fish meal (Kim and Venkatesan, 2014). At this point in the process, the only additions to the fish oil are water, heat, and pressure. The waste streams from this process include emissions of volatile organic compounds (VOCs) hydrogen sulfide and trimethylamine and wastewater. VOC emissions result during both the pre- of fish solids and fish solubles into fish meal (U.S. EPA, 1995). [2015 TR 283-296]

Fish oil may be further processed by hardening, which is performed to further purify the oil (U.S. EPA, 1995). [2015 TR 304-305]

Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002). [2015 TR 311-313]

### **International Acceptance**

[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](#)

Fish oil is allowed in feed for carnivorous aquaculture animals (EC No 2018/848, General requirements, 3.1.3.3, page 76).

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

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

**Human Health and Environmental Issues**

There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, PCBs might also be present in fish oil. Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil.

**Discussion**

At the Fall 2023 NOSB meeting in Providence, RI, NOP indicated that they would not be moving forward with NOSB's recommendation to amend the annotation on fish oil restricting sources to fishing by-products only and to fishing industries that meet third-party sustainability standards. Moving forward with the organic aquaculture standard and developing an organic production standard for wild caught fish, as required by OFPA, would facilitate the production of certified organic fish oil and could alleviate concerns about overfishing and toxic contaminants present in fish oil.

**Questions to our Stakeholders**

Are there any environmental concerns to be considered?

**Gelatin**

**Reference:** § 205.606 Nonorganic agriculturals allowed  
(h) Gelatin (CAS # 9000-70-8).

**Technical Report:** [2002 TAP](#); [2019 TR gelatin, collagen gel, and casings](#)

**Petition(s):** [2001](#); 2002 (addition as ingredient (capsules)); [2007 Petition \(addition to 205.606\)](#)

**Past NOSB Actions:** [05/2002 NOSB recommendation](#); [05/2007 recommendation to add](#); [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:** 09/12/2026

**Subcommittee Review**

**Use**

Gelatin is used in a wide range of products as a clarification or fining agent in teas, juice, and wine, as a stabilizer, texturizer, thickener, and in capsules. It may either be an ingredient or a processing aid in candies (gummy bears), desserts (puddings, jello, marshmallows), dairy products (yogurt, sour cream, ice cream), cereals and cosmetics. Fish gelatin is widely preferred for uses in kosher foods. Collagen, also on the National List, is the native form of gelatin and chemically the two are indistinguishable.

## **Manufacture**

Gelatin can be made from many different sources of collagen. Cattle bones, hides, pigskin, and fish are the principle commercial sources. Gelatin may be prepared in a way that is more like cooking and could be considered nonsynthetic. However, gelatin may also be processed in ways that would render it synthetic. All manufacturing operations extract and hydrolyze collagen found in fish skins, bovine bone, and porcine skin with subsequent purification, concentration, and drying operations. These can be either simple or complicated operations.

## **International Acceptance**

### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Allowed as ingredients classified as food additives: shall be organic if commercially available. Gelatine may be sourced from plants or animals. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.3, CAN/CGSB-32.311-2020, page 32)

Allowed as processing aids: shall be from organic sources if commercially available. Allowed sources are plants and animals. Animal gelatine may be used in preparations of canned meat or as a gelling agent for gummed candy. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.5, CAN/CGSB-32.311-2020, page 39)

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

Allowed in products of plant origin. (Annex V, Part A, Section A2, 2021/1165)

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

Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4 - page 30)

### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Allowed as a processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Additive allowed. Limited to the use in processed products of plant origin. (Appended Table 1)

## **Ancillary Substances**

It does not appear that there are any ancillary ingredients used regularly for gelatin, such as anti-caking agents, preservatives, colorings etc.

## **Human Health and Environmental Issues**

There have been no published studies on the impact of gelatin on human health. Gelatin has been widely incorporated into a range of industries, including food and medicine, and is widely regarded as biocompatible and biodegradable. It is not anticipated to have a negative impact on human health or have a negative impact on the environment or biodiversity.

## **Discussion**

The 2019 TR did not contain new information indicating that organic gelatin would be commercially available in the near future. In 2021 the Handling Subcommittee hoped that at the next sunset review, the barriers to production of organic gelatin will no longer be present.

Gelatin has been granted GRAS status by the FDA for “substances migrating from cotton and cotton fabrics used in dry food packaging,” at 21 CFR 182.70. Moreover, gelatin is generally recognized as safe (GRAS) when used “to clarify juice or wine,” at 27 CFR 24.246.

### Questions to our Stakeholders

1. Is there sufficient commercially available organic gelatin?
2. What gaps persist that necessitate gelatin to be on the national list?

## Orange pulp, dried

**Reference:** § 205.606 Nonorganic agriculturals allowed  
(m) Orange pulp, dried.

**Technical Report:** N/A

**Petition(s):** [2008 Petition](#)

**Past NOSB Actions:** [11/2008 NOSB recommendation for addition to the National List](#); [10/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Added to NL effective 03/15/2012 ([77 FR 8089](#)); Renewed 03/15/2017 ([82 FR 14420](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 9/12/2026

### Subcommittee Review

#### Use

Dried orange pulp is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use but is self-limiting after that point due to loss of desirable eating qualities.

#### Manufacture

Dried orange pulp is a byproduct of the orange juice industry and is manufactured from the washed orange peel, core and rag (membrane) remaining after juicing. The pulp is then mechanically dewatered, stabilized with heat, dried, and mill-ground to a powder. The only processing aid used is water. No chemicals are used to process the product. The petitioner notes, due to food safety and economics, dried orange pulp manufacture must be co-located with orange juice processing facilities.

#### International Acceptance

[Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Not listed

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

Not listed

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

Not listed individually as non-organic agricultural commodities allowed. However, CODEX allows for up to 5% non-organic content.

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Not listed individually as non-organic agricultural commodities allowed. However, IFOAM allows for up to 5% non-organic content.

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not listed individually as non-organic agricultural commodities allowed. However, JAS allows for up to 5% non-organic content.

#### **Ancillary Substances**

No ancillary substances are indicated.

#### **Human Health and Environmental Issues**

The only noted concern pertaining to orange pulp is the use of conventional pesticides in conventional orange production that may negatively impact the environment and potentially leave residue in the final product of orange pulp, dried.

#### **Discussion**

During the Spring 2019 review, the Handling Subcommittee voted to remove this item from the National List because orange pulp, dried, does not seem to be necessary for or consistent with organic handling (failing OFPA criteria at 7 U.S.C. 6517(c)(ii)–(iii)), and alternatives exist (failing OFPA criteria at § 6518(m)(6)). There were no comments that supported its use, nor any known organic products that include it as an ingredient. However, orange peel and orange pulp were listed as ingredients in organic products. It was noted that this listing also has a patent which may limit its use in organic products. Additionally, during the in-person Fall 2019 NOSB meeting, the petitioner for this substance provided verbal comment, and stated that they wished to continue the listing. . They indicated that they have customers who wish to continue the use of this nonorganic product in their organically labeled foods. The petitioner also clarified the supply of organic oranges is located about an hour too far away from their processing facility to use their patented process and make their dried orange pulp.

While numerous NOSB members felt that the use of dried orange pulp is very small, and in the future, the distance issues and other barriers may be overcome, a decisive vote to remove it from §205.606 was not reached, therefore the motion to remove orange pulp from §205.606 failed. (7/5)

A search in September 2023 of the Organic Integrity Database for orange pulp, dried, or dried orange pulp, resulting in zero results. However, when searching for orange pulp, 6 entities were found and when searching for orange powder, 29 entities were found.

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

1. Is there a sufficient and suitable supply of organic orange pulp, dried? If not, how can we overcome the barriers that limit organic production of orange pulp, dried
2. Are there organic products that would not be able to be produced if orange pulp, dried was removed from the National List?



## Seaweed, Pacific kombu

**Reference:** § 205.606 Nonorganic agriculturals allowed  
(q) Seaweed, Pacific kombu.

**Technical Report:** [2016 TR](#) (Marine Plants & Algae)

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** [05/2008 NOSB recommendation](#); [10/2015 sunset recommendation](#); [10/2019 sunset recommendation](#)

**Recent Regulatory Background:** Added to NL effective 03/15/12 ([77 FR 8089](#)); Renewed 03/15/2017 ([82 FR 14420](#)); Renewed 8/3/2021 ([86 FR 41699](#))

**Sunset Date:** 09/12/2026

### Subcommittee Review

At §205.606 (d)(3), (n), (v) and (z), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” when the specific product is not commercially available in “organic” form: (d)(3) beta-carotene extract color, derived from algae (CAS #1393– 59 63–1), not produced using synthetic solvents and carrier systems or any artificial preservative; (n) Kelp used only as a thickener and dietary supplement; (v) Pacific kombu; and (z) Wakame seaweed (*Undaria pinnatifida*) [2016 TR 55-61]

### Use

Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets’ demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. An informal market exists among coastal dwellers in some developing countries where there has been a tradition of using fresh seaweeds as vegetables and in salads (FAO, 2012). [2016 TR 193-195]

Kombu, produced from hundreds of hectares of brown seaweed, *Laminaria japonica* that is grown on suspended ropes in the ocean.

Seaweeds as a source of hydrocolloids dates back to 1658, when the gelling properties of agar that is extracted with hot water from a red seaweed were first discovered in Japan. Extracts of Irish moss, another red seaweed, contain carrageenan and were popular as thickening agents in the nineteenth century. [2016 TR 217-219]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled.

Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include “marine extract”, “extract of alga”, “seaweed extract” or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added. 2016 TR 252-254]

### Manufacture

Kelps are seaweed and recognized as Kombu in Japan and various kinds of food made from Kombu, one of the most important of the marine vegetable preparations. The seaweeds used in the manufacture of Kombu are coarse, broad-fronded members of the kelp family (Laminariaceae), and until *Laminaria japonica* was introduced. Other kelps utilized in Kombu manufacture are *Arthrothamnus bifidus* and *kurilensis*, *Alaria fistulosa* (Smith, 1904). [2016 TR 858-866] The gathering of kelp begins in July and ends in October and is engaged in by many fishermen. The fishermen go to the kelp grounds in open boats, each boat with one to

three men and a complement of hooks with which the kelp is torn or twisted from its strong attachment on the rocky bottom. The hooks are of various patterns; some are attached to long wooden handles, and some are weighted and dragged on the bottom by means of ropes while the boats are under way (Smith, 1904). [2016 TR 868-872]

Uses of the Argentinian seaweeds have expanded to new markets for human consumption, nutraceuticals, and cosmetics including the fucoidan industries. Local farmers directly sell the seaweeds to the processing companies or companies with concessions which directly employ their own workers for harvesting during the year and contracted divers in the summer. The National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

An Icelandic company whose products include rockweed (*Acophyllum nodosum*) and kelp (*Laminaria digitata*). Mechanical harvesting uses specialized equipment and takes place between April and October. As with other areas where *Acophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (Ingolfsson, 2010). [2016 TR 893-897]

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

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

Not explicitly mentioned.

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

Seaweeds and seaweed products are allowed for use in soil fertilizing and conditioning (Table 1, page 19). Seaweed, seaweed meal, seaweed extracts, sea salts, and salty water are allowed for plant pest and disease control (Table 2, page 22).

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Seaweed and seaweed products allowed as fertilizers and soil conditioners if obtained by physical processes, extraction with water or potassium hydroxide solutions when the minimum amount of solvent necessary for extraction is used, and fermentation (Appendix 2, page 75).

#### [Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

### **Ancillary Substances**

None

## Human Health and Environmental Issues

No known impact on human health impact and environmental issues, per 2016 TR.

### Discussion

Public comment from the previous sunset review indicated that the two seaweed materials be reviewed within the broader context of marine materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. At the fall 2023 meeting, the NOP stated that it will not take action on the NOSB's fall 2020 recommendations on other marine materials, in light of the "technical complexity of marine environments."

### Questions to our Stakeholders

Is organic Pacific kombu commercially available? If not, what barriers remain?

## Wakame seaweed

**Reference:** § 205.606 Nonorganic agriculturals allowed  
(t) Wakame seaweed (*Undaria pinnatifida*).

**Technical Report:** [2016 TR](#) (Marine Plants & Algae)

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** [04/2007 NOSB 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

Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). As the world has internationalized, seaweed consumption as food including Wakame, has expanded from China, Japan and Korea to the entire world. Farming seaweed on lines in the ocean has expanded globally for production of alginates, carrageenans, other chemicals and the edible seaweed varieties, as management of harvest of wild seaweed forests continues throughout the world (Hunter, 1975). [2016 TR 379-383] Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets' demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. [2016 TR 192-193]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled. Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include "marine extract", "extract of alga", "seaweed extract" or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added.

Whole algae incorporated into food and food additives has been used to develop healthier and more nutritious foods particularly because there is a technical advantage in the use of algae as natural ingredients in food reformulation for healthy foods and beverages. Wakame (*Undaria pinnatifida*) a widely consumed brown algae contains high levels of dietary fiber and minerals. [2016 TR 505-508]

### **Manufacture**

The edible seaweed wakame is produced by drying *Undaria pinnatifida* and is generally regarded as safe (FDA GRN No. 565 — 21 CFR 184.1120). The Republic of Korea grows three different species, and about 50 percent of this is for Wakame, produced from a different brown seaweed, *Undaria pinnatifida*, grown in a similar fashion to *Laminaria* in China.

*Undaria pinnatifida* (wakame) and *Saccharina latissima* (sugar kombu) are two of the most valuable seaweeds in northern Spain due to their high demand and economic value. On a commercial basis along the Atlantic coast of Europe, particularly in northern Spain, water movement is a key factor controlling the production and quality of kelp. *U. pinnatifida* is best cultured at more exposed sites rather than at sheltered sites, whereas both sheltered and exposed sites are suitable for *S. latissima* cultivation; hanging rope culture is best in sheltered areas, while horizontal rope culture is better suited for exposed locations. The fixed-pole anchor system for raft culture has been used successfully in exposed open-ocean sites as an alternative to the traditional system with concrete blocks; outplanting dates for the *U. pinnatifida* and *S. latissima* on the Atlantic coast of southern Europe are from October to November and from November to December, respectively. Harvesting is conducted from March to April and from April to May for these two outplanting seasons, respectively. Seawater temperature and seawater nitrogen concentration are the main determinants of the start and end of culture in the sea for both species. *S. latissima* is more economically and environmentally advantageous than *U. pinnatifida* (Peteiro et al., 2016). [2016 TR 1046-1057]

In Argentina, the National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

### **International Acceptance**

#### [Canadian General Standards Board Allowed Substances List \(CAN/CGSB 32.311-2020\)](#)

Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

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

Not explicitly mentioned.

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

Seaweeds and seaweed products are allowed for use in soil fertilizing and conditioning (Table 1, page 19). Seaweed, seaweed meal, seaweed extracts, sea salts, and salty water are allowed for plant pest and disease control (Table 2, page 22).

#### [International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Seaweed and seaweed products allowed as fertilizers and soil conditioners if obtained by physical processes, extraction with water or potassium hydroxide solutions when the minimum amount of solvent necessary for extraction is used, and fermentation (Appendix 2, page 75).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not explicitly mentioned.

**Ancillary Substances**

None

**Human Health and Environmental Issues**

No known impact on human health impact and environmental issues, per 2016 TR.

**Discussion**

Public comment indicated that the two seaweed materials be reviewed within the broader context of Marine Materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

**Questions to our Stakeholders**

Is organic wakame commercially available? If not, what barriers remain?