



**National Organic Standards Board Meeting**  
**Stoweflake Conference Center, Pinnacle Room Stowe, Vermont**  
**October 26 - 30, 2015**

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## Sunset 2017 Review Meeting 2 - Review Crops Substances October 2015

As part of the National List Sunset Review process, the NOSB Crops Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

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

[Alcohol: Ethanol](#)

[Alcohol: Isopropanol](#)

[Chlorine Materials: Calcium hypochlorite,](#)

[Chlorine dioxide, Sodium hypochlorite](#)

[Hydrogen peroxide](#)

[Soap-based algicide/demossers](#)

[Herbicides, soap-based](#)

[Newspaper or other recycled paper](#)

[Plastic mulch and covers](#)

[Soaps, ammonium](#)

[Ammonium carbonate](#)

[Boric acid](#)

[Elemental sulfur](#)

[Lime sulfur](#)

[Oils, horticultural](#)

[Soaps, insecticidal](#)

[Sticky traps/barriers](#)

[Sucrose octanoate esters](#)

[Pheromone](#)

[Vitamin D3](#)

[Coppers, fixed](#)

[Copper sulfate](#)

[Hydrated lime](#)

[Potassium bicarbonate](#)

[Aquatic plant extracts](#)

[Humic acids](#)

[Lignin sulfonate](#)

[Magnesium sulfate](#)

[Micronutrients: Soluble boron products,](#)

[Sulfates, carbonates, oxides, or silicates of zinc,](#)

[copper, iron, manganese, molybdenum,](#)

[selenium, and cobalt](#)

[Liquid fish products](#)

[Vitamin B1, C, E](#)

[Ethylene](#)

[Sodium silicate](#)

[EPA List 4 - Inerts of Minimal Concern](#)

[Microcrystalline cheesewax](#)

### **205.602 Prohibited nonsynthetic substances**

[Ash from manure burning](#)

[Arsenic](#)

[Lead salts](#)

[Potassium chloride](#)

[Sodium fluoaluminat](#)

[Strychnine](#)

[Tobacco dust \(nicotine sulfate\)](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

## Alcohols - ethanol

**Reference:** 205.601(a)(1)

(i) Ethanol. As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Technical Report(s):** 1995 TAP; [01/2014 TR - Ethanol](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Ethanol (ethyl alcohol) is currently allowed for use in organic crop production as an algicide, disinfectant and sanitizer, including irrigation system cleaning. Ethanol provides broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, and is commonly used in organic production for disinfecting pruning tools. Ethanol can be produced through natural fermentation processes, but due to the common use of genetically modified organisms and other materials prohibited in organic production, ethanol from commercial sources are considered synthetic. Essential oils can be used as disinfectants, but their efficacy is in question.

In the first round of public comments, there was support for renewal of ethanol on the National List as a safe and effective sanitizer, though some comments suggested that natural sources of ethanol should be used.

### Motion to Remove

This proposal to remove ethanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ethanol from §205.601(a)(1) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA

### Vote in Subcommittee

Motion to remove Ethanol from §205.601(a)(1)

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Alcohols - isopropanol

**Reference:** 205.601(a)(1)

(ii) Isopropanol. As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Technical Report(s):** 1995 TAP; [02/2014 TR - Isopropanol](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Isopropanol (isopropyl alcohol) is currently allowed for use in organic crop production as an algicide, disinfectant and sanitizer, including irrigation system cleaning. Isopropanol provides broad-spectrum antimicrobial activity through the dissolution of lipid membranes and rapid denaturation of proteins and is used in organic production for disinfecting irrigation lines and disinfecting pruning tools. Commercial isopropanol is produced primarily through direct and indirect hydration of propylene. Isopropanol can be produced through natural fermentation processes.

In the first round of public comments there was support for continued use of isopropanol as a safe and effective sanitizer, though some comments suggested that natural forms of ethanol should be used.

### Motion to Remove

This proposal to remove isopropanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Isopropanol from § 205.601(a)(1) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA.

### Vote in Subcommittee

Motion to remove Isopropanol from § 205.601(a)(1)

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Chlorine materials - Calcium Hypochlorite

**Reference: 205.601(a)** - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite

**Technical Report(s):** [1995 TAP](#); [2006 TR](#); [2011 TR](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/27/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Calcium hypochlorite is an EPA registered pesticide (OPP No. 014701) that is used in controlling bacteria, fungi, and slime-forming algae (2011 TR lines 86-87). In water and soil, calcium hypochlorite separates into calcium, hypochlorite ions (OCI-), and hypochlorous acid (HOCl) molecules. The hypochlorous acid molecules diffuse through cell walls of microorganisms, changing the oxidation-reduction potential of the cell and inactivating triosephosphate dehydrogenase, an enzyme essential to the digestion of glucose, destroying the microorganism's ability to function. (2011 TR lines 122-133).

Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed (TR lines 194-195).

Calcium hypochlorite is highly caustic and is a concern for occupational exposure. Acute exposure to high concentrations can cause eye and skin injury. Ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus and stomach (2011 TR lines 411-418).

For the first round of public comment, the subcommittee asked two questions:

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

None of the public comments specifically addressed those questions. However, a number of comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. One comment advised that food safety requirements make chlorine products necessary in a variety of circumstances. However, one comment argued that organic production should be chlorine-free as much as possible.

### Motion to Remove

This proposal to remove calcium hypochlorite will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Calcium hypochlorite from 205.601(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### Vote in Subcommittee

Motion to remove Calcium hypochlorite from 205.601(a)

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

## Chlorine materials - Chlorine Dioxide

**Reference: 205.601(a)** - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials - For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(ii) Chlorine dioxide

**Technical Report(s):** [1995 TAP](#); [2006 TR](#); [2011 TR](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/27/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

EPA has registered the liquid form of chlorine dioxide for use as a disinfectant and sanitizer. The Agency also has registered chlorine dioxide gas as a sterilant. Chlorine dioxide is added to drinking water as a disinfectant in some municipal water-treatment systems in the United States. EPA has set a maximum contaminant level (MCL) of 0.8 mg/L for chlorine dioxide in drinking water and 1 mg/L for chlorite (chlorine dioxide's oxidation product) (2011 TR lines 104-110).

Chlorine dioxide kills microorganisms directly by disrupting transport of nutrients across the cell wall. Chlorine dioxide is an effective disinfectant at a pH of between 5 and (2011 TR lines 149-157).

To form chlorine dioxide, sodium chlorate (NaClO<sub>3</sub>) and sulfuric acid (H<sub>2</sub>SO<sub>4</sub>) are reacted with sulfur dioxide (SO<sub>2</sub>), or chloric acid is reacted with methanol (CH<sub>3</sub>OH). Alternatively, chlorine dioxide can be formed with chlorine (Cl<sub>2</sub>) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate (2011 TR lines 206-210).

Chlorine dioxide is a severe respiratory and eye irritant. The reaction products of chlorine dioxide (chlorite and chlorate) can cause oxidative damage to red blood cells and mild neurobehavioral effects (2011 TR lines 433-436).

For the first round of public comment, the subcommittee asked two questions:

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

None of the public comments specifically addressed those questions. However, a number of comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. One comment advised that food safety requirements make chlorine products necessary in a variety of circumstances. However, one comment argued that organic production should be chlorine-free as much as possible.

### **Motion to Remove**

This proposal to remove chlorine dioxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of chlorine dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### **Vote in Subcommittee**

Motion to remove Chlorine dioxide from 205.601(a)

Motion by: Francis Thicke

Seconded by: Carmela Beck

Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

## **Chlorine materials - Sodium Hypochlorite**

**Reference: 205.601(a)** - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iii) Sodium hypochlorite

**Technical Report(s):** [1995 TAP](#); [2006 TR](#); [2011 TR](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/27/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Sodium hypochlorite is an EPA registered pesticide (OPP No. 014703) that is used in controlling bacteria, fungi, and slime-forming algae (2011 TR lines 86-87). In water and soil, sodium hypochlorite separates into sodium, hypochlorite ions (OCl<sup>-</sup>), and hypochlorous acid (HOCl) molecules. The hypochlorous acid molecules diffuse through cell walls of microorganisms, changing the oxidation-reduction potential of the cell and inactivating triosephosphate dehydrogenase, an enzyme essential of the digestion of glucose, destroying the microorganism's ability to function. (2011 TR lines 122-133).

Sodium hypochlorite is highly caustic and is a concern for occupational exposure. Acute exposure to high concentrations can cause eye and skin injury. Ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus and stomach (2011 TR lines 411-418).

Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na<sub>2</sub>CO<sub>3</sub>) (TR lines 199-202).

For the first round of public comment, the subcommittee asked two questions:

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?

None of the public comments specifically addressed those questions. However, a number of comments were received insisting that chlorine materials are necessary in organic production and handling, and that chlorine sanitizers have a wide range of uses, including sanitation of equipment and work surfaces, maintaining functioning irrigation systems, and preventing the spread of disease. One comment advised that food safety requirements make chlorine products necessary in a variety of circumstances. However, one comment argued that organic production should be chlorine-free as much as possible.

### **Motion to Remove**

This proposal to remove sodium hypochlorite will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sodium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### **Vote in Subcommittee**

Motion to remove Sodium hypochlorite 205.601(a)

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

## Hydrogen peroxide

**Reference:** 205.601(a)(4) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Reference** 205.601(i)(5) - As plant disease control.

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

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation - deferred; 06/2006 sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Hydrogen Peroxide is a very simple molecule with a formula of H<sub>2</sub>O<sub>2</sub>. While it can occur in nature fleetingly, it is manufactured through a catalytic reduction method that makes it considered synthetic. It is a weak acid but a strong oxidizer and this makes it very useful as a fungicide, cleaning agent, and disease control.

A new Technical Report (TR) was commissioned for Hydrogen Peroxide because the information on it was old and incomplete. It showed that Hydrogen Peroxide is inherently unstable and breaks down readily into oxygen and water. (TR Evaluation question 3-5). While it is toxic to disease spores and cells on contact, it has absolutely no residual effect. It has low or no impacts on birds, humans, or fish as long as it is used according to the label and protective application measures are taken. There can be some effects on soil microbiota in the very top layer of soil where it may come in contact, but because it breaks down so quickly, soil life is quickly restored. (TR 2015 Evaluation Question #8).

While there are some alternatives on the National List for sanitizers and disinfectants, as well as some essential oils with antiseptic properties, the National List items are not necessarily any better or safer than Hydrogen Peroxide, and the essential oils have not been studied to compare with Hydrogen peroxide side-by-side to see if they are equally as effective and benign. (TR Evaluation question 11). Certain bacterial and fungal products that are beneficial in controlling plant diseases may be valid alternatives for some uses as a fungicide, but often these are best used as preventative and not effective once disease has taken hold, and not good substitutes in all situations. Likewise some biological, cultural and physical methods keep the need for use to a minimum, but don't apply to every situation. (TR Evaluation question 12).

Most public comment supported keeping Hydrogen Peroxide on the National List. It was frequently mentioned that it is one of the few tools left against Fire Blight now that antibiotics cannot be used. It is widely used to clean equipment, in mushroom production, and to alternate with other materials for resistance management. No comments were put forward with new information that would contribute to the OFPA criteria review.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Hydrogen peroxide from §205.601(a) and §205.601(i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
Compatibility

**Vote in Subcommittee**

Motion to remove hydrogen peroxide from §205.601(a) and §205.601(i)

Motion by: Zea Sonnabend

Seconded by: Carmela Beck/Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: Recuse: 0

## Soap-based algicide/demossers

**Reference:** 205.601(a)(7) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Technical Report(s):** [1996 TAP](#); [2015 TR](#)

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

**Past NOSB Actions:** **Actions:** 09/1996 NOSB recommendation; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

For the first round of public comments, the subcommittee asked the question “What alternative materials are available for use as an algicide/demossers?” No comments were received that addressed that question. However, several general comments were received in favor of relisting soap-based algicide/demossers. One comment said “Soaps are not a threat to human health, they are composed of molecules that are common in the natural environment and which are readily utilized by many living organisms, as well as being readily degraded in the environment by both biological and abiotic processes.”

However, two commenters suggested that soap-based algicide/demossers should not be used for application to water. The 2015 TR indicates that while potassium and ammonium soaps degrade rapidly in the soil (lines 440-441), soaps are more toxic for aquatic organisms: “The acute and chronic toxicity of soap salts is markedly different for land- and water-dwelling organisms. Terrestrial animals—including mammals, birds, and insects—are largely unaffected by exposure to even high doses of potassium and ammonium salts of fatty acids, while aquatic animals are moderately (fish) to highly (crustaceans) sensitive to these substances” (TR lines 350-353).

The subcommittee questions whether soap-based algicide/demossers are in use by organic producers, and if they are essential for organic production. Therefore, the subcommittee is considering removing soap-based algicide/demossers from the National List.

### **Motion to Remove**

This proposal to remove soap-based algicide/demossers will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Soap-based algicide/demossers from §205.601(a)(7) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility and Alternatives.

### **Vote in Subcommittee**

Motion to remove Soap-based algicide/demossers from §205.601(a)(7)

Motion by: Francis Thicke

Seconded by: Carmela Beck

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

## **Herbicides, soap-based/ (Soaps, herbicidal)**

**Reference:** 205.601(b) As herbicides, weed barriers, as applicable (1) herbicides soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

**Technical Report:** [1996 TAP](#); [2015 TR](#)

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

**Past NOSB Actions: Actions:** [1996 recommendation](#); [11/2005 NOSB sunset recommendation](#); 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Soaps have herbicidal properties. From the 2015 TR: “the general herbicidal mode of action for soap salts involves the disruption of photosynthesis through destruction of the cell membrane, thereby resulting in plant death” (TR lines 122-123).

Soaps are considered to be relatively non-toxic to mammals and terrestrial systems. “U.S. EPA has waived all generic mammalian toxicity data requirements for potassium and ammonium soap salts due to the lack of effects at high doses in the available toxicity literature” (2015 TR lines 350-351). However, “soaps are toxic to aquatic plants and algae” (TR line 385) and “aquatic animals are moderately (fish) to highly (crustaceans) sensitive to these substances” (TR lines 347-348).

If soaps are used according to their allowed use under 205.601(b)(1) they will be applied to terrestrial systems and should not generally be a problem for aquatic organisms.

In the first round of public comments, several comments were received in favor of keeping soap-based herbicides on the National List. Comments indicated that though soap-based herbicides are sometimes only marginally effective, they are a safe alternative and some farmers rely on them for weed control on farmsteads, roadways, and other places they are approved for use. There were no comments in favor of removing soap-based herbicides.

### **Motion to Remove**

This proposal to remove Herbicides soap-based will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Herbicides, soap-based from §205.601(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### **Vote in Subcommittee**

Motion to remove Herbicides, soap-based from §205.601(b)

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## **Newspaper or other recycled paper**

**Reference:** 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspapers or other recycled paper, without glossy or colored inks.

**Reference:** 205.601(c) - As compost feedstocks - Newspapers or other recycled paper, without glossy or colored inks.

**Technical Report:** 1995 TAP; 2006 TAP

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote ; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 (77 FR 33290)

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Newspaper and other recycled paper provide organic mulching materials when natural mulches are not available. OMRI submitted comments listing six products made with newspaper or other recycled paper. The annotation prohibits colored inks out of concern for heavy metal contamination and glossy paper because it is more likely to have petroleum-based inks applied.

The CS found that changes have occurred in the processes of making newsprint and printing newspaper

that require further investigation to determine whether the annotation is necessary. Although paper can be a source of dioxins,<sup>1</sup> newsprint is made by mechanical means and processing of recycled paper, which do not use chlorine bleach.<sup>2</sup> As listed, there is some possibility of contamination with inks. Newspapers increasingly use soy-based inks, which eliminate some of the pollution from the petroleum-based vehicle (TR, lines 41-50; 64-65). Carbon black, the pigment used in black inks, is made from burning hydrocarbons and is expected to be partitioned to soil and/or carried by runoff and settle to bottom sediments.<sup>3</sup> Some colored inks still use heavy-metal-based pigments, but others contain organic chemical-based pigments that may not be more toxic than carbon black.<sup>4</sup> Glossy paper is more likely to use faster-drying petroleum-based inks.<sup>5</sup> The subcommittee findings are suggestive rather than conclusive, and an updated technical review would help the NOSB to make a decision based on the latest technology.

Newspaper does not appear to have detrimental chemical interactions with other materials used in organic farming (TR lines 251-253). Its impact is similar to other mulches and wood-based materials, assuming soy inks. Carbon black is not known to have a toxic effect (TR line 281). Carbon black persists in the environment.<sup>6</sup> Newspapers do not have detrimental effects on soil organisms, crops, or livestock (TR lines 275-276).

Natural substitutes are organic materials including wood chips, bark, straw, leaves, grass clippings, compost (TR lines 339-345). In addition plastic mulches and biodegradable biobased bioplastic mulch are on the National List. Alternative practices are mentioned in the TR: "For weed problems, options include mowing, livestock grazing, hand weeding and mechanical cultivation, flame, heat, or electrical means (USDA 2005). Proper crop rotation can serve to maintain soil organic matter, provide pest management, and provide erosion control (USDA 2005). In addition, other materials besides newspaper could be used as mulch." (TR lines 357-361).

In terms of compatibility, mulching confers multiple benefits to an organic system, and when used in conformance with OFPA (when natural mulching materials are not available), newspaper mulches can benefit the organic system.

No comments were submitted opposing the listing. Commenters pointed out that there have been many changes in newspapers since the original listing, and more investigation into newspaper production is needed to determine whether the annotation is still appropriate. One commenter stated, "There has been an exponential increase in the use of colored graphics and photography in daily papers

<sup>1</sup> Alliance for Environmental Technology, "ECF: the sustainable technology,"

[http://www.aet.org/epp/ecf\\_brochure.pdf](http://www.aet.org/epp/ecf_brochure.pdf)

<sup>2</sup> [Canopy Ecopaper Website www.canopyplanet.org/EPD/index.php](http://www.canopyplanet.org/EPD/index.php) ; [Treecycle](http://www.treecycle.com/recycling.html) Recycled Papers (definitions)

<sup>3</sup> Environment Canada, 2013. Screening Assessment for the Challenge: Carbon Black. <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2cf34283-1>

<sup>4</sup> Ink chemistry <http://www.rsc.org/chemistryworld/Issues/2003/March/inkchemistry.asp>

<sup>5</sup> Finley, Charles. 1997. *Printing paper and ink*. Albany: Delmar Publishers. p. 230. ISBN 0827364415.

<sup>6</sup> Environment Canada, 2013. Screening Assessment for the Challenge: Carbon Black. <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2cf34283-1>

since the last Technical Review was prepared and it is not easy to separate colored from black inks.” Another said, “Some colored inks may be no more harmful than carbon black, but this –and a verification procedure– should be determined based on an updated review.”

Three certifiers said newspaper is an important mulch material for the growers they certify. One said growers question the need for separating out glossy paper and paper with colored inks. Lacking an updated technical review, the CS recommends renewing the listing with the current annotation.

### **Motion to Remove**

A motion to remove Newspaper or other recycled paper will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Newspaper or other recycled paper from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### **Vote in Subcommittee**

Motion to remove newspaper or other recycled paper from 205.601(b) and 205.601(c)

Motion by: Harold Austin

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## **Plastic mulch and covers**

**Reference:** 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 (77 FR 33290)

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Plastic mulch has received much criticism because of the need to remove it at the end of the growing season, which results in plastic waste being hauled to landfills. Biodegradable bioplastic mulches are now allowed, which theoretically could eliminate some of the problems with plastic mulches. However, there is still no guidance on ensuring that bioplastic mulch degrades in the required timeframe, and it appears that no mulches are currently available that meet the criteria established by the NOSB and NOP

or are expected to be listed by OMRI this year.

Use of plastic mulch leads to environmental contamination because used plastic gets taken to landfills, and pieces are left behind on fields. (October 2012 NOSB meeting transcript.) Substitution for natural mulches reduces inputs of organic matter. Solarization effect kills microorganisms (Bioplastic mulch TR lines 574-579).

There can be contamination in manufacture and disposal because polyethylene is usually derived from either modifying natural gas (a methane, ethane, propane mix) or from the catalytic cracking of crude oil into gasoline, though it may be made from biological source,<sup>7</sup> and used plastic gets taken to landfills.

Polyethylene mulch leads to loss of water: In one season, the loss of water was 2-4 times higher and the loss of soil sediment was three times higher in plots where polyethylene mulch was used compared to those where hairy vetch residues were used (Bioplastic mulch TR lines 608-610). It substitutes for mulches that could contribute organic matter to the soil.

Natural alternatives are organic mulches and living mulches (Bioplastic mulch TR lines 684-696). Other alternatives on the National List are bioplastic mulch, recycled newspaper and other paper (Bioplastic mulch TR lines 701-721). Practices that could be used instead are: for weed control - tillage and other mulches; for soil warming - planting adapted plants (TAP p5).

The use of plastic mulch is incompatible with organic and sustainable agriculture because it is usually produced from natural gas and petroleum, creates much waste that goes to the landfill, and substitutes for organic mulches that add organic matter to the soil.

Surveys as well as grower comments all show a demand for plastic mulch by growers until biodegradable bioplastic mulches are available. However, one comment from a submitted survey raises a question as to how certifiers are enforcing the annotation of removal: "We always use black plastic mulch when we establish a vineyard. We do not irrigate, and the black plastic mulch is critical to us getting the baby vines growing well over their first three years in the ground. We always take the black plastic up after it has been in for 4-5 years." Since the material is required to be removed at the end of the growing season, this example should raise concerns about how that is carried forth.

### **Motion to Remove**

A motion to remove plastic mulch and covers will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Plastic mulch and covers from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

<sup>7</sup> Priscilla Lepoutre, The Manufacture of Polyethylene. <http://nzic.org.nz/ChemProcesses/polymers/10J.pdf>

impact on humans and the environment; compatibility and consistency.

### Vote in Subcommittee

Motion to remove plastic mulch and covers from 205.601(j)

Motion by: Harold Austin

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## 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:** [1999 TAP](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Ammonium soaps are used as a deer repellent. In the first round of public comments we received no comments against relisting ammonium soaps, and one comment from an organization indicating that some of its members depended on the use of ammonium soaps in their organic operations. In past sunset reviews, ammonium soaps were relisted each time without objections being raised. There is no compelling reason to remove ammonium soaps from the National List.

### Motion to Remove

This proposal to remove ammonium soaps will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ammonium soaps from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### Vote in Subcommittee

Motion to remove Soaps, ammonium from §205.601(d)

Motion by: Zea Sonnabend

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: Absent: 1 Recuse: 0

## Ammonium carbonate

**Reference:** 205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate — for use as bait in insect traps only, no direct contact with crop or soil.

**Technical Report:** [1995 TAP](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Ammonium carbonate is used in small quantities as an attractant in traps. It is volatile, and irritating to eyes and nose. Little damage would be expected other than the attraction of other insects. The main alternatives are manure management and enhancement of predators and parasitoids.

There is little likelihood of contamination of soil with use as fly bait (TAP p6). Escape of gas in use and manufacture is possible. It is made from ammonia and carbon dioxide. Ammonia is volatile and toxic (TAP p10). Irritant to eyes and nose.<sup>8</sup> It is incompatible with strong acids, nitrates, nickel, copper (TAP p11). However, interaction is unlikely with current annotation. Ammonium bicarbonate decomposes to ammonia, carbon dioxide, and water above 36 degrees C.<sup>9</sup> Other insects may be attracted to bait (TAP p4).

Natural alternatives include natural attractants (TAP p6). Other alternative materials are other ammonia-releasing chemicals (TAP p6). Practices that would make its use unnecessary include a good organic environment and enhancement of predators and parasitoids (TAP p4).

There was little interest in ammonium carbonate expressed in public comment. The only support came from an organization that said that because of its limited use pattern, little damage would be expected from it, and it can complement other approaches to controlling flies through manure management and enhancement of predators and parasitoids.

### Motion to Remove

This proposal to remove Ammonium carbonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ammonium from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Impact on Health and Environment and Essentiality.

<sup>8</sup> PubChem: ammonium carbonate.  
[http://pubchem.ncbi.nlm.nih.gov/compound/ammonium\\_carbonate](http://pubchem.ncbi.nlm.nih.gov/compound/ammonium_carbonate)

<sup>9</sup> PubChem: ammonium bicarbonate  
[https://pubchem.ncbi.nlm.nih.gov/compound/ammonium\\_carbonate](https://pubchem.ncbi.nlm.nih.gov/compound/ammonium_carbonate)

**Vote in Subcommittee**

Motion to remove Ammonium carbonate from 205.601(i)

Motion by: Harold Austin

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## Boric acid

**Reference:** 205.601(e) As insecticides (including acaricides or mite control). (3)Boric acid - structural pest control, no direct contact with organic food or crops.

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review:**

Boric acid, derived from the mineral borax, has long been considered a “least-toxic” pesticide because it is non-volatile when placed in bait or gel formulations, thus eliminating direct exposure. However, when used as a dust for structural pest control, exposure can occur, causing hazards for exposed populations. Boric acid is a reproductive toxicant, a suspected endocrine disruptor, and toxic to plants and animals if misused. Borax mining causes environmental damage. Boric acid raises challenging issues of health and environmental/mining impacts, and there are alternative materials and practices that may be less harmful. Of the alternative choices of pest control products, boric acid is considered to be among the least toxic, as noted in the sources used for this review.

A number of members of the public did comment regarding the listing of boric acid, and the majority supported re-listing.

The following question was put forth to the public:

“Are there situations in which boric acid is the only, or safest, means of controlling the pest?”, and some response was received.

It was stated that it is good to have as a means for control and as a back-up with insect problems.

Comment was received that natural alternatives do exist, and that management changes rather than a material application is the best if problems do occur.

There are many sub-components of OFPA criteria that are not fully met, within the criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency, however the alternatives often have equally challenging issues with compatibility.

**Motion to Remove**

This proposal to remove Boric Acid from 205.601 will be considered by the NOSB at its public meeting.

The Subcommittee proposes to remove Boric Acid from § 205.601(e) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove Boric Acid from § 205.601(e)

Motion by: Colehour Bondera

Seconded by: Carmela beck

Yes: 1 No: 4 Abstain: 0 Absent: 1 Recuse: 0

## Elemental sulfur

**Reference:** 205.601(e)(5) - As insecticides (including acaricides or mite control).

**Reference:** 205.601(i)(10) - As plant disease control.

**Reference:** 205.601(j)(2) - As plant or soil amendments.

**Technical Report:** [1995 TAP](#)

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

**Past NOSB Actions:** **Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2010 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

Elemental sulfur is on the National List at §205.601(e)(5) – As insecticides (including acaricides or mite control), §205,601(i)(10) – As plant disease control, and at §205.601 (j)(2) – As plant or soil amendments.

As an insecticide under (e)(5) it is used to help control anthropoids, mites, leprosis, and scab mites.

As plant disease control under (i)(10) it helps control powdery mildew, rusts, scab, pear scab, brown rot, rose black spot, and peach leaf curl.

As a plant or soil amendment under (j)(2) it is used to help assist in balancing the soil ph and is useful to both plant and soil beneficial insects. It can also help aid in increased water penetration.

Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery process. The latter appears to be the primary source of most elemental sulfur currently being used. Elemental sulfur has been registered for use by the EPA since 1920.

Internationally approved for use by: The E.U., IFOAM. Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013). Also allowed by Canadian Organic Standards.

In the original TAP the reviewers found Elemental sulfur to be relatively innocuous in the environment when used according to the product use label. It was also found to be of low toxicity. It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels. Could be considered to be an irritant to farm workers, this should be mitigated if label recommendations and proper PPE recommendations are followed. Two previous Sunset Material Reviews (2005 & 2010) of Elemental sulfur have resulted in all 3 use listings being re-listed.

The subcommittee did not request a new Technical Review during this current Sunset Review cycle.

During the 1<sup>st</sup> posting for public comment of this current Sunset Review cycle there were 3 specific questions posed to stakeholders to assist the subcommittee in their review of Elemental sulfur. There were 20 written public comments submitted along with numerous oral comments at the Spring meeting in La Jolla, Ca. These comments provided insight for the subcommittee in their required review of this material and helped to answer some of the questions that had been posed during the 1<sup>st</sup> posting. Some of this additional information helped to explain to the subcommittee that while there are numerous possible alternatives, many times because of certain situations or conditions, elemental sulfur still remained the best option for use in their specific operation and use pattern. It was explained that weather, humidity, location, variety sensitivity, compatibility, economics, resistance management, and cost all had to be considered by the organic producer and what was the best option for any given application be it for disease or insect control, or as a plant or soil amendment. There was over whelming support for the continued listing of Elemental sulfur by organic stakeholders. One commenter stated that a survey of their members resulted in a good cross section of how necessary elemental sulfur remains to their producers for use in controlling various bacterial diseases, pests, and as a plant and soil amendment. Another commenter stated that this material was a staple product used in organic tree fruit, grape, berries, and hop production. Certifiers provided an accounting (one certifier shows it listed on 2,042 OSP's) of how widely listed Elemental sulfur is in the OSP's of those organic producers that they certify. Two commenters, while not opposed to the re-listing, asked that specific uses and an annotation be considered by the subcommittee and full board.

After reviewing the original TAP, previous committee votes & discussions, and recently provided public comment, it would appear that Elemental sulfur is still necessary in organic crop production. No specific new information was provided that would suggest otherwise.

### **Motion to Remove**

This proposal to remove Elemental sulfur will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Elemental Sulfur from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### **Vote in Crops Subcommittee**

Motion to remove Elemental Sulfur from the National List at §205.601 (e)(5), §205.601 (i)(10), and §205.601 (j)(2).

Motion by: Harold V. Austin IV

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent : 0

## Lime sulfur

**Reference:** 205.601(e)(6) - As insecticides (including acaricides or mite control).

**Reference:** 205.601(i)(6) - As plant disease control.

**Technical Report:** [1995 TAP](#); [2014 TR](#)

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

**Past NOSB Actions:** **Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Lime sulfur is on the National List at §205.601 (e)(6) as insecticides (including acaricides or mite control) and at §205.601 (j)(6) as plant disease control. As an insecticide Lime sulfur is used to control mites (spider mites and rust mites), aphid, and san jose scale in tree fruit and other organic crops. As a fungicide it is used to control powdery mildew, anthracnose, scab, peach leaf curl, and several other plant diseases in tree fruit and berry crops. It is also part of a process that when used in conjunction (or in rotation) with other allowed materials as a replacement for the two recently removed antibiotics for assisting to control fire blight in organic apple and pear production.

Lime sulfur, is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [CaOH<sub>2</sub>] and ground sulfur (US EPA, 2005a; Hajjatie, 2006). Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the US EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

### International

- Canada – allowed as a fungicide, insecticide, or acaricide/mite control. (CAN,21)
- Codex Alimentarius – although not mentioned specifically, organic production guidelines from Codex Alimentarius Commission (CAC GL 32-1999) permit the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013).
- European Union – permits the use of lime sulfur (calcium polysulfide).
- Japanese Ministry of Agriculture Forestry and Fisheries – permits the use of lime sulfur powder for plant pest and disease control.
- IFOAM – lists lime sulfur in Section II of Appendix 3: Crop Protectants and Growth Regulators (IFOAM, 2014).
- UK Soil Association – only allows the use of lime sulfur on a case-by-case basis, when there is demonstrated a major threat to a grower's crop. (Soil Association, 2014).

The original TAP used the 1922 USDA Farm Bulletin as part of its fact finding! This TAP did not provide much information. There was a new Technical Evaluation Report developed on December 3, 2014 that has provided a source of more current and updated information. While the new TR provides a quite extensive list of alternative materials and alternative practices, it did not specify under what conditions or scenarios lime sulfur might or might not be the best option to use. The new TR did mention human health concerns from lime sulfur due to its high alkalinity, but stated that this concern would be mitigated during formulation or actual use, if proper safety procedures during manufacture and proper use (following label recommendations) are adhered to. There may be some impact on beneficial insects, such as predator mites, when used at higher rates. Attention to temperatures and weather conditions would help to minimize phytotoxicity to non-target plant species, where applicable.

There were 20 written public comments submitted for the 1<sup>st</sup> posting for public comment during the current (Sunset 2017 Review) cycle. There was an over whelming show of support for its continued listing. The commenters also stated that with the loss of the two previously allowed antibiotics and the increase in organic tree fruit production in recent years, the use of lime sulfur has actually increased. Public comments also provided insight to the subcommittee explaining that while there are alternatives, many times because of numerous contributing factors, lime sulfur is still the best option for them in their organic production, be it for disease control, insect control, or use as part of a fire blight control program. One commenter said that a poll of their members showed that it remains to be important and still very necessary for organic crop production. This commenter also stated: “Many of the materials currently under the 2017 Sunset Material Review were accepted by organic certification bodies prior to the implementation of the National Organic Program – they were considered to be part of the traditional definition of “organic” and in line with the Principles of Organic Production. In short, these materials (including lime sulfur) were a part of the foundation on which organic trade and production was built”.

Two commenters while not opposed to the re-listing of lime sulfur asked that its uses be looked at and that an annotation be added limiting its use by adding specific allowed uses.

This current Sunset Review of lime sulfur shows that it would appear to still be necessary in organic crop production. While human health concerns are of minimal concern when proper safety procedures in manufacture and use are followed, environmental concern to predators and non-target plant species are somewhat of a concern. But, these too can be mitigated (or minimized) if proper/or reduced rates and correct timing of applications (taking temperature and weather conditions into consideration) of lime sulfur are used by the organic crop producers applying this material.

### **Motion to Remove**

This proposal to remove Lime-sulfur will be considered by the NOSB at its public meeting.

Motion to remove Lime-Sulfur from the National List as listed at both §205.601 (e)(6) and §205.601 (i)(6).

The Subcommittee proposes removal of Lime-Sulfur from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### Vote in Crops Subcommittee

Motion to Remove lime sulfur from §205.601 (e)(6) as insecticides (including acaricides or mite control) and §205.601 (j)(6)

Motion by: Harold V. Austin IV

Seconded by: Carmela Beck

Yes: 1 No: 4 Abstain: 0 Recuse: 0 Absent :0

### Oils, horticultural

**Reference:** 205.601(e)(7) - As insecticides (including acaricides or mite control). —narrow range oils as dormant, suffocating, and summer oils.

**Reference:** 205.601(i)(7) As plant disease control. - narrow range oils as dormant, suffocating, and summer oils.

**Technical Report:** 1995 TAP

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

#### Subcommittee Review

Oils, horticultural are on the National List at §205.601(e)(7) –As insecticides (including acaricides or mite control) –narrow range oils as dormant, suffocating, and summer oils and at §205.601(i)(7) - As plant disease control- narrow range oils as dormant, suffocating, and summer oils.

As an insecticide under (e)(7) they are used to help control aphids, scales, leafhoppers, pear psylla, mealy bugs, and web worms in various organic crops.

As a plant disease control under (i)(7) they are used to help control scab, mildew, and various forms of rots in various organic crops.

Horticultural oils are manufactured from refined crude oil production (petroleum based).

Internationally approved for use by: a wide majority of certification groups such as, the E.U., Canada, IFOAM, Codex Alimentarius, and several others.

In the original TAP review it was mentioned that the use of dormant oils was compatible with organic systems because they attacked the pest at a weak stage in its lifecycle. The low toxicity of these materials, along with their mode of action support its use, even as a synthetic by nature. The original TAP states that even as a foliage spray, the low toxicity justifies its use. For summer uses there are other alternative materials, but the TAP mentioned that these do not target the insect eggs like the

horticultural oils do (function as an ovacide).

During the Sunset Review and vote during the November 17<sup>th</sup>, 2005 NOSB meeting the Board decided to defer the vote on oils until further technical information could be obtained. This discussion was around vegetable oils as a natural replacement for the horticultural oils. But, it was discovered that the vegetable oils contained synthetic emulsifiers (mainly derived from a petroleum base) that without these, the oils would not work properly. 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. It was also determined that the vegetable oils would not control certain pests adequately compared to the horticultural spray oils. Horticultural oils also unlike pesticides are not prone to resistance developing, because they work primarily to suffocate or detour pests and diseases. There was not a new Technical Review requested by the subcommittee during this current 2017 Sunset Review cycle.

During the 1<sup>st</sup> posting for public comment of this current Sunset Review cycle there were 3 specific questions posed to organic stakeholders and the public to assist the subcommittee in their review of Horticultural oils. There were 27 written comments submitted and several oral comments given at the Spring NOSB meeting in La Jolla, Ca. There was one commenter asking that the use patterns for oils be annotated or if not then it should be de-listed. One certifier commented that horticultural oils are listed on 1,041 of the Organic System Plans of those clients that they certify. Another commenter mentioned that a poll of their members found that this material remains important and still very necessary for organic crop producers. There was over whelming written and oral comments given in support of the continued listing and need for this material in organic crop production.

The comments received helped to provide some insight for the subcommittee and the full NOSB, in their required review of this material and helped to answer some of the questions that had been posed during the 1<sup>st</sup> posting for comment. Some of this information helped to explain to the subcommittee that while there are numerous possible alternatives, many times because of certain situations or conditions, horticultural oils still remain the best option for use in their specific operations. Commenters explained how these oils are used and why. They are allowed world-wide by most organic certifying bodies for use in organic crop production. The commenters also helped answer the question of use patterns under this current Sunset Review cycle stating that there have not been any changes in use or in alternatives that would make Horticultural oils unnecessary, in fact the use has expanded some due to growth in this segment of organic production.

Based off of extensive review of historical documents, previous subcommittee recommendations and the subsequent votes/discussion by the full board, previous and current public comments, and any other information provided to the subcommittee during this current review cycle: it would appear that Horticultural oil still remains a necessary material for use in organic crop production. There was no specific information provided that would suggest otherwise.

### **Motion to Remove**

This proposal to remove Horticultural oils will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Horticultural oils from the National List based on the following

criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### Vote in Crops Subcommittee

Motion to remove Horticultural Oil from 205.601(e) and 205.601(i)

Motion by: Harold V. Austin IV

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## Soaps, insecticidal

**Reference:** 205.601(e)(8) - As insecticides (including acaricides or mite control).

**Technical Report:** [1994 TAP](#)

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

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Generally, soaps consist of salts of fatty acid anions and potassium, sodium, or ammonium cations. Soap products are registered with the EPA as acaricides, algicides, herbicides, insecticides and animal repellents intended for residential, agricultural and commercial use ([TR for soaps, herbicidal](#)). For organic crop production, soaps are on the National List for three uses: soap-based algicides/demossers, soap-based herbicides and soap-based insecticides.

As insecticides, fatty-acid soaps disrupt the structure and permeability of the insects' cell membranes. The cell contents then leak from the damaged cells, and the insect dies. There is no residual insecticidal activity once the spray application has dried. Insecticidal soaps are most effective on soft-bodied pests such as aphids, adelgids, lace bugs, leafhoppers, mealy bugs, thrips, sawfly larvae, spider mites and whiteflies. Soap has a limited effect on non-target beneficial insects such as ladybird beetle larvae, parasitic wasps and honey bees, but it can be disruptive to soft-bodied predators, such as syrphid fly larvae and beneficial predatory mites. Once the spray has dried, however, beneficial insects can safely re-enter the treated area (Pundt).

Soaps have low mammalian toxicity. However, they can be mildly irritating to the skin or eyes. Insecticidal soaps are biodegradable, do not persist in the environment, and they do not contain any organic solvents (Pundt).

In the first round of public comments, the Crops Subcommittee heard that some organic producers use insecticidal soaps regularly, and they rated insecticidal soaps as critical to the success of their operations.

The Crops Subcommittee recommends that insecticidal soaps remain on the National List.

### Reference

[Pundt Leanne S., University of Connecticut, Extension Fact Sheet.](#)

### Motion to Remove

This proposal to remove soaps, insecticidal, will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of soaps, insecticidal, from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### Vote in Subcommittee

Motion to remove Insecticidal soaps from 205.601(e)(8)

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## Sticky traps/barriers

**Reference:** §205.601(e) As insecticides (including acaricides or mite control).  
(9) Sticky traps/barriers.

**Technical Report:** 1995 TAP

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

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

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) Sunset Date: 6/27/17

### Background

This listing covers a wide range of traps and coatings made with a number of different materials. Some are coated paper, some are coated plastic, and some are a sticky chemical that is brushed on plants. Coated plastic, at least, produces plastic waste that goes to the landfill. The sticky coating may contain petroleum distillates, and the traps may contain volatile attractants. Some are non-specific and can kill non-target insects, spiders, mites, reptiles, and amphibians.

One TAP reviewer (in 1995) suggested the traps are compatible with organic only in processing plants.

Another suggested they should be used only for monitoring or mass trapping. Twenty years since the review, there are many more types of traps, including targeted lures to attract only pest insects, and significant experience with use in organic farming without negative consequences or problems.

#### **Additional information requested and considered by NOSB**

For review, there were questions posed to the public in order to fully consider the questions at hand. Further information questions included:

1. Can/should the wide range of products covered by this listing be categorized by use and materials?
2. Are some uses of sticky traps incompatible with organic production?

Upon receipt of written, or in live testimony at the April, 2015 NOSB public meeting in La Jolla, CA, clearly the simple majority supported the relisted use of sticky traps/barriers as listed in 205.601 as a permitted synthetic. Product availability coupled with successful insect control experience was the primary reason noted.

With the concern regarding environmental impact, and the likelihood of trapping non-target animals, comment was made that the CS should consider an annotation which ensures the targeted use of said traps.

#### **Motion to Remove**

This proposal to remove Sticky Traps/Barriers will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sticky Traps/Barriers from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

#### **Vote in Subcommittee**

Motion to remove sticky traps from §205.601(e)

Motion by: Francis Thicke

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

#### **Sucrose octanoate esters**

**Reference:** 7 CFR 205.601(e), 205.603(b)

**Technical Report:** [Livestock 2005 Technical Report](#); [Crops 2005 Technical Report](#)

**Petition(s):** [2004 Sucrose Octanoate Esters](#); [Amendment #1](#); [Amendment #2](#)

**Past NOSB Actions:** [08/2005 NOSB recommendation for addition to NL](#); [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

**Use** – As a synthetic substance allowed in crop and livestock production to control soft bodied insects, such as whiteflies, aphids and mealybugs

This material is considered synthetic due to the manufacturing process, which uses a number of catalytic and chemical processes to create this otherwise naturally occurring substance in a cost effective manner. It is approved for food use by the FDA and biodegrades, with no persistence in the environment. It is registered with EPA as a biopesticide with no known risks to the environment. Although solvents are used in the manufacturing process they are of low toxicity and the patented process of the petitioner apparently recovers and reuses them so that there is no liquid and minimal air waste discharge.

According to the NOSB checklist, there are natural soaps and oils that could be used as alternatives, as well as other management practices that should be attempted before use of this product.

During the first review of this material, no concerns were raised about the use of the product. The small amount of public comment was in support, with other public comment seeking additional technical information for its use.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sucrose octanoate esters from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### Vote in Subcommittee

Motion to remove Sucrose octanoate esters from §205.601(e)

Motion by: Paula Daniels

Seconded by: Harold Austin

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

## Pheromones

**Reference:** 205.601(f) - as insect management.

**Technical Report:** 1995 TAP; 2012 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Pheromones are a volatile chemical produced in nature by a given species to communicate with other individuals of the same species to affect their behavior. Pheromones are produced naturally by many

organisms and are synthetically produced for use in agriculture. Insect pheromones are generally comprised of very specific esters. These compounds are derived by reacting an oxoacid with a hydroxyl compound, such as an alcohol or phenol, or are formed by condensing an acid with an alcohol. These are odorless materials that are released from the dispenser into the surrounding air. Inerts may be used as part of the formulation process. Considered generally non-toxic and have a low persistence in the environment.

Pheromones are used by organic (and many conventional) crop producers and are especially important for organic tree fruit production. Pheromones are used by growers in a variety of ways such as: to monitor insect presence and population density; trapping certain insects; used in 'attract and kill' systems; and for use in mating disruption or confusion.

- Trapping can be used in a couple of different use patterns: one use would involve mass trapping to help in reducing the overall numbers of an insect pest. Another use would be utilizing the pheromone (placed within a trap) for a specific insect to help the grower to identify its presence and levels of insect population pressure. Ultimately helping to identify if additional crop protection measures are needed or not.
- Attract and kill systems utilize the synthetic pheromone to bring a specific targeted insect into contact with an insecticide.
- Mating disruption/confusion uses the synthetic pheromone to saturate a targeted area that can cause the male of the target species to become confused and disoriented, thus unable to locate the species female for mating. Normally in organic crop production these pheromones are dispersed for use via a passive pheromone dispenser (including traps and lures). Some forms of these dispensers are: pheromone-impregnated polymer spirals, ropes, coils, twist ties, or tubes. The use of wires, clips, or circular tubes allows these pheromone dispensers to be placed directly in the intended area of usage.

### **International**

- Canadian General Standards Board allows pheromones. (List 4A & List 4B3)
- European Economic Community, Council Regulations # 889/2008 allows for their use
- Codex Alimentarius Commission allows for their use.

In the original TAP the reviewers found pheromones to be compatible with sustainable agriculture. During the 2011 Sunset Review there was an annotation that had been proposed for addition to the pheromone listing proposal, but was ultimately withdrawn. That annotation was: "provided that they are formulated with only approved inert ingredients". Currently the USDA permits the use of synthetic pheromones in insect management (7CFR 205.601(f)). Inert ingredients on the EPA List 3 ( inerts of unknown toxicity) and the EPA List 4 (inerts of minimal concern) may be used in conjunction with synthetic pheromone substances (7CFR 205.601(m)); however, the EPA List 3 inerts are only allowed for use in passive pheromone dispensers (7CFR 205.601(m)(2)).

There was a new Technical Evaluation Report issued on March 27, 2012. During past reviews there has

been concern raised over the inerts because they do include known irritants, sensitizers, and allergens. In the 2012 TER it mentions that some compounds could potentially be linked to asthma, cancer, or endocrine disruption. However, under the current use of pheromones utilizing passive pheromone dispensers it is not believed that they would release enough volume to leave any kind of residue on the agricultural crops being treated. It also states that dissipation takes place via volatilization and degradation, rapidly into the environment.

There were some concerns raised around the use of “encapsulated pheromones” (those concerns mentioned harm to honey bees and concerns over aerial applications). During the 1<sup>st</sup> posting for public comment the subcommittee posed several questions for stakeholder input. Comments back to those questions stated that there were no known forms of encapsulated pheromones currently being used in organic crop production.

Also during the 1<sup>st</sup> public comment period for this current Sunset Review cycle there were numerous public comments submitted (both written and oral). Several certifiers responded that their clients continue to rely upon the use of pheromones, with one stating that they are listed on 450 of their producers Organic Systems Plans. There were numerous comments stating how important to organic tree fruit production the use of pheromones are and continue to be. The loss of them would mean the removal of many acres of organic tree fruit, because this is their primary defense for codling moth (also significantly used now in conventional crop production). During this review cycle there were no comments specifically in opposition of re-listing pheromones, while there were numerous public and stakeholder comments as to how necessary pheromones continue to be for organic crop production.

It was also mentioned that during this current Sunset Review cycle the use of pheromones in organic crop production has continued to increase, as various formulations have been developed for specific target species.

Another commenter stated that their organization would support the continued listing, but asked for two specific annotations be added.

In general there was over whelming public comments offered in support of the continued listing on the National List of this material, with one specific comment against its listing.

### **Motion to Remove**

This proposal to remove Pheromones will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Pheromones from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Crops Subcommittee**

Motion to remove Pheromones from 205.601(f)

Motion by: Harold V. Austin IV

Seconded by: Carmela Beck

Yes: 0 No: 5 Abstain: 0 Absent: Recuse: 0

## Vitamin D3

**Reference:** 205.601(g) - as rodenticides.

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

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Vitamin D3 is a well-known vitamin supplement safe for use in humans. A synthetic derivative known as cholecalciferol is used at dosage levels as a rodenticide; its mechanism of action is to cause high levels of calcium in the rodent, which leads to calcification and blockage in the circulatory system.

This material is considered synthetic due to the extraction process that uses organic solvents and ultraviolet light. According to the TR there are no notable environmental impacts from its manufacture or use, and the EPA has approved its use as a rodenticide.

Alternative natural materials could be smoke bombs or castor bean oil pellets or sprays; however, these are labor intensive in use.

Other management practices could be the use of deterrents such as rotten eggs, animal scents, hair; or repellent plants such as castor bean, daffodils, squill, euphorbia; or predators such as corn snakes, cats and owls. (However, corn snakes and cats may also consume chicks and eggs). More common is the use of traps.

At the public meeting, there was discussion of the mechanism of action of this material, in that its use causes cardiac arrest in rodents, with an implication that more humane methods of extermination should be considered. There was also discussion among board members regarding the lack of effectiveness of traps and other methods. Public comment was divided, with those in favor stating that its use was critical for rodent control without viable alternatives; those opposed to relisting asserted its potential for toxicity to non-target animals as well as children and pets.

Input is sought from the public as to whether non-synthetic rodenticides are effective and should be considered as viable alternatives.

### Motion to Remove

This proposal to remove Vitamin D3 will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Vitamin D3 from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion to remove vitamin D from §205.601(g)

Motion by: Paula Daniels

Seconded by: Harold Austin

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

## Coppers, fixed

**Reference:** 205.601(i) As plant disease control. (2) Coppers, fixed —copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

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

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

**Past NOSB Actions:** 10/1995 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; [04/2011 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

Copper is an important tool for organic producers as part of a comprehensive approach to disease management in many crops. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at [§6517(c)(1)(B)(i)]. This review applies to both the listing for Coppers, fixed and the listing for Copper Sulfate on the National List 205.601.

The last Technical Report (TR) was completed in 2011 at which time the EPA had recently completed a re-assessment of copper products. The potential adverse impacts are well known and were discussed in the TR. The main concern with copper materials is their potential to accumulate to toxic levels in the environment. The TR notes the many factors that can affect copper accumulation (2011 TR lines 465 to 549). To address this concern, the copper listings on the National List have the annotation "That, copper-based materials must be used in a manner that minimizes accumulation in the soil..."

To put copper use patterns into perspective, we consulted the *Materials Fact Sheet Copper Products from the Organic Resource Guide, 2nd edition (2013)*:

<http://web.pppmb.cals.cornell.edu/resourceguide/pdf/resource-guide-for-organic-insect-and-disease-management.pdf>

"In New York, maximum soil concentration rates for copper have been recommended based on soil type; rates range from 40 ppm in sandy soils, to 60 ppm in silt loam, to 100 ppm in clay soils. These rates have been suggested in order to protect against phytotoxicity and negative impacts

on soil life (Harrison et al. 1999). Typically, each spray with a copper-based fungicide results in an application of 1 to 4 lb. of copper per acre, raising the topsoil concentration from 0.5 to 2 ppm; often several copper sprays are made per season. Under a heavy copper spray program, toxic topsoil levels could be reached in a matter of decades."

The high variability in copper use patterns and organic farming situations has led us to conclude that the annotation in place for this substance is appropriate since certifiers are able to assess copper accumulation in the context of a specific farming operation. However, to make sure that this is true, public comment was requested from growers on the importance of this material, and the ways of monitoring accumulation. Input from certifiers was sought on whether testing was being required for monitoring and whether there have been non-compliances issued for enforcement of this annotation.

The effects on human health from agricultural copper were addressed in the TR as follows:

"In "III Summary of Coppers Risk Assessments" of RED-Cu (2009), human health risk, after aggregate or combined exposure to copper compounds, was adequately assessed. The basic considerations are that copper is naturally-occurring, ubiquitous in environment, copper itself is a nutrient, copper deficiency is more of a problem than copper over-exposure, the active assimilation of copper through routes of food, drink, air, non-occupational sources, and other exposure is efficiently modulated, excessively available copper is not assimilated but instead is actively excreted, and no systematic and carcinogenic effects are observed/confirmed. The overall conclusion is that copper, when used as pesticide following the label, would not cause toxic effects." (2011 TR lines 933 - 940)

The effects of copper on the agro-ecosystem (including on biodiversity) were also discussed in the TR:

The 2011 TR (lines 647 - 761) is quite extensive and evaluates many studies on soil microorganisms, earthworms, and crops. The conclusions in all instances is that it depends on the soil composition, soil pH, concentration of copper, species being studied, and crop species being grown.

and:

Copper can have a significant diminishing effect on biodiversity in an aquatic environment such as wetlands. However it is not prone to leaching or runoff in all but the sandiest of soils and is not likely to end up in the sensitive environments if used according to label restrictions. In contrast, copper can be used to control invasive aquatic plants that out-compete native plants in some ecosystems and this would have a positive effect on biodiversity. (2011 TR lines 870 - 874)

The TR closes with a quote from the "Reregistration Eligibility Decision (RED) for Coppers – Revised May 2009":

"U.S. EPA recognized the advantages of using copper pesticides (RED-Cu, 2009): "Through extensive outreach to the public as well as additional comments and refined information provided by the user community, the Agency has determined that there are many benefits that support the significance and continued agricultural uses of copper pesticides. A significant

benefit is that copper exposure from all sources, including use as a pesticide in agricultural settings, does not pose any human health concerns. Although there is still potential for ecological effects to non-target organisms, there are many benefits to retain agricultural uses of copper pesticides" (from the 2011 TR lines 988-996, p.20)

### **Review of Public Comment from Spring 2015**

The great majority of comments received on copper noted how important of a material this is in organic production. It is used for a wide variety of plant diseases, from fire blight on apples and pears, to Late Blight on tomatoes, to Black, Blue, and Brown Rots and Spots on brassicas, peppers, beans, spinach and more. In all cases it is necessary to the production of a crop after all other efforts at control have failed. Most producers who wrote comments in try to use the minimum amount necessary and rotate copper with other biological materials. They also try to choose formulated products that have lower overall copper content if they are concerned about environmental impact. Several growers noted that it is especially important to have copper as an option for Fire Blight control now that the antibiotics are no longer allowed.

Comments from certifiers directly indicated that they require either a testing protocol or an overall copper monitoring plan for growers who include copper on their OSPs. None of the certifiers who wrote comments have issued a non-compliance for accumulation of copper, but several have done so for not having a monitoring plan in place.

While the only public comments that were opposed to copper on the National List were 3 private individuals, there were several groups who raised concerns that they would like to have addressed. Some groups wanted annotations to stipulate exactly which uses were allowed and specify application rates. A couple of groups called for further research on alternative tools for disease management in organics. Several groups noted that while the intention of the current annotation is appropriate, it is not enforced evenly and some growers are abusing copper sprays to the point where the harvested crop turns color from high copper use.

The Crops Subcommittee strongly supports the idea of further research on alternative to copper and has put this forward as our one new Research Priority for 2015. In reviewing the possibility of annotations changes and knowing how cumbersome a process that can be when over 200 materials will be reviewed in the fall of 2015, we would ask the public to consider petitioning concrete ideas on future annotation changes for the NOSB to review in 2016. With copper used on over 50 different crops for 25 or more diseases (as reported in public comments) it is a daunting task for the NOSB to get more specific. One possible annotation that could be considered is the language that some of the western certifiers had in their standards before OFPA and the USDA organic regulations were published. This annotation (which was in addition to the current one about accumulation) stated: "No visible residue is allowed on harvested crops."

The Crops Subcommittee's review has led us to believe that the current annotation is working well enough to assure that the criteria in OFPA are satisfied, although certifier enforcement of the annotation might need to be looked at by NOP auditors.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Coppers, fixed from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Sustainable Agriculture.

#### **Vote in Subcommittee**

Motion to remove Coppers, fixed from 205.601(i)

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 4 Abstain: 1 Absent: Recuse: 0

### **Copper sulfate**

**Reference:** 205.601(i) As plant disease control. (3) Copper sulfate —Substance must be used in a manner that minimizes accumulation of copper in the soil.

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

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

**Past NOSB Actions:** 10/1995 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; [04/2011 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

#### **Subcommittee Review**

See Coppers, fixed.

#### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Copper Sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Sustainable Agriculture.

#### **Vote in Subcommittee**

Motion to remove Copper Sulfate from 205.601(i):

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 4 Abstain: 1 Absent: 0 Recuse: 0

## Hydrated lime

**Reference:** 205.601(i)(4) - As plant disease control.

**Technical Report:** 1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Hydrated lime (calcium hydroxide, slaked lime, calcium hydrate, carboxide, lime water) is a synthetic produced by the slow addition of water to crushed or ground quicklime (calcium oxide), which is produced by burning various forms of limestone. The two most common uses given in public comment were as an ingredient used to make Lime Sulfur and a disease control in mushroom production.

Most of the public comments were in favor of keeping hydrated lime on the National List. No new information was received from the public about hydrated lime in relation to the OFPA criteria.

The manufacture of lime-sulfur, which many commentators said they could not farm organically without, requires the use of hydrated lime, as does the on-farm production of Bordeaux mixture (copper containing compound). Lime sulfur is used to control fungus, mites, and insects in apples, grapes, blueberries, cherries, and other tree and vine crops. It is also a key material in the control of Fire Blight in the year since the antibiotics went off the National List. Some commentators made the point that lime sulfur has been used for two hundred (200) years with no recorded loss of effectiveness (resistance).

A few commenters stated that no synthetic substances should be allowed in organic, but failed to show how these materials violate OFPA. The Crops Subcommittee found no concerns with this substance that would prevent its renewal on the National List.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes a motion to remove Hydrated Lime from §205.601(i)(4) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given.

### Vote in Subcommittee

Motion to remove Hydrated Lime from §205.601(i)(4)

Motion by: Zea Sonnabend

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: Recuse: 0

## Potassium bicarbonate

**Reference:** 205.601(i)(9) - As plant disease control.

**Technical Report:**1999 TAP; 2015 TR

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

**Past NOSB Actions:** 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Potassium bicarbonate (CAS # 298-14-6) is on the National List at §205.601(i)(9) as a plant disease control material. It is used by organic crop producers to control: Alternaria in cucurbits and cole crops; anthracnose in cucurbits, blueberries, grapes, spinach and strawberries; black dot root rot in potatoes and also early blight; sooty blotch and powdery mildew in apples; downy mildew in cucurbits, cole crops, grapes, lettuce; gray mold (*Botrytis cinerea*) in beans, lettuce, and strawberries, to name just a few of the crops and specific diseases it helps to control. Historically it has proven to be an extremely important disease control aid in organic crop production.

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.

The original TAP review found this material to be compatible with organic crop production, safer and more environmentally friendly than many of the alternatives both, organic or otherwise. It also states that the components readily dissipate in the environment. During the first Sunset Review period and the subsequent posting of the final rule published October 16, 2007, potassium bicarbonate for plant disease control was renewed. It was mentioned that a foreign government stated that this material and several others were not included in Annex 2 of the Codex Guidelines for Organically Produced Foods and asked for justification for their continued use. The response back to this comment was that that these materials had been determined by the NOSB and the Secretary to meet national statutory and regulatory provisions under OFPA. (Potassium bicarbonate (potassium hydrogen carbonate) has since been added to the Codex Alimentarius Commission Guidelines). During the 2010 Sunset Review of potassium bicarbonate, it was renewed unanimously (October, 2012 Sunset date). The subcommittee has reviewed previous decisions, historical data, and additional information that has been provided to them during this current review cycle.

The subcommittee received a Limited Scope TR on January 22, 2015. This LSTR looked at two specific Evaluation Questions: #11 Which asked about natural substances or products that may take the place

of this material. Also, # 12 Which asked about alternative practices that would make the use of potassium bicarbonate unnecessary.

While the new LSTR does a remarkable job of identifying answers to the two specific questions around alternative materials and practices, it did not provide the complete answer. Further clarification surrounding the efficacy of these materials as possible replacements and identification of under what conditions or scenarios the material under review or its possible replacement might give the better control measure for the targeted disease will need to be provided by the appropriate organic stakeholders.

We did get some information regarding this during the 1<sup>st</sup> public comment period both from written public comment as well as during oral comments at the Spring NOSB meeting in La Jolla. Public comments answered one of the subcommittee's questions regarding the question as to whether or not potassium bicarbonate is still an important material for organic crop producers. The producer response was that this material was still very necessary in organic crop production. Several certifiers stated how extensively this material showed up on those organic producers that they certify OSP's, thus showing its continuing use in organic crop production.

While there appears to be possible alternative materials or practices that might help to replace its use in certain scenarios, it does not appear based off of the information provided that the use of potassium bicarbonate could adequately be replaced by these under all circumstances or conditions. Thus potassium bicarbonate still remains necessary for use in organic crop production.

### **Motion to Remove**

This proposal to remove potassium bicarbonate will be considered by the NOSB at its public meeting.

The Crops Subcommittee proposes removal of potassium bicarbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### **Vote in Crops Subcommittee**

Motion to remove Potassium Bicarbonate from 205.601(i)(9)

Motion by: Harold V. Austin IV

Seconded by: Carmela Beck

Yes: No: 5 Abstain: 0 Absent: Recuse: 0

## **Aquatic plant extracts**

**Reference:** 205.601 (j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount is limited to that amount necessary for extraction.

**Technical Report:** [2006 TR](#)

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Plant extracts are composed of chemicals naturally found in aquatic plants, mostly derived from kelp. Aquatic plants contain proteins, lipids, sugars, amino acids, and nutrients, & vitamins. Kelp contains a wide range of naturally occurring plant nutrients & trace minerals essential to plant growth, health, and productivity. Manufacture involves an alkali extraction process using potassium hydroxide or sodium hydroxide.

The Subcommittee did not pose any questions to the public during our Spring 2015 meeting regarding this listing.

The overwhelming majority of comments were in favor of keeping aquatic plant extracts on the National List. No new information was received from the public about aquatic plant extracts in relation to the OFPA criteria.

One commenter opposed the relisting because, as they state: All of these substances are synthetic materials that feed plants directly –or, in some cases, provide other growth promotion functions. Furthermore, they continue by saying that it is inconsistent with organic production practices to use synthetic materials for these uses. However, as reiterated through extensive public comment, aquatic plant extracts are an important element of fertility programs on many organic farms & removal from the National List would significantly, negatively impact an innumerable number of growers. The Crops Subcommittee found no concerns with these substances that would prevent their renewal on the National List.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Aquatic Plant Extracts from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

### **Vote in Subcommittee**

Motion to remove Aquatic plant extracts from 205.601(j)

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## Humic acids

**Reference:** 205.601(j) As plant or soil amendments. 3) Humic acids - naturally occurring deposits, water and alkali extracts only.

**Technical Report:** [1996 TAP](#); [2006 TR](#)

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

**Past NOSB Actions:** 09/1996 meeting minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Humic acids are used as a component of traditional fertilizers, they do not provide additional nutrients to plants, but rather affect soil fertility by making micronutrients more readily available to plants. Commercially available humic acids are derived from leonardite, lignite, or coal. Extracts from nonsynthetic humates by hydrolysis using synthetic or nonsynthetic alkaline materials are permitted including the use of potassium hydroxide and ammonium hydroxide.

The Subcommittee did not pose any questions to the public during our Spring, 2015 meeting regarding this listing. The overwhelming majority of comments were in favor of keeping humic acids on the National List. No new information was received from the public about humic acids in relation to the OFPA criteria. One commenter opposed the relisting because, as they stated: humic acids do not meet the criteria under OFPA due to the environmental hazards related to the extraction process, are not essential, and are not compatible with organic production. However, as reiterated through extensive public comment, humic acids are a very critical and necessary element of nutrient management in organic farming; removal from the National List would significantly, negatively impact an innumerable number of growers. The Crops Subcommittee found no concerns with these substances that would prevent their renewal on the National List.

The issue of synthetically extracted humic acids not being allowed in Japan was discussed in subcommittee, as was the difference between synthetic alkali extractants and non-synthetic materials used for extraction. It is hoped that the Classification of Materials Final Guidance will clear up the latter issue.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Humic Acids from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

### Vote in Subcommittee

Motion to remove Humic Acids from 205.601(j)3

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 2 No: 2 Abstain: 1 Absent: 0 Recuse: 0

## Lignin sulfonate

**Reference:** 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.

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

**Petition(s):** N/A, 2014 Petition to remove as floating agent

**Past NOSB Actions:** 10/1995 NOSB Minutes and vote; 04/2006 Sunset Rec; 04/2011 NOSB Rec to amend, 04/2011 NOSB Sunset Rec

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Background from Subcommittee:

Lignin sulfonates are used as chelating agents and dust suppressants found in brand name fertilizer and soil amendments. Lignin is extracted from wood, which has been treated with sulfites in the pulping process. They are by-products of the wood and cellulose industries.. Chelates help supply nutrients to plants.

### Subcommittee Review

There was substantial public comment presented at the Spring, 2015 meeting in support of relisting this material as a chelating agent and dust suppressant. There were some concerns regarding the paper pulping process, however no new information regarding this environmental concern was provided. The Subcommittee did not pose any questions to the public at that time. The Crops Subcommittee found no concerns with these substances that would prevent their renewal on the National List.

### Motion to Remove

This proposal to remove Lignin Sulfonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lignin Sulfonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

### Vote in Subcommittee

Motion to remove lignin sulfonate from §205.601(j)(4) as chelating agent and dust suppressant.

Motion by: Carmela Beck

Seconded by: Harold Austin

**Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0**

## Lignin sulfonate

**Reference:** 205.601(l)(1) - As floating agents in postharvest handling.

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

**Petition(s):** N/A, 2014 Petition to remove as floating agent

**Past NOSB Actions:** 10/1995 NOSB Minutes and vote; 04/2006 Sunset Rec; 04/2011 NOSB Rec to amend, 04/2011 NOSB Sunset Rec

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Background from Subcommittee:**

Lignin sulfonate is used as a floating agent for pears and apples in postharvest handling facilities. Lignin is extracted from wood, which has been treated with sulfites in the pulping process. They are by-products of the wood and cellulose industries.

### **Subcommittee Review**

There was no public comment presented at the Spring, 2015 meeting in support of relisting this material for use as a floating agent in postharvest handling. The Subcommittee asked for public input on the following two questions in preparation for the spring 2015 NOSB meeting: 1) Will removal of lignin sulfonate as a floating agent disrupt your business? And 2) Should the use of lignin sulfonate be subject to documented monitoring of waste water in the OSP?

We did not receive any written or verbal comments in favor or against relisting the material nor did we receive answers to the aforementioned questions. In the absence of any industry feedback, the Crops Subcommittee recommends removal of Lignin Sulfonate because it is no longer an essential material in organic crop production. This decision was also influenced by the existing petition seeking removal for use of lignin sulfonate as a floatation agent. In 2014 a trade association conducted a poll of all certified organic pear packing facilities in the U.S. to determine if the material was still in use; their results indicated that no handlers were using Lignin Sulfonate. Alternatives to Lignin Sulfonate include the use of floatless systems that don't require floating agents or, when necessary, the use of the following National listed materials 1) sodium silicate, 2) sodium carbonate, and 3) potassium carbonate.

### **Motion to Remove**

This proposal to remove Lignin Sulfonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lignin Sulfonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

Motion to remove Lignin Sulfonate from section 205.601(l)(1) of the National List for use as a floating agent in postharvest handling, and to acknowledge support for the petition received on this removal.

### **Vote in Subcommittee**

Motion to remove Lignin Sulfonate from section 205.601(l)(1) of the National List for use as a floating agent in postharvest handling, and to acknowledge support for the petition received on this removal.

Motion by: Zea Sonnabend

Seconded by: Colehour Bondera

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

## Magnesium Sulfate

**Reference:** 205.601 (j)(5) - As a plant or soil amendment. 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 NOSB sunset recommendation; 04/2011 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Magnesium sulfate can be obtained from naturally-occurring sources (kieserite or epsomite open-pit mines) or can be manufactured by a chemical process. Mineral forms of magnesium sulfate are dehydrated, purified and reacted with sulfuric acid to create the magnesium sulfate synthetic version. The material is used to correct for magnesium soil deficiencies and helps to improve the uptake of nitrogen and phosphorus by crops, to help seeds germinate, to increase chlorophyll production, to aid in the production of flowering and is vital in maintaining crop growth and yield.

Historically, there have been no commercially available products containing mined, raw mineral magnesium sulfate in bulk quantities suitable for agriculture. For this reason, the production of synthetic magnesium sulfate has been necessary. The Crops Subcommittee asked the following question in our spring, 2015 NOSB meeting proposal: Is non-synthetic magnesium sulfate available in the marketplace? Public comment indicated that the only form of non-synthetic magnesium sulfate that has been reviewed is potassium magnesium sulfate or langbeinite. However, this material is not a reliable alternative because it is only available in limited quantities and it is impossible to determine upon purchase whether or not langbeinite is synthetic or non-synthetic.

The majority of comments were in favor of keeping magnesium sulfate on the National List. No new information was received from the public about magnesium sulfate in relation to the OFPA criteria.

One commenter opposed the relisting because, as they state: nonsynthetic magnesium sulfate is available as langbeinite and dolomite however langbeinite is constrained by supply and classification issues. While dolomite can be used to treat a magnesium deficiency it is not as effective as magnesium sulfate and was not referenced by other commenters as a viable alternative. The Crops Subcommittee found no concerns with these substances that would prevent their renewal on the National List.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium Sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

**Vote in Subcommittee**

Motion to remove Magnesium Sulfate from 205.601(j) as a plant and soil amendment

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## Micronutrients

**Reference:** 205.601 (j)(6) - As a plant or soil amendment. Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing. (i) Soluble boron products. (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

**Technical Report:** [2010 TR Micronutrients](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

Micronutrients in general may include but not necessarily be limited to the following substances: boron (B), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo), zinc (Zn), nickel (Ni), cobalt (Co), selenium (Se) and chromium (Cr). Micronutrients are essential components for plant growth and occur naturally in the soil. They are involved in virtually all metabolic and cellular functions, like energy metabolism, primary and secondary metabolism, cell protection, gene regulation, hormone perception, signal transduction, and reproduction among others. Commercial micronutrients are generally manufactured as by-products or intermediate products of metal mining and processing industries. Most micronutrients are common chemical compounds and are widely available commercially. Soil deficiency must be documented before micronutrients can be applied because over application can contaminate the soil, can be toxic & can suppress plant growth. Micronutrients are only needed in very small quantities.

The overwhelming majority of comments were in favor of keeping micronutrients on the National List. No new information was received from the public about micronutrients in relation to the OFPA criteria. Two commenters opposed the relisting, stating that the materials fail OFPA criteria, there are hazards associated with mining, zinc contamination is occurring and micronutrients can be considered heavy metals. The Crops Subcommittee is aware of the need to continue monitoring these issues; however, at the present time we have found that the concerns with these substances should not prevent their renewal on the National List.

The Crops Subcommittee asked the following question in our Spring, 2015 NOSB meeting proposal: Does the current annotation apply to today's practices and procedures? A few certification bodies weighed in and support an annotation change to allow for soil deficiencies to be documented using tools other than soil analysis. Examples include: leaf tissue analysis, Certified Professional Agronomist

recommendations, recorded visual observations of micronutrient deficiency, and documented regional soil deficiencies. The recommended annotation would change the following “soil deficiency must be documented by testing” to “soil deficiency must be documented.” A separate proposal is being put forward by the Subcommittee to propose a change to the annotation.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Micronutrients from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

### **Subcommittee Vote**

Motion to remove Micronutrients from 205.601(j) as plant and soil amendment

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## **Liquid fish products**

**Reference:** 205.601 (j) As plant or soil amendments. (7) Liquid Fish Products – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

**Technical Report:** [1995 TAP](#); [2006 TR](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Liquid Fish Products are processed from by-product fish and are either heated or enzymatically digested. The manufacturers formulate or stabilize these products through a chemical process by adding acid. These products contain fundamental nutrients and many trace minerals critical for use in organic farming. Liquid fish foliar feeds improve crop yields and reduce both insects and diseases and are more available to crops than compost or manures.

The Crops Subcommittee asked the following question in our Spring, 2015 NOSB meeting proposal: Is the annotation sufficient in which fish is blended with other ingredients? Public comment indicated that the annotation is sufficient and that the common practice is to adjust the pH of the liquid fish product prior to being blended with other ingredients. One commenter requested clarification regarding whether or not this listing includes non-fish fish including crab and shrimp products.

The overwhelming majority of comments were in favor of keeping liquid fish products on the National

List. No new information was received from the public about liquid fish products in relation to the OFPA criteria.

One commenter opposed the relisting because, as they state: liquid fish products remove valuable nutrients from marine ecosystems and may harm agro ecosystems. And while some liquid fish products are made from fish waste, others are made from whole fish harvested for the purpose. Furthermore, fish that do not have commercial value may have ecological value. While the Crops Subcommittee found no concerns with these substances that would prevent their renewal on the National List, we do want to emphasize the importance of the sustainable harvesting of fisheries.

#### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Liquid Fish Products from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

#### **Vote in Subcommittee**

Motion to remove Liquid Fish products from 205.601(j) as a plant and soil amendment

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

## **Vitamin B1, C, E**

**Reference:** 205.601 (j)(8) - As plant or soil amendment. Vitamins B1, C, and E

**Technical Report(s):** [2015 TR](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 (77 FR33290)

**Sunset Date:** 6/27/17

#### **Background from Subcommittee:**

Vitamins including, synthetically derived vitamins B1 (Thiamine), C (Ascorbic Acid) and E (Tocopherols) are generally considered non-toxic essential nutrients for terrestrial and aquatic organisms.

Nonsynthetic sources of all vitamins and synthetic sources of vitamins B1, C, and E may be used in certified organic crop production. Vitamin B1 is an ingredient in many commercially sold root stimulator products helping to establish nursery grown planting stock once transplanted. Per the Technical Review, overall, the available literature does not support the premise that foliar and soil applications of vitamin B1 are responsible for root stimulation in transplanted crops. Vitamins C and E are used to promote both growth and yields and to protect plants from oxidative stress due to salinity. However, practical information regarding their use was unavailable, therefore the TR relied on peer-reviewed scientific

literature.

An OMRI search for each of the three vitamins resulted in zero entries. However, an OMRI generic materials database search indicated that nonsynthetic plant hormones such as gibberellic acid, indole acetic acid (IAA) and cytokinins may be applied to organic crops as plant growth regulators. Additionally, there are several naturally derived, OMRI-listed substances marketed to stimulate root growth.

### **Subcommittee Review**

There was some public comment presented at the Spring, 2015 meeting in support of relisting these materials for the purpose intended. Commenters indicated that Vitamins B1, C and E are rarely used individually but are included as ingredients in some of the products reviewed for crop fertility. The only TAP on file for review of these materials was conducted in 1995. The Subcommittee did not pose any questions to the public at the Spring meeting, however, the SC did request a TR.

The TR indicated that the root growth claims associated with vitamin B1 are largely unsubstantiated. Alternative practices include encouraging the growth and productivity of beneficial soil microorganisms in the soil to help produce vitamin B1, reduce fertilizer use, refrain from applying fertilizer at the time of planting, proper irrigation of root ball and surrounding soil. There was no use information for vitamins C and E on agriculture extension websites.

### **Motion to Remove**

This proposal to remove Vitamins B1, C, and E will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Vitamins B1, C, and E from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### **Vote in Subcommittee**

Motion to remove Vitamin B1, Vitamin C, Vitamin E, from §205.601(j)(8)

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## **Ethylene gas**

**Reference:** 205.601(k) - As plant growth regulators. Ethylene gas - for regulation of pineapple flowering.

**Technical Report:** [02/2000 Supplemental TAP](#); [2007 TAP](#); [2011 Supplemental TR](#)

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

**Past NOSB Actions:** 11/1995 NOSB recommendation; 10/2001 recommendation; 11/2005 NOSB sunset

recommendation; 04/2011 NOSB sunset [recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Ethylene gas (CAS # 74-85-1) is on the National List at §205.601(k) – as plant growth regulator. Ethylene gas-for regulation of pineapple flowering.

It is a simple molecule ( $\text{CH}_2=\text{CH}_2$ ) that is a colorless gas at room temperature. Produced naturally in small amounts by some plants and functions as a hormone and ripening agent. The commercially used form which is synthetic is (chemically) identical to the natural occurring form. The synthetic form is produced from hydrocarbon feedstocks, such as natural gas liquids or crude oil.

It is used for pineapple flower induction and has been allowed for use in organic crop production since 1999. Some international organic standards, including those of the European Union (EC889-2008), also permit its use. Ethylene gas is used to induce uniform flowering of the pineapples (they produce a crop approximately every 18 months and are a very labor intensive crop), this aids in producing a crop that can be harvested uniformly at once, rather than over a several week or months. The use of ethylene allows for controlled year-round production because the growers can better manage harvest times by controlling when the plants flower. Currently ethylene gas is the only material on the National List allowed for this specific use.

During the 1<sup>st</sup> public comment period there were three questions asked looking for feedback from organic stakeholders. While there has been considerable comment during previous sunset reviews for this material, this time it was minimal. There were five public comments submitted during the 1<sup>st</sup> posting. One public commenter stated “Simply put, in their experience, without ethylene, organic tropical fruit (pineapples) would not be readily found in the produce aisle.” One certifier mentioned that they have one large client that uses this material. Another commenter stated: “I would say for large organic pineapple farmers, ethylene is absolutely necessary. I don’t know of any other way to produce pineapples consistently on a yearlong basis. For the smaller farmers, they tend to grow pineapples seasonally and don’t need or rely on ethylene”. While this issue has been discussed in great detail in the past, it helps bring into perspective the level of change in the organic industry and the diversity that now exists within it. This along with consumer expectations of a steady supply would tend to help answer the question of whether or not this material is still necessary for use in organic crop production.

Two other commenters raised issue (which has been discussed in length in previous Sunset Reviews) with the fact this material is only used by larger producers who are trying to supply a crop year round. While, smaller producers grow pineapples only seasonally and thus do not rely upon the use of ethylene. Thus bringing into question if this material is necessary and is it compatible with organic crop production. This commenter felt that it was neither necessary nor was it compatible with organic crop production.

There were no human health or environmental issues or concerns that were brought to the subcommittee or the full boards attention, that have not already been discussed at length in previous Sunset Reviews. Those issues previously raised have been found to be of minimal to no concern if the label uses and proper production practices during manufacture were followed.

The January 25, 2011 Supplemental Technical Evaluation Report provided to the described alternatives, but those seemingly applied more to small scale production and several were still in the experimental stages. Historic information, previous Sunset Reviews and their discussions, and public comment have stated how the use of ethylene gas has helped grow the organic pineapple industry and allowed organic producers to compete globally and enable them to provide a more year round supply to the market.

It is still very unclear as to whether or not organic producers raising pineapples find this material to still be necessary to their farming, especially for the larger scale producers. There seems to be several options for the small scale organic pineapple producers, but ethylene gas appears to be the only viable material that can meet the needs of the larger scale organic producers in California, Hawaii, and Central America. While it would appear that there is not a functionally viable alternative for ethylene gas, especially for the larger producers, it is concerning that there was no more support for this material via the public comment period (both written and oral), by those that have supported it in the past, especially from the producers themselves.

It would assist the subcommittee and the full NOSB in our deliberations as to whether or not ethylene gas is necessary for continued use in organic crop production, if we could receive additional input from organic stakeholders.

#### **Motion to Remove**

This proposal to remove Ethylene Gas will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ethylene Gas from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

#### **Vote in Crops Subcommittee**

Motion to remove Ethylene from 205.601(k)

Motion by: Harold V. Austin IV

Seconded by: Colehour Bondera

Yes: 4 No: 0 Abstain: 1 Absent: 0 Recuse: 0

### **Sodium silicate**

**Reference:** 205.601 (l) As floating agents in postharvest handling. (2) Sodium silicate—for tree fruit and fiber processing.

**Technical Report:** 1995 TAP; 2006 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### **Subcommittee Review**

Sodium silicate is referred to as “waterglass”. It can be produced in a rotary kiln or tank furnace by fusing quartz sand with potash or soda at temperatures between 1,100 – 1,300 C. Sodium silicate can be converted from solid glass to liquid solution at 100 C. Sodium silicate is considered synthetic due to the high temperature and sometimes high pressure required during the manufacturing process. The material is diluted and depolymerizes in the environment. It is used to raise water density in dump tank solutions to allow pears to float and to prevent damaging the pears during the post-harvest process. The material is also allowed for use in fiber processing. The TR stated that use of this material in a post-harvest setting has not been identified, however, examples of processing uses were provided including: used to process cotton and jute as a peroxide bleaching buffer; degumming agent of jute fibers; etc.

The Crops Subcommittee asked the following two questions in our Spring, 2015 NOSB meeting proposal: 1) Are there any emerging practices (mechanical or physical) for pear or other tree fruit handling during the packing process that would be a reasonable alternative to using this “waterglass” material for a “wet dump”? and 2) If lignin sulfonates are removed from the list, what impact would that have on your level of use of sodium silicate materials? There were a total of three public comments on this topic. Regarding question #1, one commenter indicated that there are viable alternatives to sodium silicate including the use of sodium carbonate, potassium carbonate and float less mechanized systems. The next substantive comment responded to question #2. The commenter stated the following, “the removal of Lignin Sulfonate from the National List will not directly result in the increased use of other floating agents because the few companies continuing to use wet packing lines have already made the switch to other allowed substances.”

There was no written comment provided in favor of relisting sodium silicate and there was no reference made to its use for fiber processing. One commenter solely mentioned its use as an alternative to Lignin Sulfonate and offered the singular response to question #1. The second commenter indicated that the material was unnecessary, incompatible with organic production and potentially poses environmental hazards and negative health effects on workers. No new information was provided to prevent renewal on the National List, however, in the absence of industry support for relisting, the Subcommittee recommends allowing this material to sunset.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sodium Silicate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility with Organic Agriculture.

### **Vote in Subcommittee**

Motion to remove Sodium silicate from 205.601(j)

Motion by: Carmela Beck

Seconded by: Colehour Bondera

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

## EPA List 4 - Inerts of Minimal Concern

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

(1) EPA List 4 – Inerts of Minimal Concern.

**Technical Report:** [2015 Limited Scope TR: Nonylphenol ethoxylates \(NPEs\)](#)

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

**Past NOSB Actions:** 02/1999 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [04/2010 recommendation](#), [10/2010 NOSB sunset recommendation](#); [10/ 2012 NOSB recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

The Crops Subcommittee is working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The NOSB will need to vote on this relationship before the reviews can start. So for this Sunset review we are proposing a renewal of the inerts listing while at the same time suggesting two annotation changes in separate proposals to be voted on at future meetings. The first and most key one will change this listing on the National List to remove the old List 4 terminology and replace it with Safer Choice reviews as well as room for individual petitioned inerts.

The Crops Subcommittee realizes that this is a slow process to work between two government agencies, and also there are a number of groups of inerts that may not pass the SCP review. Re-formulation is also a slow process. Therefore the CS had commissioned a Technical Report on the class of inerts known as Nonylphenol Ethoxylates (NPE). The US EPA is encouraging industry to eliminate the use of NPE (TR 2015, line 137) because of toxicity concerns and persistence in the environment. It is unlikely that the NPEs would pass favorably through the SCP screening process. Therefore a separate annotation proposal is put forward to remove NPEs. This will be voted on at a future meeting and then will go through rulemaking. This should give enough time for suppliers to re-formulate their products with safer choices.

In the Public Comment for the first meeting there were two questions posed concerning NPEs:

1. Commenters are urged to read the [TR for NPEs](#) linked here. Please comment on the suitability of the alternatives mentioned for specific types of generic product formulations in specific situations.
2. Would removing NPEs from use with 2 years notice (from now) be sufficient time? How would this affect your business?

As far as the first question, there was no specific feedback on individual alternatives, but there was feedback from a group representing manufacturers and formulators that noted the alternatives needed to be looked at individually for each unique product formulation. All substitutions have to go through safety and efficacy testing and extensive EPA review. This group also stated that these substances were reviewed already sufficiently by the EPA to keep them on List 4. Another trade association and a certifier questioned why we would move ahead with NPEs in particular instead of waiting for the SCP review to

be completed. They questioned how we could do an adequate review of alternatives because we do not have access to the confidential formulas. While most all of the commenters from this industry supported working with the SCP, they expressed frustration with the slowness of the process and pointed out that they have been held back on their research and development of new products because of the uncertainty over inert regulation.

Environmental and consumer groups provided comments that the review of inerts is moving too slowly. They suggested that the NOP immediately notify manufacturers to request information on current inert ingredients in use and proceed with Technical Reviews of other clusters of inerts. They would like a prompt action on the prohibition of NPEs as inert ingredients in organic materials. They pointed out the recommended language change to the inerts listing that was passed by the NOSB in 2012 (see annotation proposal). Some recommended a 2 or 3 year expiration date on the inerts listing renewal to put added pressure on the NOP.

We received very little response back from our second question about whether 2 years was enough time to make this change. We heard vaguely that it takes a long time and a few growers stated that two years was not enough time and growers would be left without tools that they need for pest control.

The Crops Subcommittee (CS) fully agrees with the frustration over how long it is taking to implement the NOSB recommendation to review inerts. The CS has also developed a separate proposal for an annotation change for inert ingredients. We sincerely hope that the vote to proceed will be taken soon so that the program to work with the Safer Choice Program can begin in 2016. Once it begins, the inerts manufacturers will have the option of submitting their products to Safer Choice to be reviewed. This will clearly favor those inerts that have the best chance of being approved, because the ones that are not likely to be approved will not apply until absolutely forced to do so. The CS believed that it would be better to put some of the inerts categories that are unlikely to end up on the SCIL list on notice sooner than the very end of the whole SCP project so that they could start moving towards reformulation sooner rather than later. That is why we started with NPE's and are considering Technical Report requests for other categories that will not pass the SCP. We are doing this expecting a long period of time before full implementation of this program so that everyone doesn't complain at the end that there wasn't enough notice.

The accompanying annotation discussion proposal to remove NPE's from organic products has one clear message from the NOSB: START REFORMULATING NOW! We may not even vote on the annotation for a few meetings, and the change will definitely not be sudden, but it is clear that eventually NPEs will not be allowed in organic. Unless all stakeholders communicate this in their messaging to their constituents, this will bog down the change even further.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of EPA List 4 Inerts from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility.

**Vote in Subcommittee**

Motion to remove EPA List 4 inerts from 205.601(m) based on compatibility with organic principles

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 1 No: 4 Abstain: 0 Absent: 0 Recuse: 0

## Microcrystalline cheesewax

**Reference:** 205.601(o) - As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

**Technical Report:** none

**Petition(s):** [2007 Petition](#); [2008 Petitioner response to questions](#)

**Past NOSB Actions:** [2008 NOSB recommendation](#)

**Recent Regulatory Background:** Federal Register rule amendment published 02/14/12 ([77 FR 8089](#))

**Sunset Date:** 3/15/17

**Background:**

Microcrystalline cheesewax is used to seal the plug or sawdust spawn that is used to inoculate logs for growing mushrooms. It is a petroleum product and, though used in small quantities, does not biodegrade. There are many data gaps in the information concerning the allowed components of microcrystalline cheesewax. “Natural” soy wax from domestically-produced non-GMO soybeans—made by hydrogenating soy oil—is now available and was not considered when microcrystalline cheesewax was listed.

**Subcommittee Review**

Input was sought to find more information from the public regarding non-synthetic materials for manufacturer;

1. Is soy wax nonsynthetic?
2. Is soy wax sufficiently available to meet the needs of producers who grow organic mushrooms on logs?

Little oral or written input was presented regarding re-listing of this material for the purpose used. Comment received stated that there exist soy-oil based alternatives that could replace the petroleum-based approved product.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Microcrystalline Cheesewax from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove Microcrystalline cheesewax from 205.601(o)

Motion by: Colehour Bondera

Seconded by: Francis Thicke

Yes: 1 No: 2 Abstain: 2 Absent: 1 Recuse: 0

## Ash from manure burning

**Reference:** 205.602(a)

**Technical Report:** none

**Petition(s):** [2014](#)

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Background from Subcommittee**

Ash from manure burning was placed on §205.602 based on its incompatibility with organic production: “Burning these materials is not an appropriate method to use to recycle organic wastes and would not be considered a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content. Burning as a disposal method of these materials would therefore not be consistent with section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)).” (Preamble to proposed rule, December 16, 1997. 62 FR 241: 65874)

**Subcommittee Review**

There have been no public comments on removing Ash from Manure Burning from the list of prohibited nonsynthetic substances. Comment was received in written form prior to the meeting in La Jolla, CA which stated that the material should remain on the prohibited list. The Crops Subcommittee believes that ash from manure burning does not meet the OFPA criteria and sees no reason to change the listing from its prohibited status on 205.602.

**Motion to Remove**

This proposal to remove Ash from manure burning will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ash from manure burning from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove Ash from manure burning from 205.602(a)

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Arsenic

**Reference:** 205.602(b)

**Technical Report:** none

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Background from Subcommittee:

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

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

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

### Subcommittee Review

There were no public comments on arsenic. The Crops Subcommittee believes that arsenic does not meet the OFPA criteria and sees no reason to remove arsenic from its prohibited status on 205.602.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Arsenic from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

### Vote in Subcommittee

Motion to remove Arsenic from 205.602(b)

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Lead salts

**Reference:** 205.602(d)

**Technical Report:** none

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

There were no public comments on lead salts. The Crops Subcommittee believes that lead salts do not meet the OFPA criteria and sees no reason to remove lead salts from its prohibited status on 205.602.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lead salts from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

### Vote in Subcommittee

Motion to remove lead salts from 205.602(d)

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Potassium chloride

**Reference:** 205.602(e) - unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

**Technical Report:** [1995](#)

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

### Subcommittee Review

Although this material continues to be used in organic agriculture, very few public comments were received with any concerns about its use or impacts of removing the annotation. One certifier asked

what the annotation means regarding what would be considered too much chloride accumulation. Materials Review Organizations have reviewed a number of products containing potassium chloride and several are blended fertilizers that would not indicate clearly on the label how much potassium chloride was in the product. No commenters asked for any change in the status of this material.

#### **Motion to Remove**

This proposal to remove potassium chloride will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of potassium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
**OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.**

#### **Vote in Subcommittee**

Motion to remove potassium chloride from 205.602(e)

Motion by: Zea Sonnabend

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

### **Sodium fluoaluminate (mined)**

**Reference:** 205.602(f)

**Technical Report:** none

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

**Past NOSB Actions:** 1996 NOSB meeting minutes and vote; 11/2005 sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

#### **Subcommittee Review**

This review of a prohibited non-synthetic material was brief. No public comment was received on this material either for or against its current status. The Crops Subcommittee believes that this material does not meet the OFPA criteria and sees no reason to remove it from its prohibited status on 205.602.

#### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sodium fluoaluminate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove sodium fluoaluminate from 205.602(f)

Motion by: Zea Sonnabend

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Strychnine

**Reference:** 205.602(h)

**Technical Report:** none

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

This review of a prohibited non-synthetic material was brief. No public comment was received on this material either for or against its current status. The Crops Subcommittee believes that this material does not meet the OFPA criteria and sees no reason to remove it from its prohibited status on 205.602.

**Motion to Remove**

This proposal to remove strychnine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of strychnine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.**

**Vote in Subcommittee**

Motion to remove strychnine from 205.602(h)

Motion by: Zea Sonnabend

Seconded by: Francis Thicke

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Tobacco dust (nicotine sulfates)

**Reference:** 205.602(i)

**Technical Report:** none

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; [10/2010](#)

[NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/17

**Subcommittee Review**

Tobacco dust (nicotine sulfate) refers to the raw material from tobacco processing as well as the extracted active substance, nicotine sulfate. Both can very toxic to humans and the environment when used as fertilizer (tobacco dust) or pest control (nicotine sulfate). The production of tobacco requires high inputs of fertilizer and pesticides and results in water pollution. These pesticides, as well as fertilizers, end up in the soil, waterways, and the food chain. In 2008, EPA received a request from the registrant to cancel the registration of the last nicotine pesticide registered in the United States. This request was granted, and since January 1, 2014, this pesticide has not been available for sale.

There were no public comments on the need to remove tobacco dust from the National Listing at 205.602 as, “Nonsynthetic substances prohibited for use in organic crop production”.

In fact there was rational provided as to why to maintain on the list in order to ensure that other means of using product (for example home-scale) are not pursued. The Crops Subcommittee believes that this substance does not meet many of the OFPA criteria and sees no reason to remove tobacco dust from its prohibited status on 205.602.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of tobacco dust (nicotine sulfate) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove tobacco dust (nicotine sulfate) from 205.602(i)

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

**National Organic Standards Board  
Crops Subcommittee  
Proposed Annotation Change  
Micronutrients, 7CFR 205.601 (j)(6)  
July 7, 2015**

## **Introduction**

Micronutrients are widely used, but in tiny amounts, by organic farmers to correct deficiencies in areas with regional deficient soils or crops with particular micronutrient needs. The existing annotation is not optimal to reflect the way organic farmers stay ahead of their problems, because it requires a corrective action once the system is out of balance, rather than a proactive action to keep an organic agroecosystem in balance. The limitation to only soil testing for deficiency is outdated and needs a more comprehensive approach.

## **Background**

205.601 (j)(6) - As a plant or soil amendment.

Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

- (i) Soluble boron products.
- (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

## **Relevant areas in the Rule**

205.601 (j) - As a plant or soil amendment.

(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

- (i) Soluble boron products.
- (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

## **Discussion**

Public comments were requested and received on the first posting (April 2015) for the Sunset 2017 Micronutrients listing. The question was posed: "Does the current annotation apply to today's practices and procedures?" A dozen or more responses from growers and certifiers indicates that the soil deficiency testing sentence was outdated. A number of other viable ways to determine deficiencies of micronutrients were offered by commenters, including:

- Tissue testing.
- Known regional deficiencies, such as zinc, iron, and boron that are confirmed by cooperative extension agents and publications.
- Professional crop advisors and agronomists who know the nutrient needs of specific crops and regions and will write recommendations for correction before the problem of deficiency occurs.

In addition it was pointed out by commenters, "Although the need for micronutrient use can be demonstrated through soil and/or plant analysis, please consider that waiting for a deficit situation to

prove the need is not healthy approach for crops. It is the equivalent of not feeding people fruits and vegetables until they are deficient in vitamins."

It was also pointed out that there may be a complex combination of soil biological components that inhibit the uptake of a particular micronutrient into the plant, even though a soil test shows that the micronutrient is present in adequate amounts in the soil. In these cases a professional agronomist or crop advisor could figure out that a nutrient was deficient even if a soil test doesn't show it.

It is also worth mentioning that several growers from the western (arid) states indicated that even with decades of intense soil building with compost and organic matter, there has been little improvement in the micronutrient concentration in soils at the levels needed for tree fruits.

Therefore a simple change to the annotation is being proposed. Instead of the sentence, "Soil deficiency must be documented by testing," we are proposing, "Deficiency must be documented." This change allows for the deficiency to be documented by other types of testing, professional recommendation, or published information specific to a crop or region.

### **Recommendation**

Motion to change the annotation for Micronutrients as follows:

205.601 (j) - As a plant or soil amendment.

(6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Deficiency must be documented.

(i) Soluble boron products.

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

### **Subcommittee Vote**

Motion by: Zea Sonnabend

Seconded by: Francis Thicke

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 25, 2015**

**National Organic Standards Board  
Crops and Livestock Subcommittees  
Proposed Annotation Change  
EPA List 4 on 205.601(m), and 205.603(e)  
August 26, 2015**

## **Introduction**

The Crops and Livestock Subcommittees are working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the Inerts Working Group and the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The NOSB will need to vote on an annotation change before this project can move forward.

## **Background**

Current Listings:

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

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

In 2010 the EPA told the NOP that EPA List 4 was no longer being maintained and that language referring to it should be removed from the Federal Rule. In 2012 the NOSB passed a recommendation to proceed with reviewing individual inert ingredients and to change the listing on both 205.601(m) and 205.603(e) (Crops and Livestock respectively) to:

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

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other (“inert”) ingredients).

With this goal in mind, the Inerts Working Group of the NOSB/NOP/EPA has been establishing a relationship with the Safer Choice Program for conducting these reviews. The steps to establishing this process include:

- The NOSB voting to proceed with an annotation change.

- A Federal Register Notice to notify stakeholders of the program and procedures, and rulemaking to amend the National List (subject to public comment).
- The inclusion of a reasonable implementation time (3-5 years) so that manufacturers can apply for SCIL consideration, or petition NOSB, and/or reformulate their products.
- An MOU or other mechanism to finalize the agreement between NOP and SCP.
- Specific instructions and outreach developed for the SCP portion of the review targeted toward manufacturers of pesticide products used in organic production.
- NOSB periodic review of the SCIL list to consider those criteria in OFPA that the SCP does not address (such as compatibility with organic agriculture).

### Relevant areas in the Rule

See above

### Discussion

The CS and LS propose the following change to 205.601(m)(1) and 205.603(e)(1), EPA List 4 – Inerts of Minimal Concern.

205.601(m) and 205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).<sup>1</sup>
- (ii) Substances included on the EPA's Safer Chemical Ingredient List.
- (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
- (iv) [Reserved] (for any other inerts individually petitioned and reviewed)]

This is very similar to the recommendation by the NOSB in 2012 except that it acknowledges the Safer Chemical Ingredient List and it includes the listing for pheromone dispensers into the main inerts listing (see Appendix II). This clarifies to all stakeholders how the inerts will be reviewed, listed, and allowed (or not) in the future.

The timeline for this process needs to be adequate in order that all inerts currently in use may be reviewed under SCIL, or petitioned and reviewed by NOSB. There also needs to be time for products to be reformulated, if necessary. The goal is to make this transition towards a new review of inerts as seamless for organic producers as possible, with an assurance that formulated

<sup>1</sup> [http://www.epa.gov/opprd001/inerts/section25b\\_inerts.pdf](http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf) . EPA has published a proposed rule at [FR 77:76979](#) to codify the list of actives and inerts eligible for minimal risk products, when finalized the NOP reference will cite this.

products that are reviewed for inerts and effective are still available to them throughout the change in policy.

The proposal provides a change in the Inerts listing, without specifying a corresponding timeline. NOSB expects that the NOP will create an appropriate grace period for making this change, as they did when the rule first came out in 2000 that limited inerts to only List 4.

The Inerts Working Group has completed a comparison between the SCIL criteria and the NOSB criteria that are used in reviewing materials (see Appendix I). There is a lot of similarity between them but also some gaps that can be addressed by the NOSB in periodic review of the SCIL.

### **Recommendation**

Proposed Motion to change the annotation for EPA List 4 Inerts as follows:

205.601(m) and 205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).<sup>2</sup>
- (ii) Substances included on the EPA's Safer Chemical Ingredient List.
- (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
- (iv) [Reserved] (for any other inerts individually petitioned and reviewed))

### **Crops Subcommittee Vote**

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Additional Discussion: none

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

### **Livestock Subcommittee Vote**

Motion to accept the List 4 annotation change proposal from the Crops Subcommittee

Motion by: Tracy Favre

Seconded by: Jean Richardson/Ashley Swaffar

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

<sup>2</sup> [http://www.epa.gov/opprd001/inerts/section25b\\_inerts.pdf](http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf) . EPA has published a proposed rule at [FR 77:76979](https://www.federalregister.gov/d/2017-07-14) to codify the list of actives and inerts eligible for minimal risk products, when finalized the NOP reference will cite this.

## Appendix I

## Comparison of Review Criteria

**Organic Foods Production Act Criteria for  
Review of Substances Used in Organic Production and  
EPA Safer Choice Program, Safer Chemical Ingredient List Criteria**

<b>Review Criteria for Substances/Chemical Ingredients</b>	
<b>USDA</b> <u>Organic Foods Production Act (7 USC 6501)</u>	<b>EPA – Safer Choice Program</b> <a href="http://www2.epa.gov/saferchoice">http://www2.epa.gov/saferchoice</a>
7 USC 6518 <b>National Organic Standards Board</b> (m) Evaluation – In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider -	
(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;	SCP considers potential biotic and abiotic interactions when information is made available; however, such information is not commonly provided with chemical submissions. SCP does review potential negative chemical reactions within products that are reviewed for Safer Chemical label program.
(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;	<p><b>(1)</b> SCP has established criteria to evaluate toxicity to mammalian and aquatic organism receptors. Importantly, all data are considered even if receptor specific SCP criteria are not established.</p> <p><b>(2)</b> SCP evaluates breakdown products and metabolites of potential concern for all chemicals.</p> <p><b>(3)</b> SCP evaluates bioaccumulation potential and fate (environmental persistence) in the environment.</p> <p>More details available at: <a href="http://www2.epa.gov/saferchoice/standard">http://www2.epa.gov/saferchoice/standard</a></p>
(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;	SCP considers intended use of products during evaluation and limits the permissible use/application method.

<p>(4) the effect of the substance on human health;</p>	<p>SCP evaluates human health using criteria for  <b>(1)</b> acute and chronic exposures (criteria for oral, dermal and inhalation routes of exposure)  <b>(2)</b> dermal and respiratory sensitization  <b>(3)</b> carcinogenicity and mutagenicity  <b>(4)</b> Reproductive and Developmental effects                  See SCIL <a href="#">Master criteria</a></p>
<p>(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;</p>	<p><b>(1)</b> SCP considers potential biotic and abiotic interactions when information is made available (although not specific to agroecosystems).  <b>(2)</b> If provided with toxicity data on soil dwelling organisms SCP would consider these data when evaluating the chemical.</p>
<p>(6) the alternatives to using the substance in terms of practices or other available materials; and</p>	<p>SCP evaluates each chemical ingredient against the appropriate functional use criteria. Chemicals meeting criteria are considered to be safer than comparable chemicals within the functional class.</p>
<p>(7) its compatibility with a system of sustainable agriculture</p>	<p>No comparable SCP criteria, however SCP evaluates impacts on environment, wildlife, and human health, and considers intended use of products during evaluation and limits the permissible use/application method.</p>
<p><b>Proposed Additional Screening for Inerts, (NOSB recommendation, Oct 2012 ):</b></p>	<p><b>Authoritative Lists Used in SCIL Review</b></p>
<ol style="list-style-type: none"> <li>1. Toxicity category from EPA :I or II (“danger” or “warning”)</li> <li>2. CA Prop 65 list- as a developmental or reproductive toxicant</li> <li>3. Carcinogen on EPA’s List of Chemicals Evaluate for Carcinogenic Potential (known/likely, probable, or possible human carcinogen)</li> <li>4. Carcinogen on IARC, U.S. NTP, CA Prop 65 (known, likely, probable, possible, reasonably anticipated to be)</li> <li>5. Nervous system toxicants including cholinesterase inhibitors or chemicals associated with neurotoxicity by other</li> </ol>	<p><u>Authoritative Sources Indicating Carcinogenicity Mutagenicity and Reproductive Toxicity:</u></p> <ul style="list-style-type: none"> <li>• International Agency for Research on Cancer (IARC). <a href="#">Agents Classified by the IARC Monographs</a>, Designated Group 1, 2A, or 2B.</li> <li>• US EPA. <a href="#">Integrated Risk Information System (IRIS)</a>, Chemicals carcinogenic to humans, likely to be carcinogenic to humans, or suggestive evidence of carcinogenic potential (2005 Guidelines).</li> <li>• California Office of Environmental Health Hazard Assessment (OEHHA). <a href="#">Proposition 65 List of Chemicals Known to the State to Cause Cancer or Reproductive Toxicity</a>.</li> <li>• European Commission Hazard Phrases</li> </ul>

<p>mechanism, or listed on Toxic Release Inventory or IRAC or CDPR as similar class</p> <p>6. Endocrine disruptors – based on EC list</p> <p>7. Adverse effect on environment, wildlife based on label precautionary statements, including toxic or extremely toxic to bees, birds, fish, aquatic invertebrates, wildlife, other non-target organisms</p> <p>8. Moderate or high mobility in soil, or soil half-life of 30 days or more, using Groundwater Ubiquity Score (GUS), or calculated using soil aerobic half life and soil binding coefficient.</p> <p>9. Has data gaps or missing information in EPA documents</p> <p>10. Contains any contaminants, metabolites that violate these criteria</p> <p>11. The substance is a known groundwater contaminate, as identified by state of CA or from historic ground water monitoring records.</p>	<p>(<a href="#">Annex VI to the CLP Regulation</a>) or Risk Phrases (<a href="#">Annex VI to the DSD Regulation</a>) indicating possible carcinogenic, mutagenic, or reproductive toxicity: H350, H350i, H351, H340, H341, H360, H361, H362, R45, R49, R40, R46, R68, R33, R60, R61, R62, R63, R64.</p> <p><i>Adverse effect on environment, wildlife, including toxicity to non-target ecological receptors is currently not included in our criteria but may be built in to the review.</i></p> <p><u>Authoritative Sources Indicating Persistence Bioaccumulation and Toxicity:</u></p> <ul style="list-style-type: none"> <li>• US EPA. <a href="#">Toxic Release Inventory (TRI)</a>. Designated PBT.</li> <li>• EU REACH. <a href="#">Substances of Very High Concern due to PBT, vPvB, or vPvT</a>.</li> <li>• Stockholm Convention <a href="#">Persistent Organic Pollutants (POPs)</a>.</li> <li>• OSPAR List of Substances of Possible Concern. <a href="#">Hazardous Substances List - Sections A-D</a>.</li> <li>• Chemicals determined to exceed <a href="#">Safer Choice's thresholds for persistence, bioaccumulation, and aquatic toxicity</a> when addressed through the <a href="#">TSCA Work Plan Chemical</a> process.</li> </ul> <p><u>Respiratory Sensitizers:</u></p> <ul style="list-style-type: none"> <li>• European Commission Hazard Phrases (<a href="#">Annex VI to the CLP Regulation</a>) or Risk Phrases (<a href="#">Annex VI to the DSD Regulation</a>) indicating possible respiratory sensitization: H334, R42.</li> </ul> <p><u>Dermal Sensitizers:</u></p> <ul style="list-style-type: none"> <li>• Dermal Sensitizers from Annex III of the EU Cosmetics</li> </ul>
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	<p>Regulation. <a href="http://ec.europa.eu/enterprise/sectors/chemicals/files/legislation/allergenic_subst_en.pdf">http://ec.europa.eu/enterprise/sectors/chemicals/files/legislation/allergenic_subst_en.pdf</a> Additional substances may be added this year.</p> <ul style="list-style-type: none"><li>• European Commission Hazard Phrases (<a href="#">Annex VI to the CLP Regulation</a>) or Risk Phrases (<a href="#">Annex VI to the DSD Regulation</a>) indicating dermal sensitization: H317 or R43</li></ul> <p><u>Other Authoritative Lists:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Environment Canada Domestic Substances List</a>, designated PBT</li><li>• <a href="#">US EPA Toxic Release Inventory (TRI)</a></li><li>• <a href="#">US EPA Work Plan Chemicals</a></li><li>• <a href="#">US EPA Ozone Depleting Substances</a> (Class I and II)</li><li>• <a href="#">US EPA Hazardous Air Pollutant</a> (HAP)</li><li>• ChemSec, <a href="#">Substitute it Now! (SIN) List</a>, designated PBT</li><li>• Association of Occupational and Environmental Clinics (AOEC), <a href="#">Exposure Codes</a></li><li>• IFRA Labeling Manual and <a href="#">IFRA Transparency List</a></li><li>• TEDX – The Endocrine Disruptor Exchange, <a href="#">List of Potential Endocrine Disruptors</a></li><li>• European Commission <a href="#">Endocrine Priority List</a></li><li>• Safer Chemicals, Healthy Families, <a href="#">Mind the Store</a></li><li>• California Department of Public Health, Safe Cosmetics Program, <a href="#">Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity</a>.</li></ul>
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## Appendix II

### EPA regulation

#### **40 CFR §180.1122 Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.**

(a) All inert ingredients of semiochemical dispenser products formulated with, and/or contained in, dispensers made of polymeric matrix materials (including the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers, and other inert ingredients) are exempted from the requirement of a tolerance when used as carriers in pesticide formulations for application to growing crops only. These dispensers shall conform to the following specifications:

(1) Exposure must be limited to inadvertent physical contact only. The design of the dispenser must be such as to preclude any contamination by its components of the raw agricultural commodity (RAC) or processed foods/feeds derived from the commodity by virtue of its proximity to the RAC or as a result of its physical size.

(2) The dispensers must be applied discretely. This exemption does not apply to components of semiochemical formulations applied in a broadcast manner either to a crop field plot or to individual plants.

(b) A semiochemical dispenser is a single enclosed or semi-enclosed unit that releases semiochemical(s) into the surrounding atmosphere via volatilization and is applied in a manner to provide discrete application of the semiochemical(s) into the environment.

(c) Semiochemicals are chemicals that are emitted by plants or animals and modify the behavior of receiving organisms. These chemicals must be naturally occurring or substantially identical to naturally occurring semiochemicals.

[58 FR 64494, Dec. 8, 1993]

**National Organic Standards Board**  
**Crops Subcommittee**  
**Petitioned Material Proposal - Laminarin**  
**June 23, 2015**

**Introduction**

The NOSB received a petition for Laminarin, a seaweed extract for disease control that is EPA registered for that purpose. The [NOSB Crops Subcommittee voted](#) that it was non-synthetic by a vote of 5-2-0 and brought it to the full NOSB in the spring of 2014. The NOSB decided that there needed to be a [Limited Scope Technical Review \(TR\)](#) to clarify the whether the extraction and purification process resulted in a synthetic material, and to examine the environmental effects of seaweed harvest and processing. That TR was completed in May 2015.

**Background**

In the National Organic Program notes that accompanied the forwarded petition from June 3, 2013 they stated:

In NOP's review of the eligibility of this petitioned substance for the National List, we reviewed the manufacturing process against the draft guidance on classification of materials (NOP 5033). Based on our preliminary review, this substance may be classified as nonsynthetic. We have moved this petition forward for NOSB review and final determination on the classification status for the following reasons:

- The classification guidance is currently in draft form
- Other aquatic plant extracts are classified as synthetic for crop production at 205.601(j)(1)
- At this time, NOP is not aware of any products containing laminarin as an active ingredient that are approved by certifying agents or third-party material review organizations, such as EPA or OMRI

The draft Guidance on Classification of Materials was reviewed in the preparation of the TR and by the Crops Subcommittee ([NOP 5033](#), section 4.6):

**4.6 Extraction of Nonorganic Materials**

Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).

For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

## Discussion

Laminarin is a low molecular weight, bioactive polysaccharide. It does not have gelling or thickening properties like other algal polysaccharides, namely alginate and carrageenan. Laminarin was petitioned for addition to the National List for use as a pre-harvest pesticide to stimulate the plants' natural disease-defense mechanisms. Its ability to stimulate plant defenses is well documented. Laminarin has also been shown to enhance the biological control of crop pests by attracting parasitic wasps (2015 TR, lines 56-60).

Laminarin can be extracted by a number of different methods that are described in the TR under Evaluation Question #2 (2105 TR, lines 184 - 264). All of the processes use some physical methods such as grinding, filtration and centrifugation. Most of them use solvents such as alcohol or acid-base reactions to produce a purified extract. Table 2 in the TR (line 245) summarizes the methods. The claim in the petition that there is no modification to the chemical structure of the laminarin is supported by research cited in the TR (lines 249 - 259).

Evaluation Question #3 of the TR goes into the potential for residual sodium or sulfate to remain in the laminarin (lines 291 - 317). Several reasons are given why the calculations posed by the minority opinion of the NOSB crops subcommittee are not accurate. While there may be some ionic forms of sodium and sulfate ions, they would not react or precipitate as sodium sulfate (TR line 300-301). This is summed up by lines 316 and 317: "In all extraction scenarios, the literature does not suggest that the residual ions resulting from the acid-base reactions lend any technical or functional effect in the laminarin ingredient once it is completely extracted." Further the last point made in the TR on lines 382 to 388 states:

"The EPA typically requires any component of a pesticide formula greater than or equal to 0.1% to be declared on the Confidential Statement of Formula (CSF), including impurities from acid-base reactions such as those described in this technical report. There can be no exceptions for listing on the CSF where 'Impurities of Toxicological Significance' are concerned (Pfieffer 2015). Based on theoretical calculations in Question 3, sulfate ions could conceivably comprise 0.0034% of a final commercial laminarin product, and sodium consists of .001%. Therefore, these residual by-products from the acid-base reaction would not likely be declared on the CSF, even as impurities."

The environmental impacts are discussed in Evaluation Question #6 of the Technical Report. (2015 TR, lines 319 - 388). The potential impacts are similar to many other non-synthetic inputs used in organic agriculture that are harvested or mined from the earth and sea. In France where the majority of the Laminaria is harvested, the production is highly regulated, but that information was not available for other locations which might have seaweed production.

Referring back to the bullet point in the Guidance on Classification of Materials 4.6 as quoted above, the subcommittee has this analysis:

- *At the end of the extraction process, the material has not been transformed into a different substance via chemical change;*

The TR indicates that laminarin is not changed in extraction.

- *The material has not been altered into a form that does not occur in nature; and*  
Laminarin does occur in nature.

- *Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.*

The reaction and filtration steps result in a purified laminarin in which the sodium and sulfate ions do not have a technical or functional effect. This is quite different than the listing for aquatic plant extracts that are classified as synthetic for crop production at 205.601(j)(1). In those the extracting agents such as potassium hydroxide does leave behind enough potassium to have a functional effect as a fertilizer. In laminarin, neither the sodium (at 0.001%) nor the sulfate ions (at 0.0034%) have a functional effect for disease suppression.

Therefore the majority of the Crops Subcommittee believes that laminarin is non-synthetic and therefore is allowed without need to add it to the National List. A checklist is included here for only the sections covered in the Technical Report.

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**Substance Fails Criteria Category:** [ ] **Comments:** none

**Subcommittee Action & Vote:**

Motion to classify laminarin as petitioned as non-synthetic  
 Motion by: Zea Sonnabend  
 Seconded by: Harold Austin  
 Yes: 5 No: 0 Abstain: 0 Absent: Recuse: 0

**Listing Motion:**

Because laminarin was classified as non-synthetic it does not need to be added to the National List.

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 25, 2015**

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 1. Adverse impacts on humans or the environment? Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		TR question 6, lines 319 - 388
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Laminarin has also been shown to enhance the biological control of crop pests by attracting parasitic wasps (TR lines 59 - 60)
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		The formulation of Laminarin from the petitioner does contain inerts which have not been evaluated, but the active ingredient does not.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 2. Is the Substance Essential for Organic Production? Substance: Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		See discussion above and TR evaluation Question #2 (lines 184 - 264)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	
8. Are there any alternative substances? [§6518(m)(6)]	X			There are disease controls on the National List that are synthetic that may be alternatives, such as potassium bicarbonate and sulfur.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]				Maybe some cultural management systems could minimize disease pressure, but there is no information yet on how well this works in an organic system because it has not been approved yet.



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Lignin Sulfonate (petition to remove)  
June 2, 2015**

**Summary of Proposed Action:**

The NOSB received a petition to remove Lignin Sulfonate from Section 205.601(l)(1) of the National List - for use as a floating agent in postharvest handling. The material has a long approval history; it was placed on the original National List and was subsequently renewed during the 2006 and 2011 Sunset Reviews. However, in 2014 a trade association conducted a poll of all certified organic pear packing facilities in the U.S. to determine if the material was still in use; their results indicated that no handlers were using Lignin Sulfonate. Based upon the results of their survey, the petitioner has filed a petition for removal based on a lack of essentiality.

Alternatives to Lignin Sulfonate include the use of floatless systems that don't require floating agents or, when necessary, the use of the following National listed materials 1) sodium silicate, 2) sodium carbonate, and 3) potassium carbonate.

The Crops Subcommittee asked for public input on the following two questions in preparation for the spring 2015 NOSB meeting: 1) Will removal of lignin sulfonate as a floating agent disrupt your business? And 2) Should the use of lignin sulfonate be subject to documented monitoring of waste water in the OSP? We did not receive any written or verbal comments in favor or against relisting the material nor did we receive answers to the aforementioned questions. In the absence of any industry feedback, the Crops Subcommittee recommends removal of Lignin Sulfonate as a floating agent because it is no longer an essential material in organic crop production. See also the separate Sunset 2017 reviews for additional uses.

**Evaluation Criteria (see attached checklist for criteria in each category)**

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

**Criteria Satisfied?**

- |   |  |                              |
|---|--|------------------------------|
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No            | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes            | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No            | <input type="checkbox"/> N/A |

**Substance Fails Criteria Category: 2**

**Subcommittee Action & Vote:**

**Listing Motion:**

Motion to remove Lignin Sulfonate from §205.601(l)(1) of the National List for use as a floating agent in postharvest handling.

Motion by: Zea Sonnabend

Seconded by: Colehour Bondera

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 25, 2015**

## NOSB Evaluation Criteria for Substances Added To the National List Crops

**Category 1. Adverse impacts on humans or the environment? Substance: Lignin Sulfonate, as floating agent**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

## NOSB Evaluation Criteria for Substances Added To the National List – Crops

### Category 2. Is the Substance Essential for Organic Production? Lignin sulfonate, as floating agent

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			1) Sodium silicate, 2) sodium carbonate, and 3) potassium carbonate.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Use of floatless systems that don't require the use of floating agents.

### NOSB Evaluation Criteria for Substances Added To the National List - Crops

**Category 3. Is the substance compatible with organic production practices? Lignin sulfonate, as floating agent**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		X		
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Sulfuric Acid  
August 4, 2015**

**Summary of Proposed Action:**

Sulfuric acid has been petitioned to be added to §205.601 Synthetic substances allowed for use in organic crop production. The petition requests that sulfuric acid be approved for use as a solubilizing agent to make micronutrients more available for plant uptake. If approved, sulfuric acid would be used in the manufacture of micronutrients in a process to adjust pH to create chelates of B, Mg, Ca, Mn, Fe, Cu and Zn through solubilization of oxides of those elements and complexation of them with amino acids. The purpose of this process is to “solubilize to a very high level the mineral oxide substances and ensure very rich micronutrient content in the end product” (from the [petition](#)).

Sulfuric acid has been petitioned for various uses in the past, including for use to stabilize livestock and poultry manures for use in organic crop production, for which a Technical Evaluation Report was prepared in February 2006. Sulfuric Acid was also petitioned for use in organic handling as a pH adjustment for production of seaweed extracts, for which a Technical Evaluation Report was prepared in May 2012. In all three cases, the NOSB voted to not add sulfuric acid to the National List.

Sulfuric acid is a very corrosive strong acid that is one of the primary chemical agents of acid rain. Facilities that manufacture sulfuric acid are among the primary sources of sulfuric acid releases to the environment (2006 TR).

The Crops Subcommittee has concerns that the process of treating micronutrients with sulfuric acid as described in this petition will produce forms of micronutrients that are highly refined and designed to spoon-feed plants in ways that circumvent the natural soil biological processes central to organic farming systems, as described in the organic standards definition of organic production (205.2): “A production system that ...[integrates] cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.”

The alternative option for micronutrients in organic production is the use of micronutrients as already on the National List at 205.601(j)(6).

**Evaluation Criteria (see attached checklist for criteria in each category)**

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

**Criteria Satisfied?**

- |                              |  |                              |
|------------------------------|--|------------------------------|
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |

**Substance Fails Criteria Category:** [1, 2, 3] **Comments:**

**Subcommittee Action & Vote****Classification Motion:**

Move to classify sulfuric acid as petitioned as synthetic

Motion by: Francis Thicke  
 Seconded by: Harold Austin  
 Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Listing Motion:**

Motion to list sulfuric acid, as petitioned, at §205.601.

Motion by: Francis Thicke  
 Seconded by: Harold Austin  
 Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair to transmit to NOSB August 4, 2015**

**NOSB Evaluation Criteria for Substances Added To the National List Crops**

**Category 1. Adverse impacts on humans or the environment? Substance: Sulfuric Acid**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X			The 2012 TR notes that sulfuric acid is a substantial source of acid rain, and that the manufacture of this material presents adverse environmental impact (lines 327-353).
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X			TR lines 327-353.
3. Are there any adverse impacts on biodiversity? (§205.200)	X			TR lines 327-353.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]			X	
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment?		X		

[§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]				
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

**Category 2. Is the Substance Essential for Organic Production? Substance: Sulfuric Acid**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			The petition indicates that other acids might work, but not as effectively as sulfuric acid.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			The alternative is use of micronutrients as already on the National List at 205.601(j)(6).

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 3. Is the substance compatible with organic production practices? Substance: Sulfuric Acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Use of highly concentrated synthetic micronutrients is not consistent with the biological principles of organic farming.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Mimics the input system of conventional agriculture.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. 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	X			
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board**  
**Crops Subcommittee**  
**Petitioned Material Proposal**  
**Brown Seaweed Extracts**  
**August 4, 2015**

**Introduction**

In 2015, the NOSB received a petition from BioAtlantis, Ltd. for Brown Seaweed Extract used as a plant strengthener (fertilizer) primarily to improve shoot growth and seed germination, increase root growth and improve soil microbial count for use in various fruits, vegetables and cereal crops. Petitioned substance is to be considered as a synthetic substance allowed for use in organic production, as set in 205.601 of the USDA organic regulations. Because of their similarities, the petition for Brown Seaweed Extract and Laminarin are concurrently being reviewed, note however that Laminarin was petitioned for use in disease control while this brown seaweed is a fertilizer. At the NOSB Spring, 2014 meeting, Laminarin was referred back to the Subcommittee and a [Limited Scope Technical Review](#) was requested to determine if the extraction and purification process resulted in a synthetic or non-synthetic material. That TR was completed in May 2015.

**Background**

The National Organic Program notes that accompanied this petition stated that Brown Seaweed Extracts have some similarities to the outstanding petition for Laminarin, since both are seaweed extracts that use sulfuric acid for pH adjustment. During their preliminary review of Laminarin, the NOP determined that the material could be classified as non-synthetic. The NOP did not make a final determination, but rather requested that the NOSB decide upon its classification status. Similarly, the Subcommittee must also determine whether or not Brown Seaweed Extract should be classified as synthetic or non-synthetic.

In order to do this, the Subcommittee reviewed the draft Guidance on Classification of Materials, including the following excerpt to finalize the classification determination:

**4.6 Extraction of Nonorganic Materials**

Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).

For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:

- 1) At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- 2) The material has not been altered into a form that does not occur in nature; and
- 3) Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

## Discussion

Brown seaweed extract (made from the following two species: *Laminaria* species or *Ascophyllum nodosum*) is composed of naturally occurring components extracted from seaweed, such as laminarin or fucoidan. The petition claims that the material helps with crop protection by strengthening plant health (Petition, page 5). Although described as a plant strengthener, the two products are labeled as a 0-0-3 fertilizer and a 0-0-1 fertilizer. Material use is through foliar applications or fertigation. Brown seaweed extracts are harvested in Ireland; the petitioner indicates that no environmental impacts have been detected until now. The Laminarin TR goes to great length to describe French government regulations in place to ensure that seaweed harvesting is sustainable.

The petitioner describes a 3-step manufacturing process that includes: 1) seaweed is harvested and extracted with tap water whose pH is lowered to a 3.5 minimum by adding a low concentration of sulfuric acid. Petitioner clarifies that the use of acid at low levels is neutralized and acts as a processing aid only; 2) mixture is centrifuged to separate seaweed insoluble from liquid extract; and 3) potassium hydroxide is added to adjust pH of liquid extract to near neutral. Sulfuric acid is NOP allowed for use to adjust the pH of liquid fish products when the amount used does not exceed the minimum needed to lower the pH to 3.5. Petitioner further clarifies that the addition of potassium hydroxide completely eliminates all trace of sulfuric acid.

The Laminarin TR describes the physical extraction methods including grinding, precipitation in an acid or base medium, ultrafiltration, and dialysis; refer to Table 2 under Question #2 for a summary of extraction methods. Laminarin TR lines 247 – 259, refer to research backing the claim that the addition of sulfuric acid does not modify the structure of Laminarin; the sulfuric acid is used as a processing aid to facilitate filtration (Laminarin TR, lines 263 – 264). Furthermore, Laminarin TR question #3, lines 316 – 317, states the following: “In all extraction scenarios, the literature does not suggest that the residual ions resulting from the acid-base reactions lend any technical or functional effect in the laminarin ingredient once it is completely extracted.” In conclusion, the Laminarin Limited Scope TR clarified the following two items, 1) the chemical structure of the material is not modified and 2) the sodium and sulfate ion synthetic residuals from the manufacturing process have no technical effect in the final product. For the abovementioned reasons, Laminarin is classified as non-synthetic.

In contrast, the Crops Subcommittee has determined that the Brown Seaweed must be classified as synthetic because potassium hydroxide is utilized in the manufacturing process. Per the [draft Guidance on Classification of Materials](#) (4.6-3), *any synthetic materials used to separate, isolate, or extract the substance [must] have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.* Potassium hydroxide is added during the manufacturing process to establish a near neutral pH; this addition has a “functional effect” in the final product. Because OFPA prohibits the use of any fertilizers containing synthetic ingredients, Brown Seaweed as petitioned cannot be added to the National List.

## Evaluation Criteria (see attached checklist for criteria in each category)

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

### Criteria Satisfied?

- Yes  No  N/A
- Yes  No  N/A
- Yes  No  N/A

**Substance Fails Criteria Category: 3**

**Subcommittee Action & Vote**

**Classification Motion:**

Motion to classify Brown Seaweed Extracts as petitioned as synthetic.

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Listing Motion:**

Motion to add Seaweed Extracts as petitioned at 205.601

Motion by: Carmela Beck

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 25, 2015**

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 1. Adverse impacts on humans or the environment? Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See Laminarin TR evaluation Question #6, (lines 319 – 388)
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 2. Is the Substance Essential for Organic Production? Substance: Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			The manufacture of brown seaweed extracts utilizes potassium hydroxide to lower the pH
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	
8. Are there any alternative substances? [§6518(m)(6)]		X		Petitioner unaware of any non-synthetic or synthetic substances on the National List or alternative agricultural methods that could be used to replace Brown Seaweed Extracts (Petition, page 5)
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		

## NOSB Evaluation Criteria for Substances Added To the National List - Crops

### Category 2. Is the Substance Essential for Organic Production? Substance: Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			The manufacture of brown seaweed extracts utilizes potassium hydroxide to lower the pH
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	
8. Are there any alternative substances? [§6518(m)(6)]		X		Petitioner unaware of any non-synthetic or synthetic substances on the National List or alternative agricultural methods that could be used to replace Brown Seaweed Extracts (Petition, page 5)
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		

## Sunset 2017 Review Meeting 2 - Review Handling Substances §205.605(a) October 2015

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

**Reference: 7 CFR 205.605 *Nonagricultural*** (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

### §205.605(a) Nonsynthetics allowed:

[Acid, Alginic](#)

[Acid, Citric](#)

[Acid, Lactic](#)

[Attapulgite](#)

[Bentonite](#)

[Calcium carbonate](#)

[Calcium chloride](#)

[Dairy cultures](#)

[Diatomaceous earth](#)

[Enzymes](#)

[Flavors](#)

[Kaolin](#)

[Magnesium sulfate](#)

[Nitrogen](#)

[Oxygen](#)

[Perlite](#)

[Potassium chloride](#)

[Potassium iodide](#)

[Sodium bicarbonate](#)

[Sodium carbonate](#)

[Waxes \(Carnauba\)](#)

[Waxes \(Wood rosin\)](#)

[Yeast](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

## Acid, Alginic

**Reference:** 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

**Technical Report:** 2015 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Alginic acid is derived from wild harvested seaweeds. Increasing demand for alginic acid and alginates has led to some concerns regarding potential for overharvesting of these wild seaweeds.

Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in pure alginic acid. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, it is clear that the free acid form does not appear in nature. (2015 Technical Review – Alginic Acid, Lines 283-286). In the 1995 TAP review for Alginic Acid, the reviewers determined that the material was non-synthetic. However, given the draft Classification of Materials document and the information presented in the 2015 TR, it could be suggested that alginic acid is synthetic.

There has been recent research into production of alginic acid and alginates from a biological fermentation process. However, this process does not currently produce sufficient quantities to be commercially available, (2015 Technical Review – Alginic Acid, Lines 299-300).

FDA limits the use of alginic acid as a stabilizers, emulsifier and thickener in soups and soup mixes.

The Handling Subcommittee had brought forth the following questions for public comment:

1. Please bring forth any information regarding the effect of alginic acid and/or alginates on human digestion.
2. Is alginic acid in use in organic handling and should it have its own National List listing? What are the non-synthetic alternatives in specific handling uses?

Public comment was mixed regarding the relisting of alginic acid. Those in favor of its relisting note the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting, and assert that the properties imparted by alginic acid are essential for some processed food formulations. Those opposed expressed concerns regarding the concentration of heavy metals in the wild harvested seaweed and the fact that alginic acid is used primarily to enhance texture in foods, and is therefore not compatible with OFPA criteria.

The Handling Subcommittee proposes that alginic acid remain on the National List. However, the Handling Subcommittee is bringing forward a separate proposal to change the listing from 205.605(a) to 205.605(b) due to the determination that alginic acid would likely be classified as synthetic under the new draft Classification of Materials document.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of alginic acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### **Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Acids – Citric, Lactic**

**Reference:** 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

**Technical Report:** 1995 TAP; 2015 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### **Subcommittee Review**

Citric acid is very 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 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.

Lactic acid appears on the National List, 7 CFR Part 205.605(a), without an annotation. 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. 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).

Common uses include, but are not limited to:

1. In sugar confectionery, it is used in 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 Mesenteric groups of bacteria.
6. It is used in jams, jellies and frozen fruit desserts.
7. In dairy products such as cottage cheese, the addition of lactic acid is preferred to fermentation.
8. Used in imitation dairy products such as cheese and yogurt powder.
9. 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.
10. Use of buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
11. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
12. 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.

Approved Legal Uses of the Substance:

Citric acid is listed under 21 CFR Part 184.1033 as Generally Recognized as Safe (GRAS). The listing allows its production from lemon or pineapple juice; through microbial fermentation from *Candida* spp.; or by solvent extraction from *Aspergillus niger* fermentation. It is allowed for use in food with no limitations other than good manufacturing practice. Additionally, sections 21 CFR 173.160 and 173.165 list *Candida guilliermondii* and *Candida lipolytica* as allowed organisms for production of citric acid through microbial fermentation. The regulation requires that the citric acid produced conforms to the specifications of the Food Chemicals Codex (Food Chemicals Codex, 2010).

Section 21 CFR 173.280 covers the solvent extraction purification of citric acid from *Aspergillus niger* fermentation. This process is discussed in detail under Evaluation Question #1 in the section on recovery of citric acid. Current good manufacturing practice (GMP) for solvents results in residues not exceeding 16 parts per million (ppm) n-octyl alcohol and 0.47 ppm synthetic isoparaffinic petroleum hydrocarbons in citric acid. Tridodecyl amine may be present as a residue in citric acid at a level not to exceed 100 parts per billion.

The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inert). The EPA allows citric acid as an active ingredient in pesticide products registered for residential and commercial uses as disinfectants, sanitizers and fungicides (EPA R.E.D. 1992) and it is exempt from tolerances per 40 CFR 180.950. Products containing citric acid in combination with other active ingredients are used to kill odor-causing bacteria, mildew, pathogenic fungi, certain bacteria and some viruses, and to remove dirt, soap scum, rust, lime, and calcium deposits. Citric acid products are used in facilities, and in or on dairy and food processing equipment.

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

Discussion: The NOSB in its initial request for public comment did not ask for any specific information from stakeholders.

While there were not specific questions asked of the public, the subcommittee did receive several comments from various stakeholders.

Several commenters in favor of relisting stated:

- One dairy company stated that they use citric acid in the fruit on the bottom of our yogurts to adjust the pH for food safety reasons. While we choose this ingredient for its functional effect, it does also have an impact on the flavor of the product. If we were no longer able to use citric acid, we would have a considerable reformulation challenge to achieve both the technical functionality and the consistent flavor profile that we are aiming for.
- Citric acid is a natural occurring substance but classified as a synthetic due to chemical processing through fermentation. Citric acid has GRAS status by the FDA. Citric acid has many uses in food production. It has a history of safe use in organic foods dating back to 1995. Natural citric may be isolated from organically grown fruit but to our knowledge is not commercially available in the quantities that would be required to service the growing organic sector. Citric acids status as a synthetic should be renewed.
- Our suppliers use citric acid in canned artichoke hearts, water chestnuts, pimentos, tomatoes and orange peel. Citric acid is use to adjust the pH of many of these ingredients as well as maintaining the quality and control of microorganisms. Alternate acids are not more natural and do not give the same flavor profile. We always confirm that the citric acid used by our suppliers is produced by microbial fermentation of carbohydrate substances. It is used for organic fruit processing and spreads as a pH adjuster. The company has been certified for 13 years and products are sold in all 50 states. There are no other alternatives that will work.
- Citric acid is critically essential to our organic processing operation.
- It provides the needed acidity and preservation, including protecting the safety of the food by keep pH below 4.6.
- We use it in many organic products, including baby food, breakfast cereals, frozen desserts, frozen entrees and certified organic personal care products.
- Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with milk. It functions as a flavor agent, preservative and acidity adjuster in foods. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation. Lactic acid is listed as GRAS at 21 CFR 184.1061 and has been shown to be safe for use in foods. We are not aware of any organic alternative to lactic acid. These three acids are important components of organic production and have unique functionality that makes them essential in many organic formulations. As all three lack organic alternatives, are consistent with organic principles and safe for use in food, we strongly urges that they be relisted on the National List at Section 205.605(a).
- We advocate keeping this material on the National List.

- Lactic acid is used in a soy based cheese alternate that we currently use. The lactic acid is present for flavor development and control of microorganisms. Alternates are not more natural and do not have the same flavor profile.
- Utilized in a wide variety of organic products. Shows the same characteristics of citric acid in providing the acidity in a product and helping to preserve the organic product. The acid profile is different than citric acid and is generally well desired in dairy products. Additionally, lactic acid is a naturally occurring element of a number of dairy products.
- One certifier stated that, Lactic Acid is primarily used for carcass wash and many of our meat processors use lactic acid.
- Commenter who opposed the relisting stated: Citric acid should be re-classified as synthetic.

While there are concerns about the relisting of this material, citric acid has been used for many years as a food processing and based on the overwhelming majority of public comments is necessary in the organic industry for proper pH control in many foods.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of Citric Acid.

#### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Acids – Citric and Lactic from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: non given

#### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

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

## **Attapulgit**

**Reference:** 205.605(a) – as a processing aid in the handling of plant and animal oils.

**Technical Report:** 2010 TR

**Petition(s):** 2009 Attapulgit

**Past NOSB Actions:** 04/2011 NOSB recommendation

**Recent Regulatory Background:** Added to National List effective 08/03/2012 [[77 FR 45903](#)]

**Sunset Date:** 08/03/17

#### **Subcommittee Review**

The petition (2009) is a comprehensive 158 page document with extensive literature review. Petition

included request for use in animal feed. Attapulgit is one of the so-called Fullers Earths used since biblical times. Modern extraction is by open pit which does have adverse environmental impact, however environmental and mining regulations are in place to remediate or mitigate impacts.

The NOSB recommendation of April 29, 2011 includes the following: “This material was petitioned to the NOSB for use as a processing aid in the production of organic plant and vegetable oils, as a natural substance used to bring oils to a marketable condition through removal of impurities such as undesirable odors, colors, and trace metals, etc. The Handling Committee voted 6 yes, 0 no, and 1 absent for the listing of this material, with the annotation “allowed as a processing aid in the handling of plant and animal oils”, to the National List, thereby recommending that it be listed. The full board voted that attapulgit be classified as non-synthetic and approved listing it with the annotation above at its April 2011 meeting.

This material satisfies the OFPA evaluation criteria.

Public comment strongly supports continued listing of this material.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Attapulgit from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Tom Chapman

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Bentonite**

**Reference:** 205.605(a)

**Technical Report:** 1995 Kaolin Clay and Bentonite

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)),

**Sunset Date:** 06/27/17

### **Subcommittee Review**

Both bentonite and kaolin are mined by open pit mining and are thus subject to environmental mitigation and monitoring by other agencies.

The subcommittee sought public comment to specifically address the ongoing need for bentonite and

kaolin and received clear indication from a range of stakeholders that it continues to be necessary. There was no public comment in opposition.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Bentonite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Lisa de Lima

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Calcium carbonate**

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### **Subcommittee Review**

Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner and to remove acidity in wines.

Public comment indicated broad support for continued listing of this material and there was no opposition to continued listing.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None Given

### **Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Tom Chapman

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

## Calcium chloride

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

**Specific Use:** Used in a wide variety of food processing applications, including as a meat tenderizer and flavor enhancer.

**Summary:** Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic. However, Dow (the major supplier) and other producers use synthetic chemicals during the purification of the brine.

In the Dow process, which accounts for 75% of the calcium chloride production in the U.S. (Kemp and Keegan, 1985). The starting material is a natural brine solution that is pumped out from underground salt beds. Synthetic materials are used in the purification process, but without changing the chemical structure of the material.

There was very little public comment on this material. One group did urge the NOSB to continue with the listing.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production

### Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

## Dairy cultures

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP; [2014 TR for Ancillary Substances](#)

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

**Use:** Dairy cultures are used by organic dairy processors to make yogurt, cheese, cultured sour cream and other fermented milk products.

**Manufacture:** There are a variety of ways a dairy culture can be produced but generally a dairy or other medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produces different flavor compounds and in turn produced different traditional dairy products.

**International:** Dairy Cultures and or Microorganisms are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex organic standards.

**Ancillary Substances:** Ancillary substances are present and will be addressed in a separate review.

There is no current TR however there is a TAP from the original 1995 listing and there was a 2014 TR for microorganisms, a related listing. There is no original petition on file. The 2014 TR for microorganisms should be sufficient for a review of ancillary substances in dairy cultures.

**Discussion:** The NOSB requested information related to (1) the need of a separate listing given dairy cultures being covered by the broader listing of microorganisms, and (2) on ancillary substances present. Comments were received from trade associations, industry, certifiers and a technical organizations. All comments were generally in favor of continued allowance of dairy cultures. Most industry, while agreeing the dairy cultures were covered under microorganisms still wanted a separate listing for dairy cultures. One commenter wanted to wait till the ancillary substance trial period with microorganisms was complete to make the change. Several certifiers and a technical organization agreed that the listing of dairy cultures was redundant to microorganisms and could be removed. Several ancillary substances were submitted from the public.

While the NOSB Handling Subcommittee notes the separate listing for dairy cultures is redundant with the microorganisms listing, the subcommittee found no issue with continued listing. The substance satisfies OFPA criteria.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Dairy Cultures from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

## Diatomaceous earth

**Reference:** 205.605(a) - food filtering aid only

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

**Subcommittee Review**

NOSB Sunset Review November 2005, Re-listed. NOSB Sunset Review April 2010, re-listed.

Diatomaceous earth is used as a filter aid in production of syrups and other products. Diatomaceous earth is not in the final organic product.

The TAP was a 3 person panel. One reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify “food grade” quality of DE. DE is also used in swimming pool filters which is not a food grade form. All DE is removed during filtering of water, vegetable oils, sugars, syrups, honey, beer etc. DE is fossilized remains of diatoms in marine sediments. As with bentonite, attapulgite and kaolin, human health can be impacted if excessive amounts are breathed into lungs over an extended period of time.

Diatomaceous earth satisfies the OFPA criteria

Public comment indicates a widespread use of Diatomaceous earth as a filter aid.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Diatomaceous earth from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Enzymes

**Reference:** 205.605(a) - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

**Technical Report:** 1995 TAP; 1996 TAP; 2011 TR; [2014 TR for Ancillary Substances](#)

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset [recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

**Use:** Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring 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 (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-148)

**Manufacture:** Microbial rennet describes a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic agriculture.

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)

**International:** The use of enzymes is permitted in organic processing in Canada, EU, IFOAM and in CODEX.

**Ancillary substances:** Explained in the Enzymes Technical Evaluation Report – Limited Scope, (NOP 2015):

“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.

Discussion: At the first posting for Enzymes the NOSB asked the public to provide input on a chart of existing ancillary substances and to identify additional ancillary substances that may be used in the formulations of enzymes. The following additional ancillary substances were identified through public comment.

An additional ancillary substance proposal will be reviewed at a later date.

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.

**Discussion:** 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.

Evaluation question #9 in the 2011 TR does 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.

Evaluation question #10 in the 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals (Tucker and Woods, 1995). FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (FDA, 1995). (TR 2011 752-758).

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Enzymes remain on the National List.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Enzymes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### **Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Jean Richardson

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

## **Flavors**

**Reference:** 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

**Technical Report:** 2005 TR

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### **Subcommittee Review**

**Use:** Natural flavors are derived from natural sources and are compound substances derived from plants, herbs, spices, botanicals and other substances. They are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product.<sup>1</sup> The significant function of flavors must be to impart flavor and not nutritional. The FDA defines Natural Flavors in 21 CFR 101.22 as:

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis,

<sup>1</sup><http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf><sup>2</sup><http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in 172.510 of this chapter.

**Manufacture:** Flavors can be derived via several different methods. Distillates are a clear, flavorful liquid produced from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture. Essential oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing. Essential oil isolate is an isolate of an essential oil. Isolates are a chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass. Oleoresin are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. Single flavor chemicals are single molecules that provide flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A Compounded Flavor is a mixture of ingredients such as extracts, essential oils and natural isolates.<sup>2</sup> Processed flavors, also known as reaction flavors, are ones which are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins and fat, which must then be heated for a length of time to yield the desired profile.<sup>3</sup>

Flavoring components as listed here can typically make up 5-100% of the formulation of a flavor. The remaining components can be carriers, preservatives and/or solvents that also act as carriers that can make up 0-95% of a flavor and non-flavor constituents to stabilize or maintain the flavor. Nonsynthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" or containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non flavoring constituents from the named product but still impart the characteristic named flavor.

**International:** Natural/Nonsynthetic Flavors are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex Standards.

<sup>2</sup><http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

<sup>3</sup> [http://www.fona.com/sites/default/files/WhitePaper\\_DevelopmentResources.pdf](http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf)

**Ancillary Substances:** Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: “must not be produced using synthetic solvents and carrier systems or any artificial preservative.” Flavoring constituents (i.e., ingredients that impart the flavor) are considered proprietary by flavoring companies and are not normally disclosed. No specific ancillary substances were submitted as part of public comment.

**Use of organic Flavors since the 2010 Sunset Review:** The NOSB completed Sunset Review of Flavors for re-listing and on September 3, 2010 and stated:

The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors...The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was practical to individually list flavors on the National List, so chose to relist the category as a single listing...In order to avoid unnecessary disruption to industry, we are recommending relisting of Flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011 the NOP issued a Policy Memorandum on Use of Natural Flavors

This states in part:

In 1995 the NOSB reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals....The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this organic market will continue to grow and develop...

On November 6th 2014, the NOP received a petition from the Organic Trade Association to change the Flavor annotation to read:

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative

A separate proposal relating to this petition will be considered at the Fall 2015 NOSB meeting.

**Discussion:** The NOSB requested additional information relating to supply of organic flavors, commercial availability, continued listing, essentiality, standardized compliance document, and Ancillary substances. A large volume of comments were received from Industry, trade associations and ACAs supporting the continued listing of natural flavors. Several ACA’s stated a standardized compliance document for flavors would be helpful. One interest group and one ACA noted that flavors could be certified organic but contain no organic flavoring constituents if the other ingredients (i.e., carriers) were organic and made up over 95% of the formulation. One interest group stated flavors should not be added to the National List if their primary function is flavoring and cited 205.600(b)(4), however 205.600(b)(4) is not germane to the flavor listing as it only applies to processing aids and adjuvants. The

HS will address the 2010 NOSB recommendations in the proposal accompanying the November 2014 petition to change the natural flavor annotation.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. The Handling Subcommittee recommends the renewal of flavors on the national list.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Flavors from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### **Vote in Subcommittee**

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

## **Kaolin**

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### **Subcommittee Review**

Bentonite and kaolin are both mined by open pit mining and thus, as with attapulgite, adverse environmental impacts are possible.

The subcommittee sought public comment to specifically address the ongoing need for Bentonite and kaolin and received clear indication from a range of stakeholders that it continues to be necessary.

There was no public comment in opposition

This material satisfies the OFPA criteria.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Kaolin from the National List based on the following criteria in

the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Magnesium sulfate

**Reference:** 205.605(a) - nonsynthetic sources only.

**Technical Report:**1995 TAP (Processing); 2011 TR

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Magnesium sulfate is used as a dietary supplement and to enhance flavor in production of tofu.

Public comment indicated that this material is used by a number of processors, and there was no opposition to continued listing

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None Given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Nitrogen

**Reference:** 205.605(a) - oil-free grades.

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Nitrogen is colorless, odorless gas. Cryogenic distillation is the most economic and high purity method for separating nitrogen from air. Basically air is compressed, cooled, and then filtered.

It is used to displace oxygen and thereby reduce oxidation of product during processing, storage and packaging. Can be used in the flash freezing of foods. Also functions as a propellant when used under pressure and doesn't have ozone-depleting properties.

There has been no public comment opposed to the relisting of nitrogen. Public comment in support of relisting was submitted by a number of food processors, ingredient suppliers, and associations.

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Nitrogen remain on the National List.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Nitrogen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### Vote in Subcommittee

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Oxygen

**Reference:** 205.605(a) - oil-free grades.

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

**Subcommittee Review**

Oxygen is colorless, odorless gas. Used in the processing of olives and modified atmosphere packaging.

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Oxygen remain on the National List.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Oxygen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Perlite

**Reference:** 205.605(a) -for use only as a filter aid in food processing.

**Technical Report:** 1996 TAP

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

**Past NOSB Actions:** NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

**Subcommittee Review**

NOSB Sunset Recommendation November 2005 to re-list. NOSB Sunset Review April 2010 re-listed. No issues raised in public comment.

Perlite is amorphous volcanic glass. It is an excellent filter aid and often substitutes for DE in filtering beer.

The subcommittee received clear indication from a range of stakeholders that perlite continues to be necessary. There was no public comment in opposition

This material satisfies the OFPA criteria.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Perlite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None Given

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Potassium chloride

**Reference:** (a) Nonsynthetics allowed:

**Technical Report:** 1995 TAP; 2015 TR\_

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

**Subcommittee Review**

Potassium chloride is a common, naturally occurring mineral. According to the Food & Drug Administration, generally recognized as safe (GRAS) affirmed uses of potassium chloride in foods are as: a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. However, potassium chloride is generally used for two main purposes in food products. The first is to provide potassium enrichment to foods. The second is as a salt replacer to reduce the sodium content in foods.

There was very little public comment on this material. One group did urge the NOSB to restrict supplemental vitamins and minerals to only those required by law. Another commenter urges the board to continue with the listing of this material.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production.

**Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Harold Austin

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

## Potassium iodide

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP; 2011 TR; 2015 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Potassium iodide and ethylenediamine dihydroiodide are commonly used as synthetic forms of iodine in trace mineral supplements. Potassium iodide is the most commercially significant iodide compound. It is produced industrially by treating potassium hydroxide with iodine. Iodine is essential in healthy thyroid hormonal function, governing key enzymes involved in metabolic processes.

According to FDA, potassium iodide may be used as food additive and can serve 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.

There was very little public comment on this material. One group urged the NOSB to restrict supplemental vitamins and minerals to those required by law. Another group urged the board to continue the listing for this material.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium iodide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Consistent with organic production.

### Vote in Subcommittee

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

## Sodium bicarbonate

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Sodium carbonates are used as raising (leavening) agents in food processing. Sodium bicarbonate (baking soda) is a common compound in baking powder; helps to regulate acidity for things like tomato soup, or in pastes and beverages. It can be used as an anti-caking agent or as a stabilizer helping to maintain the appearance and consistency of foods. Sodium bicarbonate is often used in pancakes, biscuits, muffins, crackers, and in cookies. It often is used in self-rising flour and confections. It may also be used as a neutralizer for use in butter, cream, and ice cream.

Sodium bicarbonate (baking soda) – its main source is from natural deposits of trona ore. It can also come from natural brine found in Searles Lake, California. Trona ore (sodium sesquicarbonate) is heated and then mixed with water to dissolve the soda ash and separate out the impurities. Then it is allowed to evaporate to crystallization. Carbon dioxide is added to the kiln gas to a saturated pure sodium carbonate solution, the sodium bicarbonate then precipitates out.

Sodium bicarbonate is approved for use in the following organic standards: European Union, IFOAM, Canada, Japan, and Codex.

**Discussion:** The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their previous two Sunset Reviews. There was more information in the original TAP for this material than for sodium carbonate. The original TAP, previous subcommittee reviews, public comments, historical information, and current review found no environmental concerns, and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two Sunset Reviews. The current Sunset Review and public comments (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling. The original TAP did mention that the primary source material (sodium sesquicarbonate) is from a mined source.

During the 1st public comment period there were several comments in support of its continued listing on the National List. One organic stakeholder survey showed several responses stating that it is a primary component of baking powder and is still used widely in a variety of baked goods. Several organic handlers commented that it is essential as a leavening agent.

The subcommittee would see no reason to delist this material at this time.

**Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sodium bicarbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

**Vote in Subcommittee**

Motion by: Harold Austin

Seconded by: Tracy Favre

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

## Sodium carbonate

**Reference:** 205.605(a)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

**Subcommittee Review**

Sodium carbonates are used as raising (leavening) agents. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a stabilizer. It is essential for the characteristic color in the baking of German pretzels and lye rolls. Sodium carbonate is the material used that gives the pretzels and lye rolls their brown crust without burning. It is also used in the making of ramen noodles. It can also be used as a neutralizer for butter, cream, fluid milk, and ice cream. Other uses of sodium carbonate include in the processing of olives prior to canning and in many cocoa products.

Sodium carbonate is produced in North America from natural deposits of trona ore (90% sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then allowed to evaporate to form sodium carbonate monohydrate crystals. This is considered to be the most sustainable form of producing sodium carbonate. Also, in California the two sodium carbonate materials can be produced from similar methods using natural brine (Searles Lake). There are other methods used, but they are considered to be less environmental friendly. This is a sodium salt.

Sodium carbonate is approved for use in the following organic standards: the European Union, Japan, Canada, IFOAM, and Codex.

**Discussion:** The original TAP combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their

previous two Sunset Reviews. There was more information originally provided for sodium bicarbonate than for sodium carbonate. The original TAP, previous subcommittee reviews, public comments, historical information, and current review found no environmental concerns, and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two Sunset Reviews. The current Sunset Review and public comments (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling.

During the 1st public comment period it was mentioned that this is essential for use in organic starches. Also mentioned that when used with alginates it helps to sequester calcium, also help alginates in gelling and is found naturally in the environment. Over-all public comment supported the relisting of this material. There were no comments against relisting.

The subcommittee would see no reason to delist this material at this time.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Sodium Carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

### **Vote in Subcommittee**

Motion by: Harold Austin

Seconded by: Ashley Swaffar

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

## **Waxes (Carnauba)**

**Reference:** 205.605(a) Waxes – nonsynthetic (Carnauba wax; and Wood resin).

**Technical Report:** 1996 TAP; 2014 TR - Carnauba Wax

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

**Past NOSB Actions:** NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### **Subcommittee Review**

Carnauba wax is an exudate from the leaves and buds of the palm tree *Copernicia cerifera*, also known as *Copernicia prunifera*, which grows almost exclusively in northeastern Brazil. It is used to coat fruit and vegetables, candies and as a base for chewing gum. It is touch and lustrous with a high melting point.

The main functions of this and other coatings is to retard transpiration and thus prevent water loss and to protect the plant from fungal attacks, thus postponing decay.

During the creation of the National List, Carnauba was included in the review of "Fruit Waxes" under the Crops Committee because it was considered a post-harvest handling substance. It was never classified as either agricultural or non-agricultural at that time. When the rule came out it was on the Handling section of the National List at 205.601(a).

A new Technical Report (TR) was commissioned to determine the classification, provide updated information since the very sketchy 1996 TAP, and to look at ancillary substances. This TR has led the Handling Subcommittee to conclude that this is an agricultural product and should be on 205.606. A separate proposal is being put forward for this purpose.

While there is some organic carnauba wax on the market, there was not a consensus from commenters that there is enough available to meet demand. Public comment indicated that carnauba is commonly used in conjunction with other waxes, other ingredients on the National List, and some possible ancillary substances in formulations of finished products. However raw carnauba is sold without any ancillary substances (2014 TR, Combinations of the Substance).

Public comment was primarily in favor of keeping carnauba and other coatings on the National List and no new information was provided about any of the OFPA criteria. For the specific question posed about re-classification of this to agricultural, no comment was received opposing this suggestion. In regard to the ancillary substance question, no ancillary substances were suggested for the raw carnauba, but concern was raised by public interest groups concerning a substance, morpholine, that may be used in formulated blends. Since there is ample availability of formulations that are fully NOP compliant for their ingredients according to the TR, this issue does not need further action.

One other point brought up frequently in public comment was the desire for labelling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labelled, but this is interpreted in a general way so that the label may only be on a shipping container not visible to consumers or on general signage in a store that does not specify which products are waxed. The Handling Subcommittee recognizes this issue and urges voluntary labelling of produce coatings, but is unable to put forward an additional labelling annotation.

### **Motion to Remove**

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Carnauba Wax from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Waxes (Wood rosin) (sic. Resin)

**Reference:** (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).

**Technical Report:** 1996 TAP; 2014 TR - Wood Rosin

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

**Past NOSB Actions:** NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

This listing is in need of a technical correction because the substance is wood rosin and not wood resin. As the 2014 Technical Report (TR) notes on lines 22-24, "Wood resin is the raw material exuded by coniferous trees before it undergoes distillation and refinement steps as described in this report". Wood Rosin is recognized in 7 CFR §160.12 and known by the CAS number 8050-09-7. The Subcommittee recommends that this Technical Correction be made.

The Technical Report (TR) for this substance provided considerable background on the combinations, uses and functions of Wood Rosin as a coating material. It appeared to satisfy the criteria from the rule as far as effect on human health and the environment.

In regard to the ancillary substance question, no ancillary substances were suggested for wood rosin by itself, but concern was raised by public interest groups concerning the substance morpholine that may be used in formulated blends. Since there is ample availability of formulations of other fruit coatings that are fully NOP compliant for ingredients according to the TR, this issue does not need further action.

One other point brought up frequently in public comment was the desire for labelling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labelled, but this is interpreted in a general way so that the label may only be on a shipping container not visible to consumers or on general signage in a store that does not specify which products are waxed. The Handling Subcommittee recognizes this issue and urges voluntary labelling of produce coatings, but is unable to put forward an additional labelling annotation.

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Waxes, Wood Rosin (sic resin) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

### Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Yeast

**Listing:** 205.605(a) - When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent 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); 2014 TR

**Petition(s):** 2006 Petition; 2010 Petition Supplement; 2010 Petition memo

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 2010 sunset [recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/17

### Subcommittee Review

Yeast underwent a significant review that led to a change in the listing in 2010. A new Technical Report (TR) was commissioned in 2014 to review the current status of various yeasts and look at the ancillary substances. Since there are many types of yeast and many uses for them, the NOSB at the first posting sought information about current availability of all forms of yeast.

All commenters recognized that yeast is an important substance on the National List, and no new information was submitted relevant to any of the OFPA criteria. Public comment from yeast users, suppliers, and certifiers indicated that there are some forms of yeast that are not yet available organically. These include torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. One supplier suggested that dry yeast could be removed from the list while others forms stayed.

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. One new ancillary substance was suggested for addition to the chart presented with the first posting: starch. One substance on the chart, BHT, was questioned as problematic for exposure. No specific answers were provided for the first posting question #3. "Information is sought on specifically why any of the ancillary substances in yeast do not meet the review criteria in the organic rule."

### Motion to Remove

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Yeast from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### Vote in Subcommittee

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

**Sunset 2017 Review  
Meeting 2 - Review  
Handling Substances §205.605(b)  
October 2015**

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

**Reference: 7 CFR 205.605** *Nonagricultural* (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

**§205.605(b) Synthetics allowed:**

[Acidified sodium chlorite](#)

[Alginates](#)

[Ammonium bicarbonate](#)

[Ammonium carbonate](#)

[Ascorbic acid](#)

[Calcium citrate](#)

[Calcium hydroxide](#)

[Calcium phosphates: monobasic, dibasic, tribasic](#)

[Carbon dioxide](#)

[Chlorine Materials: calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Ethylene](#)

[Ferrous sulfate](#)

[Glycerides: mono and di](#)

[Glycerin](#)

[Hydrogen peroxide](#)

[Magnesium carbonate](#)

[Magnesium chloride](#)

[Magnesium stearate](#)

[Nutrient vitamins and minerals](#)

[Ozone](#)

[Phosphoric acid](#)

[Potassium acid tartrate](#)

[Potassium carbonate](#)

[Potassium citrate](#)

[Potassium phosphate](#)

[Sodium citrate](#)

[Sodium hydroxide](#)

[Sodium phosphates](#)

[Sulfur dioxide](#)

[Tocopherols](#)

[Xanthan gum](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

## Acidified sodium chlorite

**Reference:** 205.605(b) - Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

**Technical Report:** 2008 TAP

**Petition(s):** 2006 Sodium Chlorite, Acidified

**Past NOSB Actions:** 2009 NOSB recommendation

**Recent Regulatory Background:** Added to NL effective 03/15/2012 ([77 FR 8089](#))

**Sunset Date:** 03/15/17

### Subcommittee Review

**Specific Uses of the Substance:** ASC solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation for using on direct food contact and indirect food contact:

- Direct Food Contact (Secondary Direct Food Additive) – Poultry carcass, organs and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted or formed meat products; and
- Indirect Direct Food Contact – Hard surface food contact sanitation.

**Manufacture:** In the petition, it states that ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. Sodium chlorite (25%) and citric acid (50%) solutions are stored separately in bulk on site. Both solutions are pumped by proportional pumps and a water dilution module to make the final use dilution product, which typically contains 0.1% sodium chlorite and 0.6% citric acid and 99.3% water. Sodium chlorite is made by the reduction of chlorine dioxide, which is, in turn, from the reduction of sodium chlorate in the presence of sulfuric and hydrogen peroxide or sulfuric acid and sodium chloride. The resulting solution may be dried to a solid and the sodium chlorite content may be adjusted to about 80% by the addition of sodium chloride, sodium sulfate, or sodium carbonate. Sodium chlorite is marketed as a solid or an aqueous solution (such as 25% by weight).

The acid used to acidify sodium chlorite is natural citric acid, which is stated in the petition. However, there is no information in the petition regarding how the natural citric acid was manufactured.

**Discussion:** The NOSB in its initial request for public comment asked:

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of acidified sodium chlorite to provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

Public comment did not provide any alternatives. Several handlers wrote in and stated that this product is essential for use in their OSP.

This material satisfies the OFPA Evaluation criteria.

### Motion to Remove

This proposal to remove acidified sodium chlorite will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Acidified Sodium Chlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

### Vote in Subcommittee

Motion by: Ashley Swaffar

Seconded by: Tom Chapman

Yes: No: 4 Abstain: 0 Absent: 3 Recuse: 0

## Alginates

**Reference:** 205.605(b) Synthetics allowed

**Technical Report:** 1995 TAP

**Petition(s):** 1995 Alginates

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Alginates are polysaccharides derived from brown seaweeds. The use of the alkalizing agent used to produce alginates renders them synthetic. Alginates are derivatives of alginic acid.

Alginates occur naturally in seaweed mainly in the form of sodium, potassium, calcium and magnesium salts of alginic acid (2015 Technical Review, Saltmarsh, Barlow, & eds., 2013). "Extraction involves ion exchange in an alkaline medium followed by precipitation, purification, recovery of alginic acid and conversion to the appropriate salt" (2015 Technical Review, Saltmarsh, Barlow, & eds., 2013).

Alginates are unique in that they form gels or act as coatings or thickeners without requiring heating, thereby making them ideal for applications where the food is sensitive to temperatures. Alginate materials are considered GRAS and have been used for over 50 years. Alternative materials include carrageenan, modified cellulose and some gums.

The Handling Subcommittee had brought forth the following questions for public comment:

1. Please bring forth any information regarding the effect of alginic acid and/or alginates on human digestion.
2. Is alginic acid in use in organic handling and should it have its own National List listing? What are the non-synthetic alternatives in specific handling uses?

Public comment was mixed regarding the relisting of alginates. Those in favor of its relisting note the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting, and assert that the properties imparted by alginates are essential for some processed food formulations. Those opposed expressed concerns regarding the concentration of heavy metals in the wild harvested seaweed and the fact that alginates are used primarily to enhance texture in foods, and

therefore not compatible with OFPA criteria.

The Handling Subcommittee proposes that alginates remain on the National List.

### **Motion to Remove**

This proposal to remove Alginates will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Alginates from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### **Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

## **Ammonium bicarbonate**

**Reference:** 205.605(b) - for use only as a leavening agent

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### **Subcommittee Review**

Ammonium carbonates are used as leavening agents. Ammonium bicarbonate has critical functionality as a raising (leavening) agent in certain cookies and crackers. Compared to Baking Soda it produces more gas, thus not leaving behind a salty or soapy taste in the finished baked goods, as it completely decomposes into water and gaseous products that evaporate during the baking process. It is used in baking where yeast is not used. Ammonium bicarbonate cannot be used for moist baked goods. It also helps provide certain characteristic textures (such as in crackers), as well as aids in controlling cookie spread.

This is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process. There are no organic alternatives to replace ammonium bicarbonate.

The ammonium carbonates are made from ammonia and carbon dioxide. Ammonium bicarbonate is made when carbon dioxide is bubbled through an ammonia solution. Crystals of ammonium bicarbonate precipitate from this saturated solution.

Ammonium carbonates are approved for use in the following organic standards: the European Union, Canada, Australia, New Zealand, Japan, IFOAM, and Codex. They are considered GRAS by the FDA.

**Discussion:** The original TAP combined the two ammonium carbonates (ammonium carbonate and

ammonium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their previous two Sunset Reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review found no environmental concerns and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two Sunset Reviews. The current Sunset Review and public comment periods (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling.

During the 1st public comment period of the current review cycle a responses to a stakeholder survey mentioned that this material was still critical for Handlers, especially for baking crackers and similar baked goods. Other commenters supported its continued allowance on the National List. There were no comments against its relisting.

The subcommittee would see no reason to delist this material at this time.

### **Motion to Remove**

This proposal to remove ammonium bicarbonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ammonium bicarbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### **Vote in Subcommittee**

Motion by: Harold Austin

Seconded by: Ashley Swaffar

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

## **Ammonium carbonate**

**Reference:** 205.605(b) –for use only as a leavening agent

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### **Subcommittee Review**

Ammonium carbonates are used as leavening agents. Ammonium carbonate is used as a raising (leavening) agent for flat baked goods, such as cookies and crackers. It is often referred to as “*Bakers Ammonia*” in cooking recipes and by chefs. Ammonium carbonate is also used to make breadsticks, cookies, and crackers because it helps to make them both lighter and crispier. It is also used in many traditional Greek cooking recipes. The ammonium carbonates are heat activated, so baked goods will

not rise until whatever is being baked actually goes into the oven, thus helping with food preparation and time requirements. This is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process. There are no organic alternatives to replace the ammonium carbonates.

The ammonium carbonates are made from ammonia and carbon dioxide. Ammonium carbonate is made when carbon dioxide is passed through an ammonia solution and by then allowing the vapors to distill, thus the resulting solid is ammonium carbonate.

Ammonium carbonates are approved for use in the following organic standards: the European Union, Canada, Australia, New Zealand, IFOAM, and Codex. They are considered GRAS by the FDA.

**Discussion:** The original TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. Subsequently they have been looked at together during their previous two Sunset Reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review found no environmental concerns and none have been brought to the subcommittee's attention during this current review. Likewise, there were no human health concerns raised during the original TAP review or during the following two reviews. The current Sunset Review and public comment periods (oral and written) also have not raised any environmental, human health concerns, or any other reason why this material should not continue to be allowed for organic handling.

During the 1<sup>st</sup> public comment period of this review cycle there were no specific comments either to relist or delist this material. Comments in support/or otherwise, of this material during the upcoming 2<sup>nd</sup> and final comment period would be useful in determining the final full board vote on this material.

The subcommittee would see no reason to delist this material at this time.

### **Motion to Remove**

This proposal to remove ammonium carbonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ammonium carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### **Vote in Subcommittee**

Motion by: Harold Austin

Seconded by: Ashley Swaffar

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

## **Ascorbic acid**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

#### **Subcommittee Review**

**Specific Use:** Dietary supplement and nutrient, flavor ingredient, used in 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. Ascorbic acid is one of the most common sources of Vitamin C.

**Discussion:** Ascorbic acid is a vital nutrient necessary for humans and other primates. It is added to many foods to restore Vitamin C lost during the processing. Some FDA regulations require Vitamin C fortification, which is often achieved with Ascorbic acid. It is manufactured using a culture process from dextrose.

Public comment for ascorbic acid was divided, with some comments remarking that ascorbic acid is being used as a preservative and therefore not consistent with organic agriculture. However, the majority of comments strongly supported relisting of ascorbic acid, stating the ingredient to be critically essential to maintaining nutrients and freshness in their products.

The HS is supportive of relisting ascorbic acid.

#### **Motion to Remove**

This proposal to remove ascorbic acid will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ascorbic acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

#### **Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

## Calcium citrate

**Reference:** 205.605(b)

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

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

#### **Subcommittee Review**

**Specific Uses of the Substance:** Calcium citrate provides calcium in nutritive supplements, and it can also be used as a water softener due to its chelation properties. It is used to wash processing equipment in order to eliminate off flavors, and as a pH adjuster and chelator in cleaning and sanitizing products. It is also used for its chelating properties to remove scale from boilers, evaporators and other processing

equipment. Calcium citrate is widely used in cosmetic and personal care products for many of these same functions.

**Approved Legal Uses of the Substance:** Citric acid is listed under 21 CFR Part 184.1195 as Generally Recognized as Safe (GRAS). It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate. It is permitted in food with no limitations other than current good manufacturing practice. It is also permitted by FDA in infant formula.

The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inert).

**International:** The citrate salts are generally listed as allowed, but with restrictions associated with their usage. Calcium citrate is not listed in the CODEX and JAS organic standards.

**Discussion:** The NOSB in its initial request for public comment did not ask for any specific information from stakeholders.

Several commenters in favor of relisting stated:

- Acts as a buffering agent and sequester. Also, it imparts some flavor to the product. Sourced through fermentation of the citric acid process and part of a naturally sources process.
- One certifier state that some clients use calcium citrate.

While there were not specific questions asked of the public, the subcommittee did receive very few specific comments about calcium citrate. If a handler uses this material and feels it is important to keep on the list the Handling Subcommittee would like to receive comments from users specifically on the use of calcium citrate and why it is essential to keep on the National List.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of calcium citrate.

### **Motion to Remove**

This proposal to remove calcium citrate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of calcium citrate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

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

## **Calcium hydroxide**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

sunset recommendation

**Recent Regulatory Background** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Calcium hydroxide is also known as slaked lime, which is quick lime, calcium oxide mixed with water.

**Uses:** Calcium hydroxide may be used as a component of aluminum free baking powder; it also clarifies sugar for molasses, and conditions corn for tortillas.

Although the original TAP (1995) suggest that calcium hydroxide may reduce the nutritional value of food, no health issues have been raised in public comment. No alternatives have been identified.

Public Comment indicated broad support for continued listing of this material and no opposition.

### Motion to Remove

This proposal to remove calcium hydroxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium Hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

## Calcium phosphates (monobasic, dibasic, and tribasic)

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

The original TAP looked at the calcium phosphates (monobasic, dibasic, and tribasic) and found them to be synthetic by nature. The calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminum free). All three of the calcium phosphates are used as leavening agents: dough conditioner, yeast food, or as an expanding agent. Monobasic and dibasic

calcium phosphate are often used for reduced sodium baking.

Monobasic is also a buffer, firming agent, sequestering agent, and is popular in pancake mixes (usually used in combination with sodium bicarbonate). It is also used in baked goods, such as cookies, cakes, and potato chips, and as a firming agent for canned fruits and vegetables.

Dibasic is used in enriched flour, noodle products, and in both dry and cooked forms of breakfast cereals. It is often used as a dough conditioner. It also can be used as a thickening agent for various cheese products.

Tribasic is an anti-caking agent, buffering agent. It also provides a very critical function as a free flow aid in finely powdered salt, used in baking. It is also used as a food source for yeast in bread making. It is used as an anti-caking agent in dry powders, such as in spices. Another use is as a thickener, stabilizer and as a sequestering agent for some dairy products.

Calcium is derived from either mined limestone or from oyster shells. The phosphorus is derived from mined phosphates. Calcium hydroxide is neutralized with phosphoric acid to create calcium phosphate.

**Discussion:** The original TAP combined the three calcium phosphates (monobasic, dibasic, and tribasic) for their preliminary review. Subsequently they have been looked at together during their previous two Sunset Reviews and the Reaffirmation vote (2010). They were found to be synthetic. The original TAP and the previous two Sunset Reviews all found the calcium phosphates to be of little concern to the environment, human health, of low toxicity, and of low environmental contamination concern during manufacture. (One reviewer did make mention that the raw materials do come from mining).

During the 1st posting, under the current review cycle, the Subcommittee asked if there were any changes in the source of the raw materials that make up the three calcium phosphate materials: there were no changes noted.

Also during the 1st posting under the current review cycle, there were 11 written public comments. Numerous comments were in support of the continued listing, including several organic handlers and one certifier stating it was used by several (60) handlers that they certify. Responses to an industry sponsored survey showed that it is used in baking powder, does not have an organic substitute and is essential in organic baked goods when yeast is not used in the baking process. This material had strong support for its continued listing, from those that currently use this material in their organic handling process.

There was a concern raised by a few members of the public regarding the cumulative effect on human health, with the use of the inorganic forms of phosphates as a whole, caused by an overall increase in usage. This concern would include the calcium phosphates as one of several materials mentioned. These public comments recommended either removal or annotations be added (which cannot be done during the sunset review process).

There are five phosphates (however, TSPP was voted for removal at the Spring NOSB meeting in La Jolla) on the National List at §205.605(b). 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. Given the new information and research since the last Sunset Review, the Handling Subcommittee has requested a new Technical Report. This should help clarify the probability of negative human health effects resulting from the cumulative effect of phosphates in food

products at various dose levels over time on the population as a whole, and alternative materials. Given that this Technical Review may not be received in time for the Fall 2015 meeting, the Handling Subcommittee recommends voting on this material at the Fall meeting, but, should the TR indicate probable cumulative negative health effects from phosphates, the Handling Subcommittee would make a new proposal to review all phosphates again at the Spring 2016 meeting.

### **Motion to Remove**

This proposal to remove calcium phosphates (monobasic, dibasic, and tribasic) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Calcium Phosphates (monobasic, dibasic, and tribasic) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Possible effect of the substance on human health.

### **Vote in Subcommittee**

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 1 Absent: 0 Recuse: 0

## **Carbon dioxide**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP; 2006 TAP

**Petition(s):** 2007 Carbon Dioxide

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 2007 NOSB Committee recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### **Subcommittee Review**

Carbon dioxide is used in modified atmosphere packaging, modified atmospheric storage, the freezing of foods, beverage carbonation, as an extracting agent, and for pest control in grain and produce storage.

It is available in limited supplies from underground wells and as a byproduct of various manufacturing processes. All of the processes require purification of the carbon dioxide before being used in the food processing and handling.

This material satisfies the OFPA evaluation criteria.

There has been no public comment opposed to the relisting of carbon dioxide. Public comment in support of relisting was submitted by a number of food processors and associations.

The Handling Subcommittee proposes that carbon dioxide remain on the National List.

**Motion to Remove**

This proposal to remove carbon dioxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Carbon Dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Chlorine materials

**Reference:** 205.605(b) Chlorine materials- —disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

**Technical Report:** 2006 TR - Handling

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

**Specific Uses of the Substance:** Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals. These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies. It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses.

**Approved Legal Uses of the Substance:** With regard to organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. In addition, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from all of these approved uses may not

exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L or 4ppm).

**Discussion:** The NOSB in its initial request for public comment asked:

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of chlorine materials to provide detailed comments describing the situations in which they are the most appropriate or effective antimicrobial for a given application.

Several commenters opposed to the relisting stated:

- They are concerned about the NOP guidance on the use of chlorine, which allows for a higher concentration than allowed in the Safe Water Drinking Act to be used in wash tanks. They were especially concerned about organic food products that could absorb the higher concentration of chlorine into the food. They stated that poultry, eggs, leafy vegetables, root crops and more could absorb highly chlorinated water and the final effluent after the wash tank could still only contain the required 4 PPM. To address this concern, they suggested the annotation for chlorine be amended to the following: Chlorine materials, only as present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
- Another commenter stated that the use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the wash water.
- Several commenters in support of relisting stated:
- Essential materials required for food safety. To the best of our knowledge, our partners in dairy production as well as our member farms choose chlorine materials as the preferred sanitizer for food contact surfaces. Disallowing sodium hypochlorite, calcium hypochlorite and chlorine dioxide would have a profound effect on the dairy industry. Please keep Chlorine Materials on the National List.
- Chlorine materials are vital sanitizing agents that are used to sanitize food contact surfaces such as equipment and utensils. Chlorine is desirable because it is effective and because it evaporates and leaves little residue. The majority of our organic manufacturing facilities rely on chlorine to prevent the growth of pathogenic microorganisms. We request that chlorine materials remain on the list of substances that are allowed in organic handling.

While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation. There are also specific requirements to use chlorine above the 4ppm SDWA limit in several commodity specific industries. For example, as stated in 9 CFR 590.516 Sanitizing and drying of shell eggs prior to breaking: “Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent.”

Over the past year Electrolyzed Water and hypochlorous acid have been discussed by the program and many stakeholders in the organic community. The Handling Subcommittee feels that Electrolyzed water and hypochlorous acid should be allowed under the current listing for chlorine materials on the National List. Electrolyzed water devices generate active ingredients that are equivalent to other chlorine materials on the National List. The Handling Subcommittee believes the national list could be clarified in

this matter and is reviewing a petition to explicitly add hypochlorous acid to the national list.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of Chlorine Materials.

### **Motion to Remove**

This proposal to remove Chlorine materials will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Chlorine materials from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Ethylene**

**Reference:** 205.605(b) allowed for postharvest ripening of tropical fruit and degreening of citrus.

**Technical Report:** 1995 TAP; 1999 TAP - Processing

**Petition(s):** 1995 N/A, 2008 Ethylene (for use with pears)

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote (add tropical fruit and citrus); 11/2005 sunset recommendation; 11/2008 recommendation for pears; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### **Subcommittee Review**

Ethylene is a flammable gas made from natural gas or crude oil. It's a synthetic analog of a natural gas produced by plants. It is used in the post-harvest ripening of tropical fruit and the degreening of citrus.

The subcommittee brought forth the following question for public comment:

1. The subcommittee is considering editing the annotation and removing its allowed use for the de-greening of citrus. If you use this material for the de-greening of citrus please let us know why you need to use it, and what the impact on your operation would be if it was removed from the List.

There has been no public comment opposed to the relisting of Ethylene. All public comment submitted has been in favor of relisting without an annotation change. One organization stated that "...without ethylene, organic tropical fruit would not be readily found in produce aisles." One certifier noted they have six members currently using it for the degreening of citrus.

This material satisfies the OFPA evaluation criteria.

The Handling Subcommittee proposes that Ethylene remain on the National List.

**Motion to Remove**

This proposal to remove ethylene will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ethylene from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Ferrous sulfate

**Reference:** 205.605(b) - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

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

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

Ferrous sulfate provides the iron needed by the body to produce red blood cells. It is used to treat or prevent iron-deficiency anemia, a condition that occurs when the body has too few red blood cells because of pregnancy, poor diet, excess bleeding, or other medical problems.

Public comment was divided, with some supporting ferrous sulfate remaining on the list, while others spoke to the fact that ferrous sulfate should only be used in products that by law require fortification.

**Motion to Remove**

This proposal to remove ferrous sulfate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ferrous sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

**Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

## Glycerides (mono and di)

**Reference:** 205.605(b) for use only in drum drying of food.

**Technical Report:** 1995 TAP; 2015 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources (FDA 2014). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut or palm oil (Frank 2014), and their main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils. (TR 2015 56-62).

Mono- and diglycerides are manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The process is called transesterification. Organic solvents may be used in manufacture of glycerides. The products are purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90 percent-by-weight glycerides.

Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life (Frank 2014).

However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals (Fusaro 2012). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (O'Brien 2004).

The direct-food uses for mono- and diglycerides under the FDA GRAS listing at 21 CFR 184.1505 include use as an emulsifier, dough strengthener, flavoring agent, adjuvant, lubricant, release agent, solvent, vehicle, thickener, active surface-agent and texturizer.

**History:** Mono- and diglycerides were first added to the National List in 2002 after being recommended

by the NOSB at the April 1995 NOSB Meeting. Discussion at that meeting noted that the food industry was trying to move away from their use, but that the material was still necessary for potato flake products. Thus, the NOSB voted to recommend restricting its use to drum roll drying of food. The substance was reassessed during the Sunset review process in 2010 and the NOSB voted unanimously to recommend relisting it on §205.605(b). At that time, the NOSB did not find any evidence suggesting that proposed organic alternatives were favorable replacements. In their review of original recommendations, historical documents and public comments, the NOSB did not identify any unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of the substance. The 2015 TR does not identify unacceptable human health or environmental risks.

**International:** Glycerides (mono and diglycerides) are permitted on the Canada Permitted Substances List, CAN/CGSB- 200 32.311 Table 6.3 “Non-organic Ingredients Classified as Food Additives” with the following annotation: “For use only in drum drying of products. Organisms from genetic engineering are excluded. Documentation is required. Shall be produced from organic sources unless not commercially available.”

Glycerides are not permitted for use in organic food processing in the EU, Japan or IFOAM

**Alternatives:** Glycerides are not universally used by drum drying operations. Alternatives for drying foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, etc. Drum drying is preferred for potato flakes. Freeze drying is said to be an acceptable alternative to drum drying. Organic soy lecithin and gum arabic could be alternative substances.

The NOSB requested the following information from stakeholders during the first posting of this material:

1. The subcommittee would like to better understand the extent of use of glycerides (mon- and di-) in drum drying. Are glycerides essential to organic food production? Describe the effects on your operation if glycerides were removed from the National List
2. There appear to be many alternatives to use of glycerides for drum drying of foods, such as spray drying, freeze drying, fluidized bed dryers, air lift dryers, etc. Freeze drying is said to be an acceptable alternative to drum drying. Which of these alternatives have you found to be effective in your business?

Public comment yielded little additional information and some confusion in terms of use. One certifier noted that mono-and diglycerides are important emulsifiers in organic foods. Another certifier noted that mono and diglycerides are used in 6 personal care products that they certify.

There was no opposition to the continued listing of glycerides.

### **Motion to Remove**

This proposal to remove glycerides (mono and di) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Glycerides (mono and di) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Glycerin

**Reference:** 205.605(b) - produced by hydrolysis of fats and oils.

**Technical Report:** 1995 TAP; 2013 TR

**Petition(s):** 1995 N/A, Glycerin (2012 Petition to remove)

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

In 2012 the NOSB received a petition to remove Glycerin from 205.605(b) and reclassify it as agricultural, and be listed at 205.606.

Petitioner stated as follows: “...An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used “only when the product is not commercially available in organic form.” Certified organic glycerin is currently available, but there is no “commercial availability” requirement to incentivize processors to use it or certifiers to require it. Consequently, glycerin should be removed from the National List in order to encourage organic agricultural production.” ...

This matter was discussed at length by the NOSB, and received considerable public comment over a period of two years, including presentation at the NOSB meetings in Spring and Fall 2014 and Spring of 2015.

The NOSB proposal dated October 21 2014, included the following:

“...Because of the confusion around classification of glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced glycerin, the Handling Subcommittee, after significant discussion, is proposing the listing of glycerin at §205.606 and removal of glycerin from §205.605(b). ...”

In April 2015 the NOSB voted to remove Glycerin –produced by hydrolysis of fats and oils- from 205.605(b)

The Handling Subcommittee proposes to remove Glycerin from 205.605(b), however, in order to ensure continuity of supply during Rulemaking based on NOSB votes of April 2015, we propose to renew this listing until Rulemaking is completed.

**Motion to Remove**

This proposal to remove Glycerin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Glycerin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: The Subcommittee proposes removal of Glycerin from the National List at 205.605(b) based its unanimous vote in April 2015 to reclassify Glycerin as agricultural and List it at 205.606.

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Hydrogen peroxide

**Reference:** 205.605(b)

**Technical Report:** N/A for handling use

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; \_11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Hydrogen Peroxide is widely used as a disinfectant and bleaching agent. It is an effective and an environmentally benign substance used to reduce and control microorganisms for food safety purposes. It is critical for sanitizing aseptic packaging.

**Discussion:** The NOSB in its initial request for public comment asked:

Is hydrogen peroxide essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of hydrogen peroxide to provide detailed comments describing the situations in which it is the most effective antimicrobial for a given application.

Public comment did not provide any alternatives. Several Handlers wrote in and stated that this product is essential for use in their OSP.

This material satisfies the OFPA Evaluation criteria

### Motion to Remove

This proposal to remove Hydrogen Peroxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Hydrogen Peroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

**Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

## Magnesium Carbonate

**Reference:** 205.605(b) — for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

**Technical Report:** 1996 TAP

**Petition(s):** Magnesium Carbonate (2005)

**Past NOSB Actions:** 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

This material was originally petitioned as a filter aid, but it is used as a flow agent in free flowing salt, ant-caking agent, color retention agent, drying agent, bleach additive in flour and cheese, and a color enhancer in canned green beans and peas.

Public comment indicates some processor use of the material. One NGO stated that it is not essential but since it is used only in “made with “ category it would not threaten organic integrity.

The material does not appear to be essential to organic handling.

**Motion to Remove**

This proposal to remove magnesium carbonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of magnesium Carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: available alternatives/essentiality

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Magnesium chloride

**Reference:** 205.605(b) – derived from sea water.

**Technical Report:** 1995 TAP

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

This material is used as a processing aid, coagulant/ firming agent in tofu production, but it can be used to dress cotton fibers, or as a color retention agent and other uses.

During initial Review the subcommittee requested public comment on whether or not this material should be re-classified as non-synthetic because it is derived from sea water by brine drying.

Public comment agrees that this material should be re-classified as non-synthetic and moved from a listing at 205.605 (b) to 205.605 (a).

The Handling Subcommittee will recommend that this material be re-classified as non-synthetic and listed on 205.605(a).

Public comment from tofu producers, trade associations and certifiers indicates that this material “makes a specific type of tofu texture that cannot be duplicated with other coagulants. Elimination from the National List would be extremely detrimental to all tofu manufacturers in the United States”.

The subcommittee also asked the public to provide information as to whether Nigari is an FDA allowed food ingredient, and did not receive clear public comment on this topic.

The TAP (1995) suggested that Magnesium chloride be listed only for specific uses. In 1999 when the “derived from sea water” annotation was made it was recommended that it be annotated for use only in tofu production.

In its initial review this year the Handling Subcommittee also asked whether this material should be annotated for use only in tofu production. Public comment indicated that at least one NGO recommends an annotation “as a coagulant in making tofu”. Public comment suggests that while use of magnesium chloride for making tofu is consistent with organic practices, the use of this material for color enhancement may not be consistent with organic.

### Motion to Remove

This proposal to remove magnesium chloride will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium Chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Magnesium stearate

**Reference:** 205.605(b) - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

Magnesium stearate is used as an anti-caking agent in salt. It is a flow agent, lubricant and may be an incidental additive. It is used as a lubricant, allowing manufacturers to produce more per hour as the machine can run faster. The most common use of magnesium stearate in the “made with” organic category is as a binding agent in dietary supplements.

Typically manufactured as a synthetic from hydrogenation of cottonseed or other vegetable oil.

Produced by adding aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

**Alternatives:** Organic flours and starches can replace magnesium stearate as an additive in some products. Non synthetic flow agents are available as alternatives, depending on the product and process.

In 2010 the Codex Committee on Food Additives recommended that magnesium stearate be deleted from Codex.

The Subcommittee in its initial review requested public comment on availability of alternatives and any information on possible negative human health impacts. Public comment was quite limited. Certifiers provided data on the number of processors using magnesium stearate. This is a relatively small number.

There was no information provided indicating any human health impacts and no comment recommending removing this material from the National List.

Magnesium stearate is allowed only in agricultural products labeled “made with organic” and is prohibited in agricultural products labeled “organic” and the subcommittee recommends it’s continued listing.

**Motion to Remove**

This proposal to remove magnesium stearate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium Stearate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

## Nutrient vitamins and minerals

**Reference:** 205.605(b) 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](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/21/2017

**Subcommittee Review**

Brief History of this issue

- In 1995 the NOSB added nutrient vitamins and minerals to the National list with the following annotation, “Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.” A second recommendation was also passed entitled “Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.” This stated, “Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.”
- The final rule that was published in 2000 (65 FR 13512) came out with the current annotation. It was recognized soon after that the cross reference to the FDA’s fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing is necessary.
- The existing annotation is not what the original NOSB recommended in 1995. In 2011 the

Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting and the NOSB supported relisting with existing annotation for the 2012 sunset review.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamin and minerals.
- In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a [memo to the NOSB in April 2010](#) explaining this clarification.
- On January 12, 2012 a proposed rule was published in the Federal Register ([77 FR 1980](#)) to change the annotation to:
 

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

*(b) Synthetics allowed*

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.
- This proposed rule clarified that the "nutrients" that were not on these CFR sections had to be petitioned individually for the National List because this listing did not cover them.
- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule ([77 FR 59287](#)), which renewed without change the original listing, as per the NOSB April 2011 recommendation.
- In 2011 through 2013 many other nutrients were petitioned. A few were recommended to be listed by the NOSB and most were not. No rulemaking has happened to add the recommended substances or clarify the current reference, so the prohibited ones are still in use and the allowed ones have not been added to the National List.
- In 2014 the Handling Subcommittee commissioned a new Technical Report in preparation for Sunset 2017 reviews. This was completed in February 2015. It clarifies a lot about which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.
- Both the TR and the proposed rule are required reading to understand this issue.

**Discussion:** It is clear from the long history of this issue that the annotation and possibly the name of the listing need to change. The NOP has not been able to proceed from their proposed rule and the previous changes suggested by the NOSB were not adopted. However this is a complicated issue and so the HS's approach will be to post a Discussion Document with some options for annotation changes so that a decision to change the annotation can be made as soon as possible after this sunset review. This discussion document will be posted separately for the Spring 2016 meeting.

The 2015 TR sheds light on a lot of information about vitamins and minerals that was not available to the NOSB before. The first key point is that some vitamins are produced through fermentation processes from agricultural or microbial starting points. This means that they are non-synthetic and should probably be listed on §205.605(a). The TR refers primarily to Vitamins D2, B2, B12, E, F, K, and C as being exclusively or probably non-synthetic.

Secondly, from both the TR and the 2012 proposed rule, the citation to 21CFR 104.20 is inaccurate and can be misleading. The correct citation is 21 CFR 101.9. The HS would favor the listing to be re-named and characterized as was suggested in the proposed rule:

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.

Since this is a huge group of different substances, the TR went into length about their manufacturing processes, effects on human health, effects on the environment and uses. There was no information among these pages that gave concern that these substances did not meet the review criteria. Likewise public comment was received with concerns about the unnecessary use of synthetic ingredients, but no new information was provided in comments from the first posting regarding the review criteria beyond the alternatives and compatibility issues.

Regarding alternatives, the primary alternative is for people to get their vitamins and minerals from the food itself rather than supplementation. Non-synthetic supplements, such as yeasts, can also provide some vitamins or minerals. However, there is well known data that show that food may not have as high level of vitamins and minerals as it used to because of soil depletion and other factors. Also humans are eating a lower portion of their diet consisting of fresh raw products and a higher amount of highly processed and non-nutritive foods and therefore are not getting enough vitamins and minerals. However it is unrealistic for organics to make up for all the deficiencies of the modern diet and lack of nutritive value must be balanced with consumers who wish to choose to consume fewer synthetic ingredients.

Finally there is information in the TR about the ancillary substances used in formulating vitamins and minerals. (2015 TR lines 229 - 324). The chart takes up more than a page from just one supplier of vitamins. As the TR says on lines 310 - 311, "These ancillary substances are GRAS. Good manufacturing practice (GMP) requires that they be used at levels that avoid unacceptable environmental, human health, and toxicological effects." Lines 700 and 701 of the TR states, "There is no literature to suggest

that the manufacture or use of vitamins and minerals with ancillary substances is harmful to the environment or to biodiversity." There may be a separate ancillary substance proposal presented at future date.

### **Motion to Remove**

This proposal to remove Nutrient vitamins and minerals will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Nutrient vitamins and minerals from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

None given

### **Vote in Subcommittee**

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

## **Ozone**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### **Subcommittee Review**

**Specific Uses of the Substance:** Ozone is used as a disinfectant and in post-harvest treatment for produce to retard spoilage in cold storage or in wash water. It is effective and environmentally benign substance used to reduce and control microorganisms for food safety purposes.

**Discussion:** The NOSB in its initial request for public comment asked:

Is ozone essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of ozone to provide detailed comments describing the situations in which it is the most effective antimicrobial for a given application.

Public comment did not provide any alternatives. Several Handlers wrote in and stated that this product is essential for use in their OSP.

This material satisfies the OFPA Evaluation criteria.

**Motion to Remove**

This proposal to remove Ozone will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ozone from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

**Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Zea Sonnabend

Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

## Phosphoric acid

**Reference:** 205.605(b) - cleaning of food-contact surfaces and equipment only

**Technical Report:** 2003 TAP

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

**Past NOSB Actions:** 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

**Specific Uses of the Substance:** Phosphoric acid is used in cleaning operations to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining of stainless steel, lime and scale from heat exchangers and in Clean In Place cleaning operations especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

**Discussion:** The NOSB in its initial request for public comment asked:

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of phosphoric acid to provide detailed comments describing the situations in which it is the most effective cleaner for a given application.

Public comment did not provide any alternatives. Several handlers wrote in and stated that this product is essential for use in their OSP.

This material satisfies the OFPA Evaluation criteria.

**Motion to Remove**

This proposal to remove -phosphoric acid will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Phosphoric Acid from the National List based on the following

criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

#### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Zea Sonnabend

Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

### **Potassium acid tartrate**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

#### **Subcommittee Review**

Potassium acid tartrate is a bi-product of wine making. It is used in baked goods. Public comment indicates broad support for this material from producers and certifiers.

No Public comment has been received which opposes its continued listing.

#### **Motion to Remove**

This proposal to remove potassium acid tartrate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of potassium acid tartrate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

#### **Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

## Potassium carbonate

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Potassium carbonate is a strongly alkaline white salt which is made by passing carbon dioxide through a solution of potassium hydroxide. It is a caustic material with chlorine gas a bi-product at manufacture collected to avoid environmental pollution and human health impacts. Historically it was potash.

**Uses:** pH control, leavening agent; can be a boiler water additive; used in soap production.

Commonly used in the Dutch alkali process for processing cocoa and chocolate to reduce acidity. Used in soft drinks and confections. Used as a buffering agent in making wine and mead. It is used to tenderize tripe.

The original TAP suggested that it be used only when sodium carbonate is not appropriate.

Public comment does not indicate that it is widely used. One certifier notes that it is used in the wine industry. No public comment was received opposing its continued listing.

### Motion to Remove

This proposal to remove potassium carbonate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium carbonate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

## Potassium citrate

**Reference:** 205.605(b)

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

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

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

sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Potassium citrate is manufactured from adding potassium bicarbonate and potassium carbonate to citric acid. It is an alkaline salt.

**Uses:** chelating agent, buffering agent, nutrient supplement, pH adjuster, flavor adjuvant, flavor enhancer, and as a medication.

Potassium citrate can be used to replace some phosphates in processing.

Public comment indicated support for this material remaining on the National List. There was no opposition to continued listing.

### Motion to Remove

This proposal to remove potassium citrate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Potassium Citrate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

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

## Potassium phosphate

**Reference:** 205.605(b) - 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

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Potassium phosphate is used as a pH control in milk and dairy products; it is antimicrobial in yeast. The initial TAP included a recommendation to prohibit this material in products labeled “organic”, but approved its use in “made with” products.

International: Potassium phosphate is not listed in CODEX, does not appear on the EU, JAS or IFOAM

organic standards, but is listed in the Canadian organic standard for products in the 70%-95% category only.

Some Public Comment indicates that potassium phosphate is an efficient pH buffering substance with no organic alternatives. The industry indicated that potassium phosphate is used in non-dairy beverages; that it prevents precipitation and impaired mouthfeel; that the alternatives are not as good; and loss of this product would mean impaired quality and marketability.

Public comment indicated a dramatically increased demand for phosphates in production of processed foods but that consumers are not necessarily aware of this increase in phosphorus intake because phosphorus may not appear on the nutritional panel. Without knowledge of phosphorus amounts in each organic product where phosphates are added, the consumer cannot make an informed choice. Other commenters recommended removal based on lack of essentiality and incompatibility with organic agriculture.

Public comment also raises new information relating to possible negative human health impacts associated with the cumulative effect of phosphates used as food additives. One organization stated “recent studies have shown that inorganic forms of phosphate, such as calcium and sodium phosphate, cause hormone mediated harm to the cardiovascular system.” Other commenters provided examples of peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis and heart failure. Such public commenters recommended either removal from the National List or at least an annotation to eliminate uses prohibited by 205.600 (b) (4) to ensure the OFPA criteria is met. Clinical studies appear to indicate that while the phosphorus content of each processed product may be low, and not in itself detrimental to human health, the cumulative effect of consuming many products with added phosphates as ingredients, may be considerable.

There are 5 phosphates on the National List at 205.605(b). 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. Given the new information and research since last Sunset Review, the Handling Subcommittee has requested a new Technical Report which should clarify the probability of negative human health effects resulting from the cumulative effect of phosphates in food products at various dose levels over time on the population as a whole, and alternative materials. Given that this TR may not be received in time for the Fall 2015 meeting, the HS recommends voting on this material at the Fall 2015 meeting, but, should the TR indicate probable cumulative negative health effects from phosphates, the HS would make a new proposal to review all phosphates again at the Spring 2016 meeting.

**Motion to remove:**

This proposal to remove potassium phosphate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of potassium phosphate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Effect of the substance on human health, essentiality, and its compatibility with a system of sustainable agriculture.

Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Lisa de Lima

Yes: 3 No: 2 Abstain: 1 Absent: 1 Recuse: 0

## Sodium citrate

**Reference:** 205.605(b)

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

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

**Specific Uses of the Substance:** 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.

**Approved Legal Uses of the Substance:** Sodium citrate is listed under 21 CFR Part §184.1751 as Generally Recognized as Safe (GRAS). The listing allows its production from citric acid and sodium hydroxide or sodium carbonate. It is allowed as an ingredient used in food with no limitation other than current good manufacturing practice.

The EPA lists citric acid and its salts in the 2004 List 4A (minimal risk inert).

**International:** The citrate salts are generally listed as allowed in the following international organic standards, but with restrictions associated with their usage. Canada: Sodium citrate is restricted to use with sausages or milk products (Table 6.3). CODEX: Sodium citrate is listed in Table 3 for sausages/pasteurization of egg whites/milk products. EU: Sodium citrate (E331) is allowed under EC 889/2008 Section A as an ingredient in the preparation of foods of animal origin. JAS: Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization (Table 1). IFOAM: The calcium, potassium and sodium citrates are allowed as additives.

**Discussion:** The Subcommittee stated in Meeting 1 that it is considering removing this material from the National List based on availability of alternatives that include citric acid and potassium citrate. The Subcommittee and asked those using this material to comment on whether an alternative material would be sufficient in their operation, and to comment on whether a removal of sodium citrate from the National List would have an impact on their operation.

Several commenters in favor of relisting stated:

- Sodium citrate is a common, safe material that is used in many organic cheeses. It binds calcium, reduces acidity and works as an emulsifier to provide a smooth texture to organic

cheeses. We use organic cheese ingredients that contain sodium citrate in our products. We also use sodium citrate for buffering (acid control) in organic sauces. Potassium citrate is an option, but it has an unpleasant metallic taste. Sodium phosphates are another options, but they need to be used in higher quantities and are not as effective. We request that sodium citrate remain on the national list.

- Sodium citrate is a processing aid used by a number of our brands. It is used in both "organic" and "made-with organic" products. It is used in fruit snacks, milk based drinks, plant based yogurt and plant based frozen desserts. To date, we have not found an alternative that works in our products. We did some initial research at the retail level, and found sodium citrate listed in at least four other organic food brands' products.
- We use sodium citrate as part of the process of preparing fresh fruit for use in our yogurts. We are concerned about the potential impacts of removing sodium citrate from the National List because neither citric acid nor potassium citrate would have the same effect in our fruit. We use sodium citrate primarily for its ability to buffer pH, but we know that it also does have an effect on the flavor of our products. Neither citric acid nor potassium citrate would have the same buffering effect in our products. We already use citric acid, in addition to sodium citrate, in our fruit so we know that we need these ingredients for entirely different purposes and one could not substitute for the other. It is harder to predict the outcome of trying to substitute potassium citrate for sodium citrate in our products, but we do know that it would pose a considerable reformulation challenge.
- Sodium citrate is used in a personal care product (lubricant). We have no information as to whether the alternatives listed are practical replacements or not.
- A Trade Association provided the following comments from members:
- Plant based dessert, plant based ice cream, plant based yogurt, organic fruit snacks, organic fruit gummies, 95%+ organic and made-with. Certified for over 20 years. Products sold in all 50 states. Used for cream plug in cream, emulsifier, and as a processing aid. We have not found any alternatives. Essential.
- Cheese, cheese and dairy powders and seasonings. Certified for over 15 years. Products sold in Wisconsin, Pennsylvania, Missouri, & South Dakota. Finished products are sold throughout the U.S. Used for the emulsification of cheese. Sodium phosphates are an alternative, but they are being considered for removal as well. Currently use sodium phosphate, but it is being considered for removal as well. We would not be able to manufacture our products without this ingredient. Loss of this substance would result in the loss of all organic business. Entire business unit eliminated. Ingredient is essential.
- Used in the preparation of fruit for use in our yogurts. Products are sold in all 50 states. We use sodium citrate primarily for its ability to buffer pH, but we know that it also does have an effect on the flavor of our products. Neither citric acid nor potassium citrate would have the same buffering effect in our products. We already use citric acid, in addition to sodium citrate, in our fruit so we know that we need these ingredients for entirely different purposes and one could not substitute for the other. It is harder to predict the outcome of trying to substitute potassium citrate for sodium citrate in our products, but we do know that it would pose a considerable reformulation challenge. Essential
- Fruit Snacks 50 MM dollar business. Certified since 2002. Products in 50 states. Used for pH

Buffer; critical for gel structure and flavor. For organic fruit snacks it helps the product solidify. Otherwise, it remains a liquid and we have not found another material that works for us. We are initiating an investigation on an alternative solution but do not know of one at this time.

Ingredient is essential

- Gummy confections, gummy nutritional supplements, panned jelly beans. Products are distributed around the U.S. and have been certified for up to 20 years. Used as an acidulant, flavor and sodium source. One facility uses both citric acid and potassium citrate. However, only the function can be obtained with sodium citrate in specific products. Allowed organic alternatives are not available. Products using this ingredient will have a decrease in quality and function if this material is removed. Any production loss due to decrease in quality would impact the economic health of the operation. Companies would not be able to manufacture products without this ingredient. Ingredient is essential.

One comment was received opposing relisting:

- Citric acid should be re-classified as synthetic, or annotated to require use of processes that do not involve synthetic chemical reactions. If truly non-synthetic citric acid is available, then synthetic citric acid should not be allowed. If non-synthetic citric acid is not available, then the use of synthetic citric acid –and the citrates—should be restricted to uses that are in compliance with §205.600(b)(4).

The subcommittee received several comments from stakeholders using sodium citrate supporting the relisting. Comments were received stating that handlers could not continue manufacturing specific products without the continued listing of sodium citrate. The Handling Subcommittee will further review comments during the next comment period specifically looking for any alternatives to sodium citrate. If any stakeholder knows of a suitable alternative to sodium citrate please submit written or public to the subcommittee.

This material satisfies the OFPA Evaluation criteria and the Handling subcommittee supports the relisting of sodium citrate.

### **Motion to Remove**

This proposal to remove sodium citrate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sodium citrate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Tracy Favre

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

## Sodium hydroxide

**Reference:** 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Sodium hydroxide is an extremely caustic and toxic material. It was traditionally made by running water through wood ash. It is also known as caustic soda or lye.

**Uses:** Processing aid to adjust pH. Used in production of pretzels and cocoa. Alters proteins and starch so that the surface of pretzels become smooth and brown in baking. May also be used in olive processing to reduce bitterness of some varieties of green olives. May also be used as a cleaning agent. Used in the paper industry in chemical pulping and tissue digestion. Broad range of uses in food production from poultry scalding to soft drinks processing, ice cream thickener. Because it is not always easy to obtain food grade sodium hydroxide sodium carbonate is often used instead of sodium hydroxide. Hominy corn (maize) kernels are reconstituted using sodium hydroxide to make grits. Public comment from processors indicates strong support for continued listing. No public comment indicates opposition to continued listing.

### Motion to Remove

This proposal to remove sodium hydroxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sodium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### Vote in Subcommittee

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Sodium phosphates

**Reference:** 205.605(b) - for use only in dairy foods.

**Technical Report:** 2001 TAP

**Petition(s):** 1995 N/A, 2001 Sodium Phosphate

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

The material was added in 1996 with the “dairy use only” annotation. The material is derived from phosphoric acid.

**Uses:** Acidity control agent, antimicrobial, boiler water additives, sequestrants, texturizer, nutrient, and dietary supplement. Prevents separation of water and fat in cheese; emulsifier in non-fat cheese and milk; creates organoleptic characteristics not otherwise present.

Use in the soy processing was not added to the range of uses permitted for sodium phosphates because the reviewers found that the petitioner did not adequately justify its essentiality.

The petition, dated March 21, 2001, was a request from the manufacturer for use of sodium phosphate in “Food and Beverage Products formulated with Soymilk and Dry Soymilk Similar to or equivalent to Dairy Products.” A Technical Panel Report was requested.

TAP, dated September 21 2001, indicates a lack of consensus of the use of these orthophosphates (mon-di- and tri sodium phosphate). One reviewer suggested prohibition based on review of all OFPA criteria; one reviewer suggested use only as limited by 21 CFR requirements. Another reviewer suggested that it be listed with stringent conditions on all uses of sodium orthophosphates, which would allow all FDA permitted uses, but only with a case by case determination of need, essentiality, nutritional impact and alternatives.

The TAP Review (2001) notes that “toxicity of sodium phosphates is generally related to sequestration of calcium and the subsequent reduction of ionized calcium. It is an irritant, and ingestion may injure the mouth throat and gastrointestinal tract, resulting in nausea, vomiting, cramps and diarrhea” (p 5). Other human health/medical impacts were noted by TAP reviewers related to use of phosphates as bowel purgatives and cleansers. The also noted low calcium reported in susceptible individuals (TAP p 6).

The relationship between sodium phosphate and calcium sequestration raises issues of concern given that use of this material is for use only in dairy products. When calcium combines with phosphate the body’s ability to absorb calcium is reduced. Phosphates also combine with iron and magnesium and perhaps niacin.

There appear to be a number of alternatives that could be used such as lecithin, agar, alginic acid, pectins and gums.

**International:** Sodium phosphates are permitted on the Canadian organic standards' list for dairy products only, but not listed in the following organic standards: EU, CODEX, IFOAM or JAS.

**Public comment:** Public comment from industry indicates support of this material, especially as an emulsifier in cheese production where its use is considered essential. It is also considered essential in making high protein smoothies, stabilizing the texture of the product. Another comment indicates its use as a chelating/buffering agent in ultra-pasteurized heavy cream, reducing production time.

Public comment indicated a dramatically increased demand for phosphates in production of processed foods but that consumers are not necessarily aware of this increase in phosphorus intake because phosphorus may not appear on the nutritional panel. Without knowledge of phosphorus amounts in each organic product where phosphates are added, the consumer cannot make an informed choice. Other commenters recommended removal based on lack of essentiality and incompatibility with organic agriculture.

Public comment also raises new information relating to possible negative human health impacts associated with the cumulative effect of phosphates used as food additives. One organization stated "recent studies have shown that inorganic forms of phosphate, such as calcium and sodium phosphate, cause hormone mediated harm to the cardiovascular system." Other commenters provided examples of peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal renal function, from cumulative phosphorus, and specifically from cumulative impact of sodium phosphate. A daily limit of 70 mg/kg/day was recommended in one study.

Such public commenters recommended either removal from the National List or at least an annotation to eliminate uses prohibited by 205.600 (b) (4) to ensure the OFPA criteria is met. Clinical studies appear to indicate that while the phosphorus content of each processed product may be low, and not in itself detrimental to human health, the cumulative effect of consuming many products with added phosphates as ingredients, may be considerable.

**In Conclusion:** There are 5 phosphates on the National List at 205.605(b). 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. Given the new information and research since last Sunset Review, the Handling Subcommittee has requested a new Technical Report which should clarify the probability of negative human health effects resulting from the cumulative effect of phosphates in food products at various dose levels over time on the population as a whole, and alternative materials. Given that this TR may not be received in time for the Fall 2015 meeting, the HS recommends voting on this material at the Fall 2015 meeting, but, should the TR indicate probable cumulative negative health effects from phosphates, the HS would make a new proposal to review all phosphates again at the Spring 2016 meeting.

Further, the subcommittee seeks clarification about which dairy food products have sodium phosphate as an ingredient, or as a processing aid and whether or not the material is always listed on the label or appears on the nutritional panel?

**Motion to Remove**

This proposal to remove sodium phosphates will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sodium phosphates from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Effect of substance on human health; essentiality; compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion by: Jean Richardson

Seconded by: Harold Austin

Yes: 1 No: 4 Abstain: 1 Absent: 1 Recuse: 0

## Sulfur dioxide

**Reference:** 205.605(b) for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

**Technical Report:** 1995 TAP; 2011 TR

**Petition(s):** 1995 N/A; 2010 Sulfur Dioxide

**Past NOSB Actions:** 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 12/2011 petition review

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

**Use:** Sulfur dioxide is used to prevent spoilage and oxidation in wine. Sulfur compounds have long been an integral part of traditional winemaking, and some sulfur dioxide is naturally occurring in grapes. Sulfites are used to prevent oxidation and to halt malolactic fermentation. Wines without added sulfites have a very short shelf life and must be kept in optimized storage conditions in order to remain viable. The use of sulfur dioxide in organic products is strictly limited to wine production and those products may only be labeled as “Made with organic grapes.” The NOP provides guidance on the use of sulfur dioxide in wines made with organic grapes in Policy Memo 10-2.

**Manufacture:** According to the 2010 technical report: The most common method of production occurs by burning sulfur, but sulfur dioxide can be produced by purifying and compressing sulfur dioxide gas from smelting operations (ATSDR, 1998). Sulfur dioxide has been produced by burning molten sulfur in a special burner with a controlled amount of air. The burner gas, free of dust and cooled, is dissolved in water in a series of two towers. In a third tower, the solution is sprayed at the top and flows down while steam is injected at the base. The gas issuing from the third tower is then cooled to remove most moisture and passed up a fourth tower against a countercurrent of sulfuric acid. The dried gas is liquefied by compression

**International:** The use of sulfur dioxide is allowed in wines and some other alcoholic products under the following organic standards: Canadian, EU, IFOAM and Codex. These Japanese Agricultural Standards (JAS) do not apply to alcoholic products. According to the 2010 technical report: “The Canadian organic standard permits the use of sulfurous acid (sulphurous acid) as a preservative only in alcoholic beverages labeled as organic made from grapes or other fruit. The minimum use of sulfur dioxide is recommended, however labeling wines containing sulfites as ‘organic’ is permitted. The maximum allowable level of sulfur dioxide in alcoholic beverages with less than five percent residual sugar is 100 ppm and 30 ppm for total sulfites and free sulfites, respectively. In alcoholic beverages with five percent or more and less than ten percent residual sugar, 150 ppm and 35 ppm, respectively, are permitted. In alcoholic beverages with ten percent or more residual sugar, 250 ppm and 45 ppm respectively, are permitted.... The European Economic Community (EEC) permits the use of sulfur dioxide in fruit wines without added sugar (including cider and perry) or in mead labeled as organic. The maximum permissible level of sulfur dioxide in these products is 50 mg/L. In this context, ‘fruit wine’ is defined as wine made from fruits other than grapes. The maximum permissible level of sulfur dioxide in cider and perry prepared with addition of sugars or juice concentrate after fermentation is 100 mg/L (EEC 889/2008, 2008). Sulfur dioxide is listed as an acceptable food additive in wine, cider, perry, and mead labeled as organic by the CODEX Alimentarius Commission (CODEX Alimentarius Commission, 2010; GL 32-1999). Sulfur dioxide is permitted for use in making cider and perry (14.2.2), grape wines (14.2.3) and wines made with fruit other than grapes (14.2.4). Sulfur dioxide is also acceptable for use in mead (14.2.5).”

**Ancillary Substances:** No ancillary substances were mentioned in the 2010 technical report or by public comment.

**Discussion:** In 2010, a petition was submitted to remove the restrictive annotation limiting the use of sulfur dioxide to wines “made with organic grapes,” effectively expanding the use of sulfur dioxide to all organic wines. A motion to amend this annotation at the Fall 2011 NOSB meeting did not pass. The handling subcommittee did not ask any specific questions about the substance. Limited public comment was received noting the substance was used as a preservative but its limited to the “made with...” category did not threaten organic integrity. The substance satisfies OFPA criteria.

### **Motion to Remove**

This proposal to remove sulfur dioxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sulfur dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion by: Tom Chapman

Seconded by: Harold Austin

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

## Tocopherols

**Reference:** 205.605(b) derived from vegetable oil when rosemary extracts are not a suitable alternative

**Technical Report:** 1995 TAP; 2015 limited scope TR

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

### Subcommittee Review

Mixed tocopherols for use as antioxidants in foods or animal feeds are manufactured in liquid and powder forms. They are commonly extracted from distillates of vegetable oils. Tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. Tocopherols are added to foods to help prevent oxidation of the fatty acids present in the lipid components of the food. Tocopherols are one of the main sources of Vitamin E.

In the first 2017 Sunset public posting for tocopherols, a table from the most recent Technical Review (TR) showed some of the more common formulations along with their ancillary substances. The Handling Subcommittee sought public comment on the following:

1. The following table shows ancillary substances used in common tocopherol formulations. Please provide information as to whether these ancillary substances or others are also used in organic tocopherol formulations.

There were no direct responses to the question posed, however some additional ancillary substances were identified. Public comment was divided on the relisting of tocopherols, with some comments stating that the material's primary use is as a preservative and therefore inconsistent with organic production. Additionally, commenters asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic. However, the majority of comments were strongly in favor of relisting, stating that tocopherols are critically essential to maintaining food safety, preventing rancidity and providing nutrients to their products. Some comments stated the use of rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers.

Further, some comments addressed the issue of ancillary substances and stated that due to the myriad formulations required for some technical and functional effects, they would not be in favor of restrictions on the ancillary substances used in tocopherol formulations.

Given the feedback on the commercial availability of non-synthetic tocopherols, the Handling Subcommittee is considering a proposal to reclassify tocopherols to 205.605(a) and seeks input on how that might impact organic producers.

**Motion to Remove**

This proposal to remove tocopherols will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of tocopherols from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

**Vote in Subcommittee**

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

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

**Xanthan gum**

**Reference:** 205.605(b)

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/2017

**Subcommittee Review**

Xanthan gum is an extracellular polysaccharide derived from a microorganism through a fermentation process followed by purification. It is used in many products as a thickener and stabilizer. Its unique advantages over other gums are that it can be used in lesser quantities that enable products to comply with the 95% organic rule, and that it works well at low temperatures so that heating can be avoided.

One supplier pointed out that xanthan gum is produced in a very similar fashion to gellan gum and therefore should be considered non-synthetic and moved from 205.605 (b) to 205.606(a). Other commenters agreed that the fermentation is an allowed non-synthetic process and the extraction steps with alcohol do not chemically change to xanthan gum and are not present in the final product to have a functional effect.

On the other hand, some public interest commenters believe that more guidance is needed before determining that fermentation is always a natural process and that xanthan gum should have a new Technical Review before making such a change or renewing it on the National List.

Information was brought up about the potential harm to premature infants, citing a link between one product containing xanthan gum and infants developing necrotizing enterocolitis. This particular situation unfolded between 2011 and 2013 and caused the recall of the formulated product from one (of several) plants producing it because of likelihood of contamination of the product with other bacteria. While it was deemed inconclusive whether the problem came from the xanthan gum itself, the

other ingredients in this one product's formula, or outside contamination, there is not a clear enough research link here on xanthan gum to warrant removal from the National List. It could however be suggested to not feed xanthan gum to premature infants.

The only ancillary substance identified for xanthan gum is guar gum. Because guar is already on the National List, there is no supplemental ancillary substance proposal at this time.

### **Motion to Remove**

This proposal to remove Xanthan gum will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Xanthan gum from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

**Sunset 2017 Review  
Meeting 2 - Review  
Handling Substances §205.606  
October 2015**

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

**Reference: 7 CFR §205.606** Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

[Casings](#)  
[Celery powder](#)  
[Chia \(\*Salvia hispanica\* L.\)](#)  
[Colors \(proposed removals\)](#)  
[Colors \(proposed relisting\)](#)  
[Dillweed oil](#)  
[Fish oil](#)  
[Fructooligosaccharides](#)  
[Galangal, frozen](#)  
[Gelatin](#)  
[Gums: Arabic, Carob bean, Guar, Locust bean](#)  
[Inulin-oligofructose enriched](#)  
[Kelp](#)  
[Konjac flour](#)  
[Lecithin—de-oiled](#)  
[Lemongrass-frozen](#)  
[Orange pulp, dried](#)  
[Orange Shellac - unbleached](#)  
[Pectin \(non-amidated forms only\)](#)  
[Peppers \(Chipotle chile\)](#)  
[Seaweed, Pacific kombu](#)  
[Starches, Cornstarch \(native\), Sweet potato](#)  
[Turkish bay leaves](#)  
[Wakame seaweed \(\*Undaria pinnatifida\*\)](#)  
[Whey protein concentrate](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

## Casings

**Reference:** 205.606(a) casings, from processed intestines

**Technical Report:** N/A

**Petition(s):** 2006 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

**Uses:** The intestines of beef, lamb and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

**Manufacture:** Intestines are washed in pure water with no chemicals, and salted in NaCl salt and water. No other ingredients or processing aids are used. Animal intestines used may be from organic or non-organic animals. Slaughterhouses do not separate certified organic and non-organic offal.

Certified organic intestines from certified animals are not available commercially.

**History:** On 4/21/2007 the NOSB found that “.no processor with the equipment or technology to process slaughter by-products into casings, from processed intestines, has organic certification and /or is unwilling to use their equipment for a batch so small as size as would be needed to fulfill current organic requirements.”

In 2007 there were no public comments specifically opposing the listing of casings from processed intestines.

In 2015 the NOSB requested additional information during first posting of this material:

1. Are there companies manufacturing casings made from certified organic livestock?
2. Are casings from intestines of organic animals commercially available in the US or internationally?
3. What chemicals, other than salt, are used to process animal intestines into casings?

**Public Comment:** Although more organic animals are being slaughtered than in 2007, no public comment provided any new information as to the manufacturing process or possible availability of certified organic intestines.

Industry strongly supports continued listing and no commenter asked for removal.

### Motion to Remove

This proposal to remove Casings will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Casings from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### Vote in Subcommittee

Motion to remove Casings from 205.606(a)

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 0 No: 6 Abstain: 1 Absent: 0 Recuse: 0

## Celery powder

**Reference:** 205.606(b)

**Technical Report:** N/A

**Petition(s):** 2007 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

**Use:** 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 (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. According to the petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to create the typical cure attributes. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted.

**Manufacture:** Celery is cleaned, macerated, physically separated (liquid/solid), the liquid is concentrated by evaporation, heated and vacuum dried. There are no other chemicals or preserving agents used in the manufacturing process. Celery powder is typically standardized to specific nitrite content. According to the petitioner, meat preservation via natural nitrites/lactic acid is an ancient technology dating back thousands of years. There are other vegetables and minerals which contain natural nitrates including beets, spinach and sea salt. Although each has its benefits and challenges none are an identical equivalent to natural celery powder in quality, form and function.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Celery powder is not listed in the EU Organic Standards, however, sodium nitrate is allowed for meat products (an alternative to celery powder not currently listed on the National List).

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Public comment was received from industry, certifiers and trade association about its use in processed meat products and its necessity for certain “cured” meat products. One commenter provided details for their search for organic celery powder but noted organic versions so far were unable to meet necessary nitrite standardization profiles for the functional use. The same commenter noted why other alternatives did not function equivalent to celery powder. The original petitioner also notes the need for cured meat products to better utilize

organic meat trim byproduct from organic meat processors. Several comments received were in general opposition to any agricultural items being listed and others commented on the need for OFPA criteria to be applied to the review of conventional agricultural ingredients. Further one comment noted that farmer worker poisonings, pesticide uses, residues and pollinator impacts need to be accessed for conventional agricultural items. It should be noted that under the NOP, products certified to the “made with organic...” claim, and containing 70%+ organic content, may use non-organic agricultural ingredients that are not listed on §205.606 or undergo a review for compliance with OFPA criteria – although such ingredients are still required to comply with § 205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or excluded methods.

The Handling Subcommittee recommends celery powder remain on the National List given the unavailability of a functional organic version or alternatives, low usage level, and its necessity in manufacturing traditional “cured” meat products. This material satisfies the OFPA evaluation criteria.  
Motion to Remove

This proposal to remove celery powder will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of celery powder from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

#### **Vote in Subcommittee**

Motion to remove celery powder from 205.606(b)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

### **Chia (*Salvia hispanica* L.)**

**Reference:** 205.606(c)(*Salvia hispanica* L.)

**Technical Report:** N/A

**Petition(s):** 2007 Petition

**Past NOSB Actions:** 03/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** : Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

#### **Subcommittee Review**

**Use:** Chia seeds are consumed directly and added to variety of food products, mostly for their omega 3 fatty acid profile and other nutrient content.

**Manufacture:** Chia seeds are grown, harvested and mechanically separated and cleaned.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements

(IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Chia seeds are not listed in the EU Organic Standards.

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting Chia noting its wide commercial availability. No specific comments received supported relisting or addressed commercial unavailability of Chia. The Handling Subcommittee recommends Chia (*Salvia hispanica* L.) be removed from the National List.

### **Motion to Remove**

This proposal to remove Chia (*Salvia hispanica* L) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Chia (*Salvia hispanica* L.) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic therefore it is inconsistent with organic farming and handling.

### **Vote in Subcommittee**

Motion to remove Chia (*Salvia hispanica* L) from 205.606(c)

Motion by: Tom Chapman

Seconded by: Zea Sonnabend

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

**Colors - Black/Purple Carrot Juice color, Blueberry Juice color, Carrot Juice color, Cherry Juice color, Chokeberry/Aronia Juice color, Elderberry Juice color, Grape Juice color, Grape Skin Extract color, Paprika color, Purple Potato juice color, Red radish Extract color, Saffron Extract color, Turmeric Extract color**

**Reference:** 205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(4) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(5) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(6) Carrot juice color (pigment CAS #1393-63-1)

(7) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

- (9) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (10) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (11) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (12) Paprika color (CAS #68917-78-2)—dried, and oil extracted
- (14) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (16) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
- (17) Saffron extract color (pigment CAS #1393-63-1).
- (18) Turmeric extract color (CAS #458-37-7)

**Technical Report:** 2015 TR - Colors (all)

**Petition(s):** 2007 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Section 205.606 allows for use of non-organic agricultural materials when organic supplies are not commercially available. Colors were added to the National List in 2007 and in 2010 the listing was updated to clarify that they must not be produced using synthetic solvents and carrier systems or artificial preservatives.

**Uses:** Colors are added to food products to enhance attractiveness of food, assure uniformity in color, add back color lost during processing, protect light susceptible vitamins and preserve flavor (TR 2015, 22-25). Global sales of natural colors were approximately \$600 million in 2011, an increase of almost 29% four years earlier. More recent estimates put the annual growth of the natural colors market at 3–4% annually. The food industry is the largest consumer of natural colors—accounting for 70% of the market share—with the remaining 27% in soft drinks and 3% in alcoholic beverages. The use of natural colors is highest in Europe, where 85% of new products launched between 2009 and 2011 used natural colorants (IFT, 2013). (TR 347-351)

**International:** Canada permits natural colors; CODEX does not list specific colorants but allows natural sources of colors; EU Organic Standards allow some natural colors and provides for petition for ingredients meeting specific criteria; Japanese Agricultural Standard (JAS) does not discuss colors per se; International Forum of Organic Agricultural Movements (IFOAM) states “...substances should “not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the

replacement of nutrients is required by law.” The individual colors are not listed in the IFOAM Norms (IFOAM, 2014). (TR 408-411). FDA states that GRAS does not apply to colors (TR 613-622)

**Manufacture, Human Health:** Natural colors appear to meet the criteria in OFPA related to manufacture and human health, in fact some of the colors are beneficial to human health (TR 681-682, Table 8).

**Alternatives:** For all of the listed colorants, organically grown (as opposed to conventionally-grown) vegetables and fruits can be used as an alternative source for the colorant. Manufacturers of the non-organically grown colorants claimed in their 2007 National List petition that the supply of organic fruits and vegetables was insufficient to allow for colorant uses. It is unknown whether organic fruit and vegetable production has become sufficient since 2007. However if sufficient stocks of organically grown fruits and vegetables used for colorants are now available or become available in the future, then the organically grown fruits and vegetables can be used as alternatives for colors derived from non-organic agricultural products. (TR 82-826). Given the expansion in the production of certified organic fruits and vegetables it would appear that most if not all colors should be available commercially in organic form.

**Public Comment:** Some public comment states that use of non-organically produced products allowed as ingredients in or on processed products labeled as “organic” fail to meet OFPA criteria not only because organic alternatives are available, but also because they are not compatible with a system of sustainable agriculture.

Other public comment indicates that most of the colors are now available in organic form with the possible exception of the following 4 colors: Beet Juice extract color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage extract color. One certifier stated that 73 of its clients use organic colors (122 actual colors used).

Based on its present understanding that, except for the above four (4) colors that may not presently be commercially available in organic form, the Handling Subcommittee recommends removing from the National List the following 13 colors: Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color.

#### **Motion to Remove**

This proposal to remove : Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of : Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Material is available in organic form.

**Vote in Subcommittee**

Motion to remove the thirteen (13) colors as listed above from 205.606

Motion by: Jean Richardson

Seconded by: Lisa de Lima

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

## Colors - Beet juice extract color, Black Currant juice color, Pumpkin Juice color, Red Cabbage Extract color

**Reference:** 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(1) Beet juice extract color (pigment CAS #7659-95-2)

(3) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

(13) Pumpkin juice color (pigment CAS #127-40-2)

(15) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

**Technical Report:** 2015 TR - Colors (all)

**Petition(s):** 2007 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

**Subcommittee Review**

Section 205.606 allows for use of non-organic agricultural materials when organic supplies are not commercially available. Colors were added to the National List in 2007 and in 2010 the listing was updated to clarify that they must not be produced using synthetic solvents and carrier systems or artificial preservatives.

**Uses:** Colors are added to food products to enhance attractiveness of food, assure uniformity in color, add back color lost during processing, protect light susceptible vitamins and preserve flavor (TR 2015, 22-25). Global sales of natural colors were approximately \$600 million in 2011, an increase of almost 29% four years earlier. More recent estimates put the annual growth of the natural colors market at 3–4% annually. The food industry is the largest consumer of natural colors—accounting for 70% of the market share—with the remaining 27% in soft drinks and 3% in alcoholic beverages. The use of natural colors is highest in Europe, where 85% of new products launched between 2009 and 2011 used natural colorants (IFT, 2013). (TR 347-351)

**International:** Canada permits natural colors; CODEX does not list specific colorants but allows natural sources of colors; EU Organic Standards allow some natural colors and provides for petition for ingredients meeting specific criteria; Japanese Agricultural Standards (JAS) does not discuss colors per

se; IFOAM states “...substances should “not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law.” The individual colors are not listed in the IFOAM Norms (IFOAM, 2014). (TR 408-411). FDA states that GRAS does not apply to colors (TR 613-622)

**Manufacture, Human Health:** Natural colors appear to meet the criteria in OFPA related to manufacture and human health, in fact some of the colors are beneficial to human health (TR 681-682, Table 8).

**Alternatives:** For all of the listed colorants, organically grown (as opposed to non-organically grown) vegetables and fruits can be used as an alternative source for the colorant. Manufacturers of the non-organically grown colorants claimed in their 2007 National List petition that the supply of organic fruits and vegetables was insufficient to allow for colorant uses. It is unknown whether organic fruit and vegetable production has become sufficient since 2007. However if sufficient stocks of organically grown fruits and vegetables used for colorants are now available or become available in the future, then the organically-grown fruits and vegetables can be used as alternatives for colors derived from conventional agricultural products (TR 82-826). Given the expansion in the production of certified organic fruits and vegetables it would appear that most if not all colors should be available commercially in organic form.

**Public Comment:** Some public comment state that use of non-organically produced products allowed as ingredients in or on processed products labeled as “organic” fail to meet OFPA criteria not only because organic alternatives are available, but also because they are not compatible with a system of sustainable agriculture. Other public comment indicates that most of the colors are now available in organic form with the possible exception of the following 4 colors: Beet Juice extract color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage extract color. Based on its present understanding that the above four (4) colors are not presently commercially available in organic form the Handling Subcommittee recommends leaving these four materials on the National List

### **Motion to Remove**

This proposal to remove Beet Juice Extract Color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage Extract color will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Beet Juice Extract Color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage Extract color from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none given

### **Vote in Subcommittee**

Motion to remove the four (4) colors as listed above from 205.606

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

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

## Dillweed oil

**Reference:** 205.606(e) Dillweed oil (CAS # 8006-75-5)

**Technical Report:** none

**Petition(s):** 2006 Petition

**Past NOSB Actions:** 2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

**Use:** Dillweed oil is used in the manufacture of dill pickles and used in place of dillweed to provide the traditional and characteristic flavor of dill pickles.

**Manufacture:** Dillweed oil is produced from harvested dillweed that is steam distilled to remove the oil. The resulting condensate is purified and standardized.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. It is possible dillweed oil could be used in the EU under the Annex IX allowance for fats and oils not from cocoa, coconut, olive, sunflower, palm, rape (canola), safflower, sesame or soya (soy).

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of dillweed oil. It appears the dillweed oil also meets the definition of flavors, non-synthetic. Searches of publically available organic sourcing pages by the NOSB in the February of 2015 resulted in sources of both organic dillweed and organic dillweed oil. The Handling Subcommittee recommends dillweed oil be removed from the National List.

### Motion to Remove

This proposal to remove dillweed oil will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of dillweed oil from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic therefore it is inconsistent with organic farming and handling.

### Vote in Subcommittee

Motion to remove dillweed oil from 205.606(e)

Motion by: Tom Chapman

Seconded by: Harold Austin

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

## Fish oil

**Reference:** 205.606(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 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Section 205.606 allows for use of non-organically produced ingredients to be used in processed products labeled “organic” when the ingredient is not commercially available in organic form.

The NOP does not presently have production standards for aquaculture, therefore organic fish cannot be commercially available.

**Uses:** 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 (Chang et al., 2009; Lee et al., 2014). 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 (Rizliya and Mendis, 25 2014). (Technical Report 2015 lines 19-25).

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.

**History:** Fish Oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report or TAP. The NOSB 2007 Recommendation indicated that the OFPA criteria were met in all categories, but provided no scientific rationale or citations to support such findings. However, the NOSB Final Recommendation May 9, 2007 stated ...”pursuant to the judgment in *Harvey v. Johanns*, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed on § 205.606. These criteria were finalized in the NOSB “Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606” of October 19, 2006. “That recommendation allows for pro-active listing on § 205.606 of materials which may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather or trade-related issues.

Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a § 205.606-listed material may be used, on a case by case

basis. ...” “.... After discussion, the Board decided to add an annotation to the recommendation to list Fish Oil to the National List. The annotation is “stabilized using only allowed ingredients on the National List.” The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market.”...

“The Handling Committee (2007) noted that agricultural substances are only required to be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

6517(c)(1)(a)

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

The NOSB (2007) further noted that “There were no public comments specifically opposing the listing of Fish Oil on §205.606....” In its Five Year Review in April 2010 the NOSB received no public comment and fish oil remained on the List.

In February 2015 the NOSB posed the following questions in the first posting of this material under the new Sunset procedure:

1. What are the primary geographic sources of fish oil and primary fish species harvested for the purpose of oil extraction?
2. Are there conservation and environmental issues surrounding harvest of wild caught fish for fish oil?
3. What is the manufacturing and purification process?
4. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB’s for example? How is purity assessed?
5. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
6. What is the most current research on plant-derived alternatives such as flax and chia and how comparable are they to the Omega 3 in fish and algal oils?

In addition, in preparing for the 2017 Sunset Review the NOSB requested a full Technical Report which was received in March 2015 after the posting of the initial Sunset review.

The 2015 TR provides a valuable in-depth analysis and provides up to date research and citations allowing the subcommittee to re-evaluate the fish oil comprehensively against the OFPA criteria.

**Sources:** Fish oil is derived from a wide range of wild caught fish species including, tuna, mackerel, sardines, anchovy, halibut, (TR lines 69-79). NOTE: The TR also lists fish oil from whales and seal under fish, although these are mammals. (TR lines 75-76). Fish oil is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil (TR lines 283-284). Farmed fish are not a source of fish oil, they are often fed fish oil supplements to boost their own levels of omega 3 fatty acids (TR 332-333). Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States

(Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports. Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). (TR 90-110)

**Manufacturing:** Fish oil remains intact through the purification process and is not chemically modified (TR 338). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). 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) (TR 307-320). There are also other purification methods, which are discussed in the TR.

**Human Health:** Fish oil is a naturally sourced product which appears to provide a multitude of health benefits (as listed above under "Uses"). It is one of the best sources of Omega 3 EPA and DHA fatty acids. Fish oil such as cod liver oil which has been given to children in many areas of the world for generations to promote healthy brain development and prevent inflammation. Fish oils are added to many foods and taken as dietary food supplements to promote heart health and reduce risk of atherosclerosis.

However, the health benefits from consumption of fish oil is currently a debated topic in the scientific community (TR 471) and some sources suggest that there are health risks from fish consumption that may outweigh the benefit of omega 3 fatty acids from fish oil (TR 489-494).

Fish bioaccumulate many contaminants (TR 503-507). A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for EPA 407 and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012). PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 ( $\pm$  415 8) ppb (Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012). Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009). The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively

(GOED, 2012). There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. (TR 404-426).

Note: The TR addresses the February 2015 NOSB Questions 1, 2, 3 and 6 listed above under History, and partially answers Question 4, but it is not clear if the Voluntary Standard for contaminant limits is still in effect (Question 5).

**Conservation issues:** There is a very high demand for fish oil. 81% of fish oil goes to Aquaculture. Demands on fisheries may overburden the current supply of fish (TR 441-450). Fish oil used is from wild caught and not farmed fish. Overfishing may also lead to species extinctions and a decrease in biodiversity. There are more than 100 confirmed cases of extinctions in marine fish population's worldwide (Jenkins et al., 2009). Exploitation of fisheries is the largest contributor to marine extinctions, higher than habitat loss, climate change, invasive species, pollution, and disease (Dulvy et al., 2003) (TR 462-465). While some countries have highly regulated fisheries to prevent overfishing, many do not. According the Food and Agriculture Organization's (FAO) State of the World's Fisheries and Aquaculture, most of the pelagic fish stocks, globally, are considered either fully fished or overfished. Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department (2014). The State of the World Fisheries and Aquaculture. pp. 39. While many different species are used for fishmeal and fish oil, small pelagics are most commonly used due to their high oil content. Peruvian anchoveta, Japanese anchovy, and Atlantic herring are the most common pelagic species harvested for fishmeal and fish oil, with primary stocks in the Southeast Pacific, Northwest Pacific, and Northeast and Northwest Atlantic, respectively. In 2010, all of these were either fully exploited or depleted. (Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department. (2010) The State of the World Fisheries and Aquaculture. pp. 35. Available at: <http://www.fao.org/docrep/013/i1820e/i1820e.pdf> )

In the Mediterranean, sardine and anchovy stocks have been assessed as fully fished (FAO 2014, p 40). According to FAO, fisheries that target species of a specific trophic level, such as those that target pelagics for fishmeal and fish oil production, remove "one ecosystem component without considering cascading effects on the dependent species...Concerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems." (FAO 2014, p 136). Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds, serving as an important link in the transfer of energy from plankton to species higher in the marine food web, some of which are endangered (FAO 2014, p 137), such as humpback whales.

**Plant derived alternatives:** Flaxseeds are a good source of both omega-3 (linolenic) and omega-6 (linoleic) fatty acids, with both oil types combined comprising about 40 percent of the flax seed mass. The oil content will vary depending on where and how the flaxseeds were grown, but omega-3 fatty acids can make up 30–60 percent of the total oil content, while omega-6 fatty acids make up 10–20 percent of the oil content (Teneva et al., 2014). Chia seed oil and perilla seed oil are additional sources of LC-PUFA, and their oil content distribution is very similar to that of flaxseed oil (Ciftci et al., 2012). Chia, perilla, and flax seed oils all contain ALA in relatively high amounts ranging from approximately 58 to 61 percent of the total oil (Ciftci et al., 2012). Humans can convert dietary ALA to EPA and DHA, but

synthesis from ALA is inefficient in the body. Several species of seaweed and algae can provide some fatty acids, but not with the same profile of fatty acids as fish. (TR 539-576)

**International:** Fish oil is not listed as allowed for organic processing in Canada, Japan, EU, or under IFOAM and is not listed in CODEX (TR 245-275). However, it should be noted that CODEX, IFOAM and JAS do not have discreet lists for non-organic agricultural substances. The EU does have a positive list and it does not list fish oil, but the EU Organic Standards also allow for organic certification of aquaculture. Thus the international status of fish oil in organics is not entirely clear.

**Public Comment:** Public comment is divided on the subject of fish oil use. There is a high consumer demand and industry strongly supports continued listing, especially as there are no organic sources. Industry comments (April 2015) include the following: “Used in Gummy Confections, Gummy Nutritional Supplements, Panned Jelly Beans... Fish Oil is used in our products as a natural source of DHA. An organic form is not available.... No alternative management practices that would eliminate the need for the specific substance. This ingredient is essential to our organic products.”

Other Industry comments: “Fish oil provides nutritional benefits which our consumers are seeking”; “Peru fisheries are well regulated”; “specification sheets indicate levels of PCB’s, arsenic, cadmium and lead are tested 3 times a year to meet very strict guidelines; plant sources of omega 3 are not as complete as found in fish oil”.

On the other hand conservation groups are concerned about impact on world fisheries, and NGO’s are concerned about the cumulative risk impact of fish oil on human health recommend removing fish oil as it fails to meet OFPA criteria relating to human health, environmental conservation and compatibility with a sustainable system of agriculture.

Answers to Questions 3, 4, and 5 above relating to voluntary standards and controlled fisheries and contamination limits were very limited in scope or detail and further clarification of those issues would be very helpful.

### **Motion to Remove**

This proposal to remove fish oil will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of fish oil from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: 6517(c)(1)(a): effect of the substance on human health, environmental conservation, its compatibility with a system of sustainable agriculture and alternative availability of a wholly natural substitute.

### **Vote in Subcommittee**

Motion to remove fish oil from 205.606(f)

Motion by: Jean Richardson

Seconded by: Lisa de Lima

Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

## Fructooligosaccharides

**Reference:** 205.606(h) Fructooligosaccharides (CAS # 308066-66-2)

**Technical Report:** 2006 TAP; 2015 TR

**Petition(s):** 2006 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

**Use:** Fructooligosaccharides (FOS) is on the National List as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic.” FOS is a non-digestible carbohydrate that is used as a soluble prebiotic fiber, sweetening agent, flavor enhancer, bulking agent and humectant. It is used in many foods including yogurts, infant foods, medical food, baked goods, candies, soups beverages and other dairy products. FOS is mostly indigestible by human digestive enzymes.

**Manufacture:** There are two common commercial methods to produce FOS: Inulin and Sucrose.

**Inulin derived.** Inulin, a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchockes), agave and other plants. Chicory inulin is extracted from the source material via water extraction – the resulting inulin undergoes a partial enzymatic hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger*. The hydrolysis breaks long chain inulin into the shorter chain FOS.

**Sucrose derived.** Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas*. The *A. japonicus* cells must be immobilized for production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicus* culture suspended in calcium alginate, an immobilizer. *A. japonicus* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfers fructose molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicus* is generally inefficient, and higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzymatic reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid (a strong acid) or sodium hydroxide (a strong base); potassium phosphate is also used for pH control. The FOS produced can then be further purified through filtration or further fermentation.

**Ancillary Substances:** According to the 2014 TR: “There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation.”

**International:** FOS is not specifically listed in the Codex, EU or Japanese organic standards however non-organic agricultural products are not listed in these standards. FOS is not specifically listed on the Canadian organic standards.

**Discussion:** The NOSB requested information from the public related to (1) ancillary Substances, (2) commercial demand, (3) availability of organic sources, (4) alternatives and (5) function need. No comments were received from public on ancillary substances, availability of organic sources or alternatives. An organic ingredient broker and one manufacture of the substance asked for the continued listing and noted its usage in baked products. Upon reviewing draft guidance NOP 5033 on Agricultural/Non-Agricultural Classification and the information contained in the Technical Review the handling committee continues to believe the Agricultural classification is correct. No alternatives or organic versions were identified.

### **Motion to Remove**

This proposal to remove Fructooligosaccharides will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Fructooligosaccharides from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: 6517(c)(1)(a)(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products.

### **Vote in Subcommittee**

Motion to remove Fructooligosaccharides from 205.606(h)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

Yes: 1 No: 4 Abstain: 2 Absent: 0 Recuse: 0

## **Galangal, frozen**

**Reference:** 205.606(i) Galangal, frozen

**Technical Report:** none

**Petition(s):** 2006 Petition

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Galangal is a rhizome in the ginger family and is used in various Asian cuisines.

**Manufacture:** Galangal, frozen is harvest, cleaned and frozen. Other forms of Galangal are fresh, dried and powdered.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards list “lesser galanga.”

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of galangal, frozen. Searches of publically available organic sourcing pages by the NOSB in February of 2015 resulted in sources of both organic galangal in Southeast Asia and a producer of galangal, frozen in Hawaii. The Handling Subcommittee recommends galangal, frozen be removed from the National List.

### **Motion to Remove**

This proposal to remove galangal, frozen will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of galangal, frozen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic therefore it is inconsistent with organic farming and handling.

### **Vote in Subcommittee**

Motion to remove galangal, frozen from 205.606(i)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

## **Gelatin**

**Reference:** 205.606(j) Gelatin (CAS # 9000-70-8)

**Technical Report:** 2002 TAP

**Petition(s):** 2001 Petition; 2007 Petition

**Past NOSB Actions:** 05/2002 NOSB recommendation for addition to the National List; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Gelatin on the National List can be derived from cows, swine, or fish. Gelatin is used in a wide range of products as a clarification or fining agent in teas and wine, as a stabilizer and thickener, and in capsules. It may either be an ingredient or a processing aid.

While there is starting to be organic gelatin available from cows, there definitely is not from fish. One trade association and several certifiers indicated that while some products use organic gelatin, there is not enough supply for all uses. Fish gelatin is widely preferred for uses in kosher foods and is never available as organic. Some individuals expressed concerns over the use of animal gelatin from conventionally raised animals and the level of contamination that might be present from conventional

practices. However, no specific new evidence was presented that such gelatin had been identified as harmful in organic food.

One commenter indicated that gelatin is formulated with sodium hexametaphosphate for cross linking. An ancillary substance proposal for this is accompanying this review.

### **Motion to Remove**

This proposal to remove gelatin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of gelatin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion to remove gelatin from 205.606(j)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Gums: (Arabic, Guar, Locust bean , and Carob bean)**

**Reference:** 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

**Technical Report:** 1995 TAP

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

The listing for gums has four different names that refer to three different source products (locust bean and carob bean are two common names for the same plant species). They are used as binders and thickening agents in a very large variety of foods. The Handling Subcommittee recognized that the 1995 TAP review was really old and incomplete as far as the extraction process for these gums, and a new TR was requested but was not done because it was not among the highest priority substances for new reviews.

Public comments generally were favorable to the continued use of these gums, especially as they are alternatives to some of the other gums from seaweed or microorganisms. Written comments and testimony from product formulators and users identified how each type of gum has its unique situations where use is necessary, and many times the gums are used in combination to produce the desired effect. Guar gum, for instance, can hydrate rapidly at low temperatures, while locust bean gum can retard ice crystal formation.

Some commenters mentioned that locust and guar gum are available from organic suppliers. Others indicated that this supply is inconsistent and one mentioned that guar gum had had some contamination issues in the past and so was not reliably available in suitable organic form.

No commenters provided any ancillary substances used in gum formulations.

### **Motion to Remove**

This proposal to remove Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion to remove Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) from 205.606(k)

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Inulin-oligofructose enriched**

**Reference:** 205.606(l) Inulin-oligofructose enriched (CAS # 9005-80-5)

**Technical Report:** 2015 TR

**Petition(s):** 2007 Petition

**Past NOSB Actions:** 04/2007 recommendation; [2010 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Inulin-oligofructose enriched (IOE) is on the National List as a nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.” IOE is a non-digestible carbohydrate that is used to increase calcium bioavailability and absorption, as a soluble dietary fiber, as a non-caloric sweetener, and for functional effects on the texture/consistency of food. It is used in many foods including yogurts, baked goods, candies, jams and other dairy products.

**Manufacture:** IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin however it is the common commercial method to produce the oligofructose from inulin when used in IOE production. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), agave and

other plants. Chicory inulin is the most commercially available inulin, however organic inulin is generally derived from agave (Mexico) and Jerusalem artichokes (China). Chicory inulin is produced by shredded chicory roots, which are treated with hot water, juiced, and filtered to remove the raw inulin. The raw inulin is purified by treatment with calcium hydroxide, carbonated, and filtered and spray-dried. The resulting inulin polymers range in chain length from 2–60 units. The shortest polymers range from 2–10 fructose units and are called oligofructose. The longer polymers range from 10–60 units. If insufficient amounts of oligofructose are present, polymers range from 10–60 units are treated with inulinase enzyme from *Aspergillus niger* to create more oligofructose and is mixed back in with the original inulin.

**Ancillary substances:** The 2015 TR found no ancillary substances but noted that IOE could contain up to 20% glucose, fructose, and sucrose left over from the chicory source material or enzymatic conversion. Further the TR noted processing aids are removed in favor of a pure IOE product. The amounts of these remaining substances may vary, but the general approach in producing IOE is to purify the IOE solution and thereby limit the amount of processing aids that remain. The TR for fructooligosaccharides (FOS) noted the follow residuals: glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol. There are no ancillary substances to list for IOE.

**International:** IOE is not specifically listed in the Codex, EU or Japanese organic standards however non-organic agricultural products are not listed in these standards. IOE is not specifically listed on the Canadian organic standards.

**Discussion:** The NOSB requested information from the public related to (1) ancillary substances, (2) current use of IOE, (3) commercial availability of organic inulin and if conventional FOS could be used with organic inulin in place of conventional IOE, (4) other alternatives. No public comment was received on ancillary substances. Public comment was received from one organic handler on the usage of IOE in fruit fillings. One certifier noted they had seen clients switching to organic inulin. No comments were received about the unavailability of inulin or the short comings in the available organic supply. No comments were received about the availability of alternatives. Other public comment questioned the classification of IOE as agricultural. Upon reviewing draft guidance NOP 5033 on Agricultural/Non-Agricultural Classification and the information contained in the Technical Review the handling committee continues to believe the Agricultural classification is correct. Given the availability of organic inulin, the separate listing of FOS, information from certifiers of operations switching to organic inulin, and the absence of information on continued commercial unavailability of the organic inulin, the Handling Subcommittee recommends this item can be removed from the National List at this time.

### **Motion to Remove**

This proposal to remove Inulin-oligofructose enriched will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Inulin-oligofructose enriched from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: 6517(c)(1)(a): unavailability of a whole natural substitute product

### **Vote in Subcommittee**

Motion to remove Inulin-oligofructose enriched from 205.606(l)

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

## Kelp

**Reference:** 205.606(m) Kelp—for use only as a thickener and dietary supplement.

**Technical Report:** [1995 TAP](#)

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

**Past NOSB Actions:** 04/1995 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Kelp is a term used for seaweeds belonging to the brown algae (Phaeophyceae) class in the order Laminariales. There are about 30 genera and many species. Kelp is dark green or brown in color and has a salty, characteristic taste. Through the 19th century, the word "kelp" was closely associated with seaweeds that could be burned to obtain soda ash (primarily sodium carbonate). The seaweeds used included species from both the orders Laminariales and Fucales. The word "kelp" was also used directly to refer to these processed ashes. The material is harvested, dried and then ground or chopped for use in food. Giant kelp can be harvested fairly easily because of its surface canopy and growth habit of staying in deeper water.

Used for centuries in traditional Japanese food, kelp provides a unique flavor profile and can be used as a thickening agent or as a base for broth. Kelp can also be used as a source of iodine within maximum daily iodine intake limits. (TAP Review, March 5, 1995)

While the term "kelp" generally refers to seaweeds belonging to the brown algae in the order Laminariales, by tradition some forms of kelp have more specific names, for instance, wakame or kombu. Most kombu is from the species *Saccharina japonica* (*Laminaria japonica*). However, some edible kelps in the family Laminariaceae are not always called kombu, such as arame, kurome (*Ecklonia kurome*) or *Macrocystis pyrifera*.

The name "wakame" was derived from the Japanese name wakame. Starting in the 1960s, the word "wakame" started to be used widely in the United States, and the product (imported in dried form from Japan) became widely available at natural food stores and Asian-American grocery stores.

There was very limited public comment regarding this material. One commenter did suggest removing the annotation that limits kelp's use as a thickener and dietary supplement. A second commenter objected to the continued listing of kelp, citing that all non-organic agricultural ingredients should be eliminated from the National List. Another raised possible issues of some contamination and harvesting. There is organic kelp available, but not in large enough commercial supply to meet demand.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the sunset review to make changes to the listings on the National List.

### **Motion to Remove**

This proposal to remove Kelp will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Kelp from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: compatibility.

### **Vote in Subcommittee**

Motion to remove Kelp from 205.606

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Konjac flour**

**Reference:** 205.606(n) Konjac flour (CAS # 37220-17-0).

**Technical Report:** None

**Petition(s):** [2001 Petition](#)

**Past NOSB Actions:** 05/2002 NOSB minutes (determined to be agricultural); 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** 2007 Interim Rule ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Konjac flour is derived from tubers of the elephant yam, *Amorphophallus konjac*. It is also called glucomannan. It has been used in traditional foods in Asia such as Shirataki noodles and konjac curd. It is considered a binder, gelling agent, thickener and stabilizer. What makes konjac flour unique is that it can absorb up to 50 times its weight in water. It is now widely used in weight loss supplements because it promotes a sense of fullness and pushes more calories out through the colon instead of letting them be absorbed. It is one of the few fibers that are tolerated by diabetics and it helps lower serum cholesterol and blood glucose.

No public comment was received with new information on the OFPA criteria regarding konjac flour, and no sources of organic konjac flour were identified in public comment. One trade association indicated that it was still important, particularly for use with meat products like sausages and in fruit gels. Other starches and gums do not produce the unique combination of functions that konjac flour has.

An internet search for organic konjac turned up several websites that offered organic konjac noodles (such as <http://www.konjacfoods.com/>) and organic konjac powder (such as <http://www.alibaba.com/showroom/organic-konjac.html>). All sources apparently originate from China. It is difficult for this Subcommittee to assess the availability from these sources, as well as whether they are suitable in form and function for the needs of organic processors.

**Motion to Remove**

This proposal to remove Konjac Flour will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Konjac Flour from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

**Vote in Subcommittee**

Motion to remove Konjac flour from §205.606

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

## Lecithin -de-oiled

**Reference:** 205.606(o) Lecithin—de-oiled.

**Technical Report:** [1995 TAP](#); [2009 TR](#)

**Petition(s):** [Lecithin, bleached \(remove 2008\)](#)

**Past NOSB Actions:** 04/1995 minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606)

**Recent Regulatory Background:** Annotation change effective 03/15/2012 ([77 FR 8089](#))

**Sunset Date:** 03/15/17

**Subcommittee Review**

Lecithin is a very widely used ingredient in food, as an emulsifier, dispersing agent, and to reduce the hydration properties of powders in water and milk products. Lecithin occurs naturally in several foods, such as egg yolks and soybeans. Historically lecithin has been produced commercially from soybeans, but there are now alternative sources available from sunflowers, canola and other crops.

In 2009, the NOSB corrected the listing for lecithin on the National list, by removing it (lecithin—bleached) from § 205.605(b) and adding it to § 205.606 in the de-oiled form only. This also corrected the terminology for the types of lecithin by removing the terms "bleached" and "unbleached" from the listing. The fluid form of lecithin is now widely available from organic soybeans. The 2009 NOSB recommendation to amend the listing stated that de-oiled lecithin was the only form appropriate for certain types of uses and it was not yet available organically.

For this sunset review the Subcommittee heard testimony from one supplier that organic, de-oiled soy lecithin has been available since 2013. They also stated that the resistance to using fluid lecithin is mostly a matter of convenience for users rather than necessity.

Multiple companies who use lecithin, however, stated that there was consistency of supply issues with the organic de-oiled lecithin, and that they were reluctant to rely on just one supplier of this important ingredient. It was also noted that it had a unique functionality that is not achieved in either liquid lecithin or other powdered lecithin, in that the hydrophilic/lipophilic balance is much higher so that it disperses in oil-in-water solutions.

Furthermore, there was no public comment that sunflower or other lecithins were available as organic de-oiled, and the supplier of the organic soy said they did not have organic de-oiled sunflower or other source lecithins. These sources are important for formulators to try to avoid soy in their products.

The Subcommittee believes that progress is being made towards having all types of lecithin available in organic form but believes the market has not reached that point at this time for lecithin from all source ingredients. Therefore the de-oiled lecithin is recommended for renewal on § 205.606.

### **Motion to Remove**

This proposal to remove Lecithin – de-oiled will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lecithin – de-oiled from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion to remove Lecithin - de-oiled from §205.606

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

## **Lemongrass**

**Reference:** 205.606(p) Lemongrass—frozen.

**Technical Report:** N/A

**Petition(s):** [2006 Petition](#)

**Past NOSB Actions:** 04/2007 recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Cymbopogon or lemongrass is part of the grass family (Poaceae) and its leaves are used in various Asian cuisines.

**Manufacture:** Frozen lemongrass is harvested, cleaned and frozen. Other forms of lemongrass are fresh, dried, cut and powdered. According to the petitioner, lemongrass is commercially grown in South and Central America and Asia.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list lemongrass.

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Comments were received from a cross-section of the organic community in support of delisting frozen lemongrass noting it is commercially available. No specific comments received supported relisting or addressed commercial unavailability of frozen lemongrass. The Handling Subcommittee recommends lemongrass-frozen be removed from the National List.

### **Motion to Remove**

This proposal to remove Lemongrass—frozen will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lemongrass—frozen from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic, therefore, it is inconsistent with organic farming and handling.

### **Vote in Subcommittee**

Motion to remove Lemongrass—frozen. from 205.606(p)

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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

## **Orange pulp, dried**

**Reference:** 205.606(q) Orange pulp, dried.

**Technical Report:** N/A

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

**Past NOSB Actions:** 11/2008 NOSB recommendation for addition to the National [List](#)

**Recent Regulatory Background:** Added to NL effective 03/15/2012 ([77 FR 8089](#))

**Sunset Date:** 03/15/17

### **Subcommittee Review**

**Use:** According to the petitioner, dried orange pulp is a fiber with about 33.3% soluble fiber and 34.9% insoluble fiber. It 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 and 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:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list dried orange pulp.

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments received supported relisting or addressed commercial unavailability of dried orange pulp. While the NOSB could not find organic dried orange pulp during a search of publically available sourcing resources in February 2015, there were several listed organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp. The Handling Subcommittee recommends dried orange pulp be removed from the National List.

### **Motion to Remove**

This proposal to remove Orange pulp, dried will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Orange pulp, dried from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: its compatibility with a system of sustainable agriculture and availability of a wholly natural substitute.

### **Vote in Subcommittee**

Motion to remove Orange pulp, dried, from 205.606(q)

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

## **Orange shellac**

**Reference:** 205.606(r) Orange shellac-unbleached (CAS # 9000-59-3).

**Technical Report:** [2002 TAP](#); [2014 TR](#)

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

**Past NOSB Actions:** 10/1999 NOSB minutes and vote; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Orange shellac is the purified product of the natural resin lac which is the hardened secretion of the insect *Kerria lacca*, the lac insect. It is used as a coating for fruit and vegetables as well as a confectionary glaze.

A new Technical Report (TR) was commissioned for this review to provide updated information and to look at ancillary substances. Shellac is usually used in combination with other coatings such as carnauba or wood rosin.

Public comment was primarily in favor of keeping carnauba and other coatings on the National List and no new information was provided about any of the OFPA criteria. In regard to the ancillary substance question, no ancillary substances were suggested for the raw ingredient, but ancillaries may be used once it is formulated with other coating agents. Since there are fully compliant organic formulations on the market, this does not need further action.

One other point brought up frequently in public comment was the desire for labeling of fruit and vegetables that have been coated with these products. Both the 2014 TR and the public comments mentioned that organic consumers do not expect their produce to be waxed. Federal laws from the FDA specify that waxed produce must be labeled, but this is interpreted in a general way so that the label may only be on a shipping container not visible to consumers or on general signage in a store that does not specify which products are waxed. The Handling Subcommittee recognizes this issue and urges voluntary labeling of produce coatings, but is unable to put forward an additional labeling annotation.

### **Motion to Remove**

This proposal to remove Orange shellac – unbleached (CAS # 9000-59-3) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Orange shellac – unbleached (CAS # 9000-59-3) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given.

### **Vote in Subcommittee**

Motion to remove Orange Shellac from 205.606(r)

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Pectin**

**Reference:** 205.606(s) Pectin (non-amidated forms only).

**Technical Report:** [1995 TAP](#); [2009 TR](#); [2010 supplemental TR](#); [2015 TR](#) (limited scope)

**Petition(s):** [2005 Petition – low methoxy pectins](#)

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

**Recent Regulatory Background:** Sunset Review effective 06/27/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Pectin is extracted from citrus and pome fruits but so far there is no organic source of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. The excess sugar has the potential for more negative human health effects than pectin.

Pectin was widely supported in public comment from its users. No negative comments were received with substantive information on why pectin would not meet the OFPA criteria.

Ancillary substances used in pectin include sugar and dextrose for standardizing products, and trisodium citrate (or other salt buffers described in the 2015 TR). A separate ancillary substance proposal is accompanying this substance.

### **Motion to Remove**

This proposal to remove Pectin (non-amidated forms only) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Pectin (non-amidated forms only) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion to remove Pectin (non-amidated forms only) from §205.606(s)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

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

## **Peppers (Chipotle chile)**

**Reference:** 205.606(t) Peppers (Chipotle chile)

**Technical Report:** N/A

**Petition(s):** [2006/2007 Petition](#)

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Chipotle chiles are added to a variety of food products as a flavoring to give products a distinct hot (spicy) and smoky chili flavor common in Latin foods.

**Manufacture:** Chipotle chiles and smoked dried-jalapeños. Harvested chiles are sorted, smoked-dried and then are used whole, crushed or powdered.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Chipotle peppers are not listed in the EU Organic Standards.

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting chipotle chiles noting commercial availability. No specific comments received supported relisting or addressed commercial

unavailability of chipotle chiles. The Handling Subcommittee recommends peppers (Chipotle chile) be removed from the National List.

#### **Motion to Remove**

This proposal to remove Peppers (Chipotle chile) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Peppers (Chipotle chile) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic, therefore, it is inconsistent with organic farming and handling.

#### **Vote in Subcommittee**

Motion to remove Peppers (Chipotle chile) from §205.606(t)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

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

### **Seaweed, Pacific kombu**

**Reference:** 205.606(u) Seaweed, Pacific kombu

**Technical Report:** N/A

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** 05/2008 NOSB recommendation

**Recent Regulatory Background:** Added to NL effective 03/15/12 ([77 FR 8089](#))

**Sunset Date:** 03/15/17

#### **Subcommittee Review**

Kombu is an edible kelp belonging to the family Laminariaceae. It is dark green or brown in color and has a salty, characteristic taste. Most *kombu* is from the species *Saccharina japonica* (*Laminaria japonica*), and is extensively cultivated on ropes in the seas of Japan and Korea. With the development of cultivation technology, over 90% of Japanese *kombu* is cultivated, mostly in Hokkaidō, but also as far south as the Seto Inland Sea. The material is harvested, and typically dried and then ground or chopped for use in food. Used for centuries in traditional Japanese food, kombu provides a unique flavor profile and can be used as a thickening agent or as a base for broth.

The 2008 NOSB recommendation stated that there are certified organic seaweeds but they do not impart the same characteristics as kombu. Although there are a number of specific varietal identifications of “kombu,” the common term Pacific kombu was determined to be adequate and appropriate for identification. That petitioner was unable to locate a source of certified organic kombu. The separate inquiries of Board members supported this finding. It was felt that it might be possible in the future that kombu could be certified organic under the “Wild Harvest” portion of the Rule (§ 205.207). The Board concluded that the material satisfied the criteria of all four categories required for a material to be listed on § 205.606.

There was very limited public comment regarding this material. One commenter did object to the continued listing of kombu, citing that all non-organic agricultural ingredients should be eliminated from the National List.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the sunset review to make changes to their listings on the National List.

### **Motion to Remove**

This proposal to remove Seaweed, Pacific kombu will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Seaweed, Pacific kombu from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility.

### **Vote in Subcommittee**

Motion to remove Seaweed, Pacific kombu from §205.606(u)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Starches; cornstarch, sweet potato**

**Reference:** 205.606(v) Starches.

(1) Cornstarch (native).

(2) Sweet potato starch - for bean thread production only.

**Technical Report:** [1995 TAP - Cornstarch](#)

**Petition(s):** N/A – Cornstarch; [2007 Petition - Sweet Potato Starch](#)

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/2010 sunset review Sweet potato starch; 10/2010 sunset recommendation on cornstarch

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Starches are used in many foods as thickeners, formulation aids, bulking agents and moisture adsorption agents. Cornstarch is made from special strains of corn that are high in amylose and amylopectin. Sweet potato starch is specifically used as a formulation aid for bean thread production.

There is an organic cornstarch on the market, but it is not suitable for all uses. Cornstarches are described by the relative content of two glucose polymers: amylopectin and amylose. Special strains of corn are grown to achieve the right ratio of the polymers and these special varieties are all identity preserved to maintain their amylose ratio and so are never genetically engineered. A supplying company

and a trade association indicated that there is not a supply of organic moulding cornstarch, or the type with very high amylose content, or special strains with freeze-thaw properties.

No public comments were received with new information about any of the other OFPA criteria other than a concern over GMOs in cornstarch. GMO cornstarch would not be allowed in organic food in any case, but is unlikely to occur as discussed above.

### **Motion to Remove**

This proposal to remove Starches; cornstarch, sweet potato will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Starches: cornstarch, sweet potato from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria 7 U.S.C. 6518(m)(7) compatibility with a system of sustainable agriculture.

### **Vote in Subcommittee**

Motion to remove Cornstarch (native), and Sweet Potato Starch from §205.606(v)

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

## **Turkish bay leaves**

**Reference:** 205.606(x) Turkish bay leaves.

**Technical Report:** N/A

**Petition(s):** [2006 Petition](#)

**Past NOSB Actions:** 04/2007 recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Turkish bay leaves are an herb that has been used traditionally to flavor food.

**Manufacture:** Turkish bay leaves (*Laurus nobilis*) are widely cultivated in the Mediterranean and Asia. Leaves are harvested, sorted and then sold as fresh or dried.

**International:** There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list Turkish bay leaves.

**Ancillary Substances:** No ancillary substances were provided.

**Discussion:** The NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. One commenter, the original

petitioner, noted that they have identified a source of Turkish bay leaves but believe the supply is too fragile to have the listing removed at this time. Searches of publically available organic sourcing pages by the NOSB in June of 2015 resulted in 85 NOP organic certificate holders of bay leaves with 12 specifying *Laurus nobilis*. Additionally 3 spice companies were contacted and all had sources of Turkish bay leaves from Turkey, India or both. One commenter noted that plantings, pesticide uses and residues, and pollinator impacts need to be assessed for conventional agricultural items. It should be noted that under the NOP, products certified to the “made with organic...” claim, and containing 70%+ organic content, may use non-organic agricultural ingredients that are not listed on §205.606 or undergo a review for compliance with OFPA criteria – although such ingredients are still required to comply with § 205.105, which prohibits ingredients that are irradiated, produced with sewage sludge or excluded methods. Additionally, the commenter provided no data specifically on pesticide usage and residues on Turkish bay leaves and just cited EPA tolerance levels for pesticides on herbs subgroup 19A. The Handling Subcommittee recommends Turkish bay leaves be removed from the National List.

### **Motion to Remove**

This proposal to remove Turkish bay leaves will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Turkish bay leaves from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic therefore it is inconsistent with organic farming and handling.

### **Vote in Subcommittee**

Motion to remove Turkish bay leaves from 205.606(x)

Motion by: Tom Chapman

Seconded by: Lisa de Lima

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

## **Wakame seaweed**

**Reference:** 205.606(y) Wakame seaweed (*Undaria pinnatifida*).

**Technical Report:** N/A

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Wakame is an edible seaweed, most often served in soups and salads. Native to cold temperate coastal areas of Japan, Korea, and China, in recent decades it has become established in New Zealand, the United States, France, Great Britain, Spain, Italy, Argentina, and Australia. It was nominated one of the 100 worst invasive species in the world. It has been grown for centuries in Japan and Korea, where it is still primarily consumed. The name "wakame" was derived from the Japanese name *wakame*. In the

1960s, the word "wakame" started to be used widely in the United States, and the product (imported in dried form from Japan) became widely available at natural food stores and Asian-American grocery stores.

The material was petitioned in 2007, where the petition stated that organic wakame (*Undaria pinnatifida*) was not available. While other organic seaweeds were, they did not provide the same flavor profile and could not be used in the instant soup for which wakame was being petitioned as an ingredient.

In 2010, the NOSB reaffirmed a recommendation for the continued listing of wakame along with additional § 205.606 materials: Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list these materials. As § 205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products.

There was very limited public comment regarding this material. One commenter did object to the continued listing of wakame, citing that all non-organic agricultural ingredients should be eliminated from the National List.

There has been some confusion around the separate listings on the National List for wakame and kombu, both forms of edible seaweeds. While the Handling Subcommittee acknowledges this issue, it is beyond the scope of the Sunset review to make changes to their listings on the National List.

### **Motion to Remove**

This proposal to remove Wakame seaweed (*Undaria pinnatifida*) will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Wakame seaweed (*Undaria pinnatifida*) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility.

### **Vote in Subcommittee**

Motion to remove Wakame seaweed from 205.606(y)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## **Whey protein concentrate**

**Reference:** 205.606(z) Whey protein concentrate.

**Technical Report:** [2015 TR](#)

**Petition(s):** [2007 Petition](#)

**Past NOSB Actions:** 05/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Use:** Whey protein concentrate is used in dairy products, protein bars, and infant formulas. Whey protein concentrate is used as a source of protein, as a fat replacer, and as a texturizer.

**Manufacture:** Whey protein concentrate is a soluble fraction of bovine milk composed of protein, minerals and lactose and is a byproduct of cheese manufacturing. The primary method of production mixes milk with rennet to coagulate the casein to make cheese curds, the resulting liquid is whey. Another method of production is via microbiological fermentation or direct addition of lactic acid that acts to reduce the pH and coagulate the casein. The whey undergoes an ultra-filtration process to remove a large portion of the lactose and minerals. Low temperature processing ensures retention of both nutritional and functional properties. Whey protein concentrate is evaporated then spray-dried and sold as a dry ingredient. The whey protein concentrate may also be bleached with hydrogen peroxide or benzoyl peroxide if it was the product of colored cheddar cheese. Whey protein concentrate can be concentrated to different protein levels (i.e., 35%) but max out around 80%. Concentrations higher than 90% are considered whey protein isolate.

**International:** Whey protein concentrate is not specifically listed in the Codex, Canadian, or Japanese organic standards. "Whey powder 'herasuola'" is listed on the EU Organic Standards.

**Ancillary Substances:** Soy lecithin added as an "instantizing" ancillary substance was identified.

**Discussion:** The NOSB requested information from the public related to (1) ancillary substances, (2) commercial demand, (3) commercial availability, (4) other alternatives, (5) use in the industry. One public comment was received from a certifier on the use of soy lecithin as an ancillary substance. No information was provided on commercial demand, alternatives or its use in the industry. One trade association commented on its essentiality and lack of supply but provided no detailed information on why the supply identified by the NOSB was insufficient. One certifier noted they have clients producing and selling whey protein concentrate. The Subcommittee asked the original petitioner to comment to which they noted they have had a secure supply of organic whey protein concentrate for several years. Given the availability of organic whey protein concentrate and the absence of information on continued commercial unavailability from industry the Handling Subcommittee recommends this item be removed from the National List at this time.

### **Motion to Remove**

This proposal to remove Whey protein concentrate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Whey protein concentrate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Commercially available as organic therefore it is inconsistent with organic farming and handling.

**Vote in Subcommittee**

Motion to remove Whey Protein Concentrate (WPC) from 205.606

Motion by: Tom Chapman

Seconded by: Jean Richardson

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National Organic Standards Board**  
**Handling Subcommittee Proposal**  
**Re-classification of Alginic Acid to §205.605(b)**  
**June 2, 2015**

**Summary of Proposed Action:**

The Handling Subcommittee proposes reclassification of Alginic Acid from §205.605(a) to §205.605(b) of the National List.

**Subcommittee Review**

Alginic acid is derived from wild harvested seaweeds. Increasing demand for alginic acid and alginates has led to some concerns regarding potential for overharvesting of these wild seaweeds.

Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in pure alginic acid. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, it is clear that the free acid form does not appear in nature. (2015 Technical Review – Alginic Acid, Lines 283-286). In the 1995 TAP review for Alginic Acid, the reviewers determined that the material was non-synthetic. However, given the draft Classification of Materials document and the information presented in the 2015 TR, it could be suggested that Alginic Acid is synthetic.

There has been recent research into production of Alginic Acid and Alginates from a biological fermentation process. However, this process does not currently produce sufficient quantities to be commercially available, (2015 Technical Review – Alginic Acid, Lines 299-300).

FDA limits the use of Alginic Acid as a stabilizers, emulsifier and thickener in soups and soup mixes.

The Handling subcommittee proposes that Alginic Acid remain on the National List. However, the Handling subcommittee is bringing forward a proposal to change the listing from 205.605(a) to 205.605(b) due to the determination that Alginic Acid would likely be classified as synthetic under the new draft Classification of Materials document.

**Vote in Subcommittee**

Motion to reclassify Alginic Acid from 205.605(a) to 205.605(b) of the National List.

Motion by: Tracy Favre

Seconded by: Lisa De Lima

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015**



**National Organic Standards Board  
Handling Subcommittee Proposal  
Re-classification of Carnauba Wax to §205.606  
August 4, 2015**

**Introduction**

In the course of the Sunset 2017 Review of Carnauba Wax, information from the Technical Report (TR) from 2014 indicates that this is an agricultural substance.

**Background**

During the creation of the National List, Carnauba was included in the review of "Fruit Waxes" under the Crops Committee because it was considered a post-harvest handling substance. It was never classified as either agricultural or non-agricultural at that time. When the rule came out it was on the Handling section of the National List at 205.601(a).

Carnauba wax is an exudate from the leaves and buds of the palm tree *Copernicia cerifera*, also known as *Copernicia prunifera*, which grows almost exclusively in northeastern Brazil. It is used to coat fruit and vegetables, candies and as a base for chewing gum.

**Relevant areas in the Rule**

§205.605(a) and §205.606.

**Discussion**

Evaluation Question #2 of the 2014 TR goes into detail on how the Carnauba wax is extracted from the palm trees. The subcommittee compared this process with the Draft Guidance on Classification of Materials (NOP Guidance 5033) and determined that carnauba wax could be considered agricultural based on the definition of "agricultural product" at §205.2 of the Federal rule. Furthermore, there is some organically grown carnauba on the market.

When the question of re-classification was posed in the first round of public comments, no comments were received that posed concerns about this change.

**Subcommittee Vote**

Motion to classify Carnauba Wax as agricultural and move its listing to section §205.606

Motion by: Zea Sonnabend

Second: Tracy Favre

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015**



**National Organic Standards Board**  
**Handling Subcommittee**  
**Petitioned Material Proposal**  
**Sodium Lactate and Potassium Lactate**  
**August 25, 2015**

**Summary of Proposed Action:** To add Sodium Lactate and Potassium Lactate to the National List under section §205.605(b). This request was made to the National Organic Standards Board to take under consideration by the National Organic Program, in a memorandum dated June 25, 2014. The original joint petition was submitted on January 5, 2004.

### **History**

On January 5, 2004 the NOP received a combined petition for two substances to be added to the National List for use in organic handling, these substances were Sodium Lactate and Potassium Lactate (the salts of lactic acid). Lactic acid is listed on the National List at §205.605(a) as an approved non-synthetic material for use in products labeled as “organic” or “made with organic (specified ingredients of food group(s)). Lactic acid appears in “Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic)”.

On January 22, 2004, the NOP notified the petitioner that their petition would not be necessary since the materials (sodium hydroxide, lactic acid, and/or potassium hydroxide), that these two substances were formulated using, were already included on the National List. Eventually, this interpretation was deemed to not be consistent with previous NOSB recommendations on the classification of materials and was causing some confusion within the organic industry regarding the status of the two materials (Sodium lactate and potassium lactate) as well as other lactate salts (example: calcium lactate)(McEvoy 2014). Thus, the NOSB (Handling Sub-committee) took up the request for the consideration for inclusion to the National List, for sodium lactate and potassium lactate on §205.605 (b) Synthetics Allowed.

The original 2004 petition was submitted for the following use: Both sodium lactate and potassium lactate are used in meat processing as a pathogen inhibitor that is added to meat as an ingredient for use in controlling *Listeria monocytogenes* in Ready-to-Eat meat and poultry products. Both of these materials have been recognized by the USDA-FSIS (Food Safety and Inspection Service) as being two of the few known antimicrobials validated through scientific studies to inhibit the growth of *Listeria monocytogenes*, *E.coli*, Salmonella, and other pathogens. They also control *Clostridium Botulinum* (botulism) in meats, as well. Sodium and potassium lactate can replace nitrates/nitrites in meat products and are generally recognized as safe (GRAS).

In the February 17<sup>th</sup>, 2015 Technical Evaluation Report it mentions that both sodium and potassium lactate are affirmed as GRAS. Sodium lactate is affirmed GRAS at 21 CFR 184.1768 and Potassium Lactate at 21 CFR 184.1639. However, the FDA does not authorize their use in infant foods and formulas.

Sodium lactate and potassium lactate come as a liquid and may be added to meat as an ingredient at the rate of 1% to 4.8% as prescribed by the USDA-FSIS regulations, depending on the product. Whether a handling operation uses sodium lactate or potassium lactate is at the discretion of the processor or by the requirements of the specific recipe – i.e. low sodium products (Applegate Farms 2004).

**Manufacture:**

Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugarcane or sugar beets) or starch. This substrate is fermented by food grade micro-organisms to form lactic acid. Sodium hydroxide (NaOH) is produced by the electrolysis of a concentrated sodium chloride (table salt) solution. Potassium hydroxide (KOH) is a synthetic, inorganic compound produced by an electrolysis process using only potassium chloride (approved for use in organic foods per §205.605(a)) and water.

Sodium and/or potassium lactate are generally produced from natural (fermented) lactic acid, which is then reacted with either sodium hydroxide or potassium hydroxide, respectively (Houtsma 1996).

Lactates are naturally produced in the human body.

**Discussion:**

The original petition asked that sodium and potassium lactate be added to the National List, for use in meat processing as a pathogen inhibitor. While the petitioned request for these materials covered a very specific usage, it is not completely clear whether or not the intended use is currently the only way that these two materials are being utilized in organic handling. This is part of the confusion from the action taken in 2004 by the NOP's decision to not accept the need for the petitioner's request to have sodium lactate and potassium lactate added to the National List.

There does not appear to be any human health concerns associated with either of these two materials according to the information provided in the Technical Evaluation Report. Both materials are considered to be GRAS by the FDA according to this same report. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid. This concern seems to have been mitigated by utilizing this by-product material (gypsum) as a soil additive (Gypsoil and ADM 2011) and by research being implemented to look at other ways to produce lactic acid. According to a report published by the EPA lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008).

In the Technical Evaluation Report from February 17, 2015 it does state that no additional ingredients (e.g., stabilizers, preservatives, carriers, anti-caking agents, or other materials) are added to the commercially available forms of these materials. Thus, it would stand to reason that there are no ancillary substances associated with either of these two materials. However, the TR does mention that sodium diacetate (below 2%) sometimes may be combined with either of these two materials to help lower the pH of the surface meat products and therefore decrease microbial growth. Sodium diacetate is GRAS, contains 60% sodium acetate and 40% acetic acid (Miller 2010).

Both sodium lactate and potassium lactate have been allowed for use in organic handling since the January 22, 2004 decision was rendered by the National Organic Program (McEvoy 2014). This decision (to not require a petition for sodium and potassium lactate for inclusion to the National List) was originally based on the fact that all three of the materials used to produce sodium lactate and potassium lactate were already approved and on the National List. That decision was not consistent with previous NOSB Recommendations on classification of materials. The intent of this proposal is to correct that previous decision and go through the appropriate process (Petitioned Material Proposal) to see whether or not these two materials should in fact be added to the National List of Allowed Substances. It is the intent of the subcommittee and ultimately that of the entire National Organic Standards Board by moving forward with this proposal we can clear up the confusion, re-establish a concise and transparent process by which these two materials shall be reviewed and ultimately voted on.

**Sodium Lactate**

There are three mechanisms by which sodium lactate can have an antimicrobial affect. The first is by changing water activity (it lowers the water activity of meat and thereby slows microbial growth). The second occurs as sodium lactate passes through the cell membrane and lowers intracellular pH. The third takes place as sodium lactate affects cellular metabolism by inhibiting ATP generation (ATP- adenosine triphosphate, a nucleoside triphosphate which transports chemical energy within cells for metabolism (Biology Online 2010)). The lactic acid portion of sodium lactate has antimicrobial properties, as it can be incorporated into the microbial cell. The lactic acid then interferes or slows down the normal metabolic process that generates cell energy in the cell. (Miller 2010).

**Potassium Lactate**

Potassium lactate has a potassium ion rather than the sodium ion found in sodium lactate. It has been shown to decrease microbial growth and to limit the growth of some major meat pathogens with similar capabilities to those of sodium lactate. Potassium lactate can be used as a substitute for sodium lactate as a non-meat ingredient, with similar functionality, but does not have the salty taste (Miller 2010).

Again, the original petitioned use for these materials was for use in Ready-to-Eat meat and poultry products as an ingredient to function as a pathogen inhibitor, especially for use in controlling *Listeria monocytogenes*.

It should be noted that in the TR it states that meat products that contain sodium and potassium lactates can no longer be labeled as “natural” without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005).

It would assist the NOSB in our consideration of these two petitioned materials if the appropriate organic stakeholders and/or certifiers could provide any additional information regarding the extent that these two materials are being used. Furthermore, are there any additional ways that these materials are currently being used other than the original petitioned use that we should be aware of? Finally, between sodium lactate and potassium lactate is one more commonly used than the other?

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

**Substance Fails Criteria Category:** NA

**Subcommittee Action & Vote:**

**Classification Motion:**

**Motion to** classify both Sodium Lactate and Potassium Lactate as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

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

**Listing Motion:**

Motion to list Sodium Lactate and Potassium Lactate on section 205.605(b) with the following annotation: for use as an antimicrobial agent only.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

Yes: 4 No: 1 Abstain: 2 Absent: 0 Recuse: 0

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015**

## NOSB Evaluation Criteria for Substances Added To the National List - Handling

### Category 1. Adverse impacts on humans or the environment? Sodium and Potassium Lactate

Question	Yes	No	N/A	
<p>1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]</p>		X		<p>The EPA Screening-Level Hazard Characterization of High Production Volume Chemicals report for Lactic Acid and its salts (2008) concluded that the manufacture and use of natural lactic acid constitutes a low potential risk to human health or the environment. According to the data assessed in the report, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment. Further, the potential acute hazard of lactic acid to aquatic organisms is low (Environmental Protection Agency 2008). February 17, 2015 TR Lines: 770-774.</p>
<p>2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]</p>	X			<p>During the fermentation process to make lactic acid, the pH is stabilized by adding calcium carbonate (lime) which neutralizes the acid and results in the formation of calcium lactate. A by-product of the purification process of the calcium lactate during the production of lactic acid is insoluble calcium sulfate (gypsum). In the TR (Feb. 17, 2015) lines 782-784 states about gypsum: It is a by-product in the process and is produced at a rate of 1 ton per 1 ton of lactic acid produced (Pal 2012). Gypsum disposal can be a problem. Lines 792-794 states: One of the main commercial lactic acid manufacturers, Archer Daniels Midland Company (ADM), has partnered with a fertilizer company to sell and distribute much of the gypsum by-product to growers (Gypsoil and ADM 2011). Lines 800-802 states that: another commercial manufacturer, Corbin (Purac): The company is investing in the development of a proprietary gypsum-free technology that does not rely on the use of calcium carbonate or sulfuric acid in the acidification and purification processes. This technology appears to be in the initial stages of development, and more information on the details of this technology is needed.</p>

3. Are there any adverse impacts on biodiversity? (§205.200)		X	
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X	
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X	According to the February 17, 2015 TR, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment. Further, the potential acute hazard of lactic acid to aquatic organisms is low (Environmental Protection Agency, 2008).
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X	In the TR (February 17,2015) lines 815-817 states: Lactates have been reported to have low oral toxicity, with a lack of adverse effects in feeding studies in which up to 3,900 mg/kg body weight/day was administered to rats for 2 years. Likewise, lactates were proven to be non-genotoxic and non-mutagenic (Purac 2008). TR lines 828-830, As described in other sections of this report, the use of lactic acid and its sodium and potassium salts in certain food applications may reduce risk of foodborne pathogens because of their antimicrobial properties. However, the FDA does not authorize its (sodium or potassium lactate) use in infant foods and formulas.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA’s good manufacturing practices? [§205.600(b)(5)]	X		Sodium Lactate is affirmed as GRAS at 21 CFR 184.1768 for use in food with no limitation other than current good manufacturing practice. (Feb. 17, 2015 TR Lines: 203-204) Potassium Lactate is affirmed as GRAS at 21 CFR 184.1639 for use in food with no limitation other than current good manufacturing practice. (Feb. 17, 2015 TR Lines 209-210) In the TR Lines 204 and 210 it states (pertaining to the GRAS statements for these two lactates) However, the FDA does not authorize their use in infant foods and formulas.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X	

## Category 2. Is the Substance Essential for Organic Production? Sodium and Potassium Lactate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			See answer below for Cat. 2, question 3 and 4.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			According to the TR (Lines 612-615) Sodium lactate and potassium lactate are produced by combining non-synthetic lactic acid and sodium hydroxide or potassium hydroxide, respectively.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		According to the TR (Lines 601-602) Lactic acid, produced from fermentation, is currently listed on the National List, 205.605(a) as a non-synthetic material with no restrictions on use. However, to form either sodium lactate or potassium lactate either sodium hydroxide or potassium hydroxide is added, which both of these materials are on the National List as synthetics allowed.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		TR line 615-616 states “There does not appear from the literature to be a non-synthetic version of sodium lactate or potassium lactate.
6. Is there an organic substitute? [§205.600(b)(1)]	X			TR lines 1,042-1,043 says “research into the use of <b>natural antimicrobials</b> in organic and natural meat products is being done with promising results. Research is also being done to look at <b>agricultural antimicrobial alternatives</b> such as: cranberry, cherry, lime and vinegar powders. Lines 1,092-1094 states: According to the research, the addition of the antimicrobials appeared to improve control of <i>L.monocytogenes</i> , but these products demonstrated a slight variation of inhibitory activity, suggesting that other inhibitory factors are involved. <b>Essential Oils</b> (oily mixes of volatile and complex compounds that are extracted from different parts of aromatic plants) are also under going research as possible alternatives as an antimicrobial. <b>Multi-barrier Preservation Systems</b> is another potential alternative, which uses multiple substances

				to give control of <i>L. monocytogenes</i> .
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			TR (Feb. 17,2015) Lines 913-917 states: There is concern that organic meat products could potentially pose a food safety hazard if they do not contain antimicrobials that are comparable to formulated sodium nitrate (NaNO <sub>2</sub> ) in concentrations known to be highly effective in inhibiting the growth of many food borne pathogens such as <i>Listeria monocytogenes</i> (Niebuhr, et al.2010) However, more research into natural antimicrobials in organic and natural meat products is being done with promising results.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Sodium nitrate is commonly used in curing non-organic meat and poultry products, except for bacon. Vinegar, essential oils and vegetable and fruit juice powders are possible natural/agricultural alternatives that researchers are currently looking at. Campops, et al. (2011) TR lines 936-938 , looked at the effectiveness of organic acids in controlling <i>L. monocytogenes</i> . The results of these studies were promising; Lactic Acid cultures also can be used for dry sausage and ham. Bacteriophages (micro-organisms) are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing. Bacteriophage products are typically sprayed directly on food products prior to packaging (GRN 468; GRN 218; (OMRI 2014b)). TR 984 & 985.
9. Are there any alternative substances? [§6518(m)(6)]	X			Lactic Acid Cultures can be used for dry sausage and ham. Bacteriophages (micro-organisms) are utilized as an antimicrobial to control bacteria and control the growth of pathogens such as <i>Listeria monocytogenes</i> , <i>Salmonella</i> , and <i>Campylobacter jejuni</i> in refrigerated foods (TR 983-984) also phage preparations are sprayed onto the surface of RTE meat and poultry products. According to the product data information for LISTEX™ product, phages are considered processing aids and do not have to be declared on the finished product label (Mircros B.V. 2012). This is a different situation from sodium lactate and potassium lactate, which are

			<p>added to meat as ingredients at the rate of 1% to 4.8% as prescribed by USDA-FSIS regulations, depending on the product (Applegate Farms 2004). TR lines 1011-1015.</p>
<p>10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]</p>	<p>X</p>		<p>The TR mentions 3 possible alternatives listed in the USDA – FSIS, Listeria Rule for Ready-To-Eat products. (Lines 853 – 870) discusses these alternatives: (1) a post-lethality treatment and the use of an antimicrobial agent (either of the lactates could be used for this). Example: deli or hotdog products that are steam pasteurized after packaging and have lactates added in the formulation. (2) either a post-lethality treatment or an antimicrobial agent, or antimicrobial process is applied. Under this alternative, sodium lactate and potassium lactate could be used or the post-lethality treatment or the antimicrobial process. Example: a hotdog or deli product that is treated with a post pasteurization treatment after packaging, such as a steam treatment, and does not contain lactates or any antimicrobial agents. And (3) none of the other options are applied and instead the establishment relies on its sanitation program to control Lm. Example: refrigerated chicken nuggets that are not treated with a post lethality treatment or antimicrobials. Additional verification testing requirements for establishments that produced deli or hotdog products are enforced. (Lethality step: defined as cooking or another process such as fermentation or drying that results in a product that is safe for human consumption without further preparation. (USDA FSIS 2012).</p>
<p>11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.</p>	<p>x</p>		

**Category 3. Is the substance compatible with organic handling practices? Sodium and Potassium Lactate**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Materials (both sodium lactate and potassium lactate) have been allowed for use in organic handling, but are now needing to be petitioned for inclusion to the National List, due to the Memo from the NOP to the NOSB dated June 25 <sup>th</sup> , 2014.
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
6. Is the primary use as a preservative? [§205.600(b)(4)]	X			In the original petition from Purac America & Trumark Co.'s in 2004, both sodium lactate and potassium lactate were petitioned for use in organic meat processing as a pathogen inhibitor. In the TR (Lines 670 – 671) it states: " One of the primary uses of sodium lactate and potassium lactate is as a preservative in meat. As stated above, sodium (and potassium) lactate has the ability to extend shelf-life of meat products. The petitioner stated that their targeted use of these two materials was as a pathogen inhibitor primarily to control <i>Listeria monocytogenes</i> .
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		TR (lines 721-723) says: Similar to lactate acid, sodium and potassium lactates do not recreate or replace flavors, colors, textures, or nutritive values lost in processing, but are often used to improve or enhance flavors and textures of food products, especially meat. Sodium lactate is known to enhance meat flavor due to the salty taste that it provides, potassium lactate offers similar attributes but is less salty. Sodium lactate results in enhanced overall flavor and beef flavor intensity (TR line 729-730).

**Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable?** [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Sodium and Potassium Lactate**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			
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 <b>form</b> to fulfill an essential function in a system of organic handling?	X			
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 <b>quality</b> to fulfill an essential function in a system of organic handling?			X	
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 <b>quantity</b> to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information about unavailability include (but is not limited to) the following?			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Other issues which may present a challenge to a consistent supply?			X	



**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Flavors, Nonsynthetic  
August 25, 2015**

**Summary of Proposed Action:** Flavors are currently listed on §205.605(a) of the National List as an allowed nonsynthetic under the following listing: *Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.* A petition was received from the Organic Trade Association on November 6, 2014 to revise the flavors annotation to read: *Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.* The NOSB Handling Subcommittee is recommending the listing to be revised to read as: *“Flavors – Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.”*

### History

Flavors were not added to the National List as the result of a petition. Instead, they were included among substances initially placed on the National List when USDA promulgated regulations pursuant to the Organic Food Production Act of 1990. The NOSB has debated the issue of using natural flavors as ingredients in organic foods. On October 31, 1995 the NOSB recommended the addition of Natural Flavors and stated the following:

The Committee has debated the issue of the use of natural flavors as ingredients in organic foods. The focus of the debate has been whether natural flavors, with certain constraints, are appropriate for use in "organic foods" (95%-100% organic ingredients) or whether natural flavors should be restricted to use in foods "made with organic ingredients" (50%-95% organic ingredients) only...

Recommendation:

Upon implementation, all manufacturers will be required to have certification from the producers of the natural flavors that,

For "organic foods" (95%-100% organic ingredients):

- 1) All of the flavor constituents used in the natural flavor are from natural sources and have not been chemically modified in a way which makes them different than their natural chemical state.
- 2) The natural flavor has not been produced using any synthetic solvent and carrier systems or any artificial preservatives.

For "foods made with organic ingredients" (50%-95% organic ingredients):

- 1) All of the flavor constituents used in the natural flavor are from natural sources and have not been chemically modified in a way which makes them different than their natural chemical state.
- 2) The natural flavor does not contain propylene glycol, any artificial preservatives, and is not extracted with hexane.

Additionally, manufacturers shall provide written documentation in their Organic Handling Plan showing efforts made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:

Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. Grain ethanol, non-synthetic glycerin and non-synthetic acetic acid).

Organic flavor constituents, organic carrier base, and organic preservative agents.

Organic flavor constituents extracted using organically produced solvents, organic carrier base, and organic preservative agents.

The rule was published with the annotation: *Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.* This annotation is applicable to both “organic” and “made with organic” products. On April 20 2006 the NOSB stated the following in their Sunset Review:

There were many comments recommending the continued allowance of non-synthetic flavors in organic handling. The federal register notice regarding Sunset Review asked the public to provide evidence and address concerns for any substance they believed should be discontinued. There was a comment addressing the concern that colors and flavors were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of flavors on October 14, 2005. This technical review offered no information that would suggest that either non-synthetic flavors are inconsistent with organic practices. The use of flavoring substances is regulated by the FDA. All flavoring substances, non-synthetic, fall into one of two categories. They are either GRAS (Generally Recognized as Safe) a designation granted by a panel of technical experts whose authority is accepted by the FDA, or they are food additives that have been reviewed and approved by the FDA directly. To obtain approval from the FDA for a flavor as a food additive, the manufacturer must submit a petition demonstrating safety of the substance with information including manufacturing process, stability data, safety studies and toxicity data. Consequently, all non-synthetic flavoring substances are subject to pre-market approval requirements. There were numerous comments specifically opposing the renewal of non-synthetic flavors on 205.605a. Of these, all but one requested that non-synthetic flavors be listed instead on 205.606, an action which cannot be taken as part of Sunset.

On February 16, 2007 the NOP issued “Guidance for Certifiers on Flavors.” This guidance includes the following:

Flavors do not need to be petitioned to be placed on 205.606 as long as they meet the definition of a flavor, according to FDA, and they are from nonsynthetic sources and are not produced using synthetic solvents and carrier systems or any artificial preservatives. We realize that there are some ACAs certifying flavors, which contradicts the National List...if we have flavors listed as non-agricultural, non-synthetic, how can we at the same time be stating that there are flavors out there able to meet NOP standards, eligible for certification?...

The NOSB completed Sunset Review of Flavors for re-listing and on September 3, 2010 and stated:

The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors...The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was

practical to individually list flavors on the National List, so chose to relist the category as a single listing...In order to avoid unnecessary disruption to industry, we are recommending relisting of Flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing

of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011 the NOP issued a Policy Memorandum on Use of Natural Flavors, this states in part:  
 In 1995 the NOSB reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals....The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this organic market will continue to grow and develop...

The 2017 Sunset review is being considered at the fall 2015 meeting concurrently with this proposal.

**Manufacture:** Flavors can be derived via several different methods. Distillates are a clear, flavorful liquid produced from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture. Essential oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing. Essential oil Isolate is an isolate of an essential oil. Isolates are chemicals or fractions obtained from a natural substance by further distillation. For example, citral can be isolated from lemon oil or lemongrass. Oleoresin are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A Compounded Flavor is a mixture of ingredients such as extracts, essential oils and natural isolates.<sup>1</sup> Processed flavors, also known as reaction flavors, are ones which are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins and fat, which must then be heated for a length of time to yield the desired profile.<sup>2</sup>

Flavoring components (i.e., those ingredients that impart the flavor) as listed here can typically make up 5-100% of the formulation of a flavor. The remaining components are preservatives, carriers and/or solvents that can make up 0-95% of a typical flavor formulation. Nonsynthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" (with other natural flavors) - containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non-flavoring constituents from the named product but still impart the characteristic named flavor.

#### **Discussion:**

As this proposal is focused on revising the annotation, a review of OFPA criteria is not included here.

<sup>1</sup> <http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

<sup>2</sup> [http://www.fona.com/sites/default/files/WhitePaper\\_DevelopmentResources.pdf](http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf)

The goal this proposal is to further the usage of organic flavors while not negatively disrupting business. The Subcommittee agrees with the petitioner that subdividing the flavors into “unavailable categories” or “allowable and unallowable” components would cause unnecessary disruption. Individually listing distinctly different natural flavors would be impractical due to the larger number in usage. Additionally, the petition and rule making process is too long in duration to meet the needs of new product development both in terms of availability of organic flavors and development of formulated organic products.

There are concerns from the Handling Subcommittee that this proposal does not go far enough and that certifiers will be unable to effectively apply commercial availability to flavors. It is the subcommittee’s opinion that this is just a first step and that future NOSB’s should continue to push industry in the development and adoption of organic flavors along the lines original envisioned in 1995:

Current - Natural flavor constituents and non-synthetic carrier base and preservative agents

Proposed, when commercially available: Organic flavor constituents, organic carrier base, and organic preservative agents

Future: Organic flavor constituents, organic carrier base, and organic preservative agents and then Organic flavor constituents extracted using organically produced solvent, organic carrier base, and organic preservative agents.

Comments were received during the 2017 sunset review of flavors (at the spring 2015 meeting) in support of the OTA’s petition from trade associations, ACAs and industry. Additional comments were received about labeling of organic flavors. Concerns were raised about the labeling of organic flavors of a named ingredient when the formulation of the flavor was 95% organic carriers and solvents but all flavoring constituents are non-organic. This proposal while not fully addressing this issue would require commercial availability to be applied by the certifier of the flavor manufacturer, which may serve to crack down on this practice indirectly. The proposal does not directly address this concern and this may be better addressed through certifier guidance from the NOP.

The handling subcommittee revised the original petition by remove the following crossed out words: Flavors – Non-synthetic flavors may be used in ~~products labeled as “organic”~~ when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative. The line “in products labeled as ‘organic’” was removed to make it clear that both flavors and this annotation are applicable to both “organic” and “Made with organic” products.

#### **Subcommittee Action & Vote:**

**Proposed Annotation Motion:** Move to revise the Flavors annotation to read: *Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.*

Motion by: Tom Chapman

Seconded by: Jean Richardson

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

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015**

**National Organic Standards Board  
Handling Subcommittee Proposal  
Ancillary Substances Permitted in Microorganisms and Dairy Cultures  
August 4, 2015**

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in their processing, many may remain in the final product in tiny amounts.

Many public commenters for the first posting were concerned about a process for amending the ancillary substances included in this review between sunset periods. The Handling Subcommittee believes that this captures all of the functional classes in use for microorganism and Dairy Cultures products. Additional ancillaries that fall within one of the functional classes below do not need to be reviewed further to be used. Any new functional class of ancillaries however will have to be petitioned.

**1. Identity of Ancillary Substances Permitted for use in Microorganisms and Dairy Cultures**

<b>Functional class</b>	<b>Substance name</b>
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

2. Identify any ancillary substances, or categories of substances prohibited for use in Microorganisms:  
None Known
3. Describe need for the ancillary substances, review of materials, discussion, and subcommittee vote.

Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species. Capsules forms may have additional cryoprotectants and excipients. (See criteria below for discussion points).

**Evaluation Criteria** (provide narrative responding to each question, repeat as necessary for additional ancillary substances or groups)

1. **Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26). There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

2. **Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

All the substances in the chart above are necessary because they are what keep the microorganism alive, pure and able to perform its function. Formulations of the desired microorganism products are not available without some of these ancillary substances. The availability of organic carriers and substrates is sometimes possible and the NOSB encourages the use of organic ancillary substances whenever possible.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

"There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

#### **Subcommittee Action & Vote:**

Motion to approve the functional classes of ancillary substances in the chart above for use with Microorganisms and Dairy Cultures.

Motion by: Zea Sonnabend

Seconded by: Tom Chapman

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

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 4, 2015**

**National Organic Standards Board  
Handling Subcommittee Proposal  
Ancillary Substances Permitted in Pectin  
August 4, 2015**

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in their processing, many may remain in the final product in tiny amounts.

Many public commenters for the first posting were concerned about a process for amending the ancillary substances included in this review between sunset periods. The Handling Subcommittee believes that this captures all of the functional classes in use for pectin products. Additional ancillaries that fall within one of the functional classes below do not need to be reviewed further to be used. Any new functional class of ancillaries however will have to be petitioned.

1. Identity of **Ancillary Substances Permitted for use in Pectin**

Functional class	Substance name
Stabilizers/standardizing agent.	Sugars (including dextrose)
Buffering agents	Trisodium citrate and other salts

2. Identify any ancillary substances, or categories of substances prohibited for use in Pectin:

None Known

3. Describe need for the ancillary substances, review of materials, discussion, and subcommittee vote.

Ancillary substances for pectin consist only of sugars to standardize the amount of pectin in a product, and buffering salts to stabilize the product.

**Evaluation Criteria** (provide narrative responding to each question, repeat as necessary for additional ancillary substances or groups)

1. **Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

No

2. **Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

The pectin from natural sources is not a consistent product as many variables will influence the concentration and pH of pectin extracted from fruit. Therefore the stabilizing sugars and salt are absolutely necessary to use in processing so that a consistent result is achieved with each batch.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

Yes.

**Subcommittee Action & Vote:**

Motion to approve the functional classes of ancillary substances in the chart above for use with Pectin.

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

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

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 4, 2015**

**National Organic Standards Board  
Handling Subcommittee Proposal  
Ancillary Substances Permitted in Yeast  
August 4, 2015**

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in their processing, many may remain in the final product in tiny amounts.

Many public commenters for the first posting were concerned about a process for amending the ancillary substances included in this review between sunset periods. The Handling Subcommittee believes that this captures all of the functional classes in use for yeast products. Additional ancillaries that fall within one of the functional classes below do not need to be reviewed further to be used. Any new functional class of ancillaries however will have to be petitioned.

**1. Identity of Ancillary Substances Permitted for use in yeast**

Functional class	Substance name
Antioxidants	butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate (PG).
Preservatives	ascorbic acid
Emulsifiers	soybean oil, cottonseed oil, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate, sorbitan monpalmitate.
Defoaming agents	many in TR <sup>1</sup>
Substrate that may remain in final product	food waste, microorganisms, molasses, starch

2. Identify any ancillary substances, or categories of substances prohibited for use in Yeast:  
None Known
3. Describe need for the ancillary substances, review of materials, discussion, and subcommittee vote.

Ancillary substances for yeasts consist primarily of emulsifiers, antioxidants and defoaming agents. These compounds make a more uniform product that maintains its quality and form until used and prevents excess foaming during production.

**Evaluation Criteria** (provide narrative responding to each question, repeat as necessary for additional ancillary substances or groups)

<sup>1</sup> 2014 TR, Table 5, Line 351

1. **Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

While some of the compounds in the chart may have effects on humans or the environment if misused, the tiny amounts necessary to put into yeast ingredients have not been shown to be of concern to human health or the environment. The Handler Subcommittee has confidence that yeast manufacturers are following all regulations about disposing of wastes and worker safety to prevent undue exposure.

2. **Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

Yeasts are very precise strains for the desired end product and great pains are taken to maintain product purity when it is grown. Yeast from natural sources is not a feasible choice for most uses. The ancillaries are necessary to help maintain the purity and to enable the yeast to be a consistent performer.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

Yes.

**Subcommittee Action & Vote:**

Motion to approve the functional classes of ancillary substances in the chart above for use with Yeast.

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

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

**Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 4, 2015**

**Sunset 2017 Review**  
**Meeting 2 - Review**  
**Livestock Substances §205.603, §205.604**  
**October 2015**

As part of the National List Sunset Review process, the NOSB Livestock Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic livestock production.

**Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production**

[Alcohols: Ethanol](#)

[Alcohols: Isopropanol](#)

[Aspirin](#)

[Atropine](#)

[Biologics, Vaccines](#)

[Butorphanol](#)

[Chlorhexidine](#)

[Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Electrolytes](#)

[Flunixin](#)

[Furosemide](#)

[Glucose](#)

[Glycerin](#)

[Hydrogen peroxide](#)

[Iodine](#)

[Magnesium hydroxide](#)

[Magnesium sulfate](#)

[Oxytocin](#)

[Parasiticides: Fenbendazole](#)

[Parasiticides: Ivermectin](#)

[Parasiticides: Moxidectin](#)

[Peroxyacetic/Peracetic acid](#)

[Phosphoric acid](#)

[Poloxalene](#)

[Tolazoline](#)

[Xylazine](#)

[Copper sulfate](#)

[Formic Acid](#)

[Iodine](#)

[Lidocaine](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Procaine](#)

[Sucrose octanoate esters](#)

[Methionine](#)

[Trace minerals](#)

[Vitamins](#)

[EPA List 4 - Inerts of Minimal Concern](#)

[Excipients](#)

**Livestock 205.604 Prohibited nonsynthetic substances**

[Strychnine](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

## Alcohols - Ethanol

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive

**Technical Report:** 1995 TAP; 2014 TR Ethanol

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### Subcommittee Review

Ethanol is a volatile, flammable, colorless liquid. Its use in organic livestock production is limited to use as a disinfectant and sanitizer and is prohibited as a feed additive. It is an active ingredient in antimicrobial solutions and in wipes, and is commonly used to disinfect surfaces, production implements such as ear tagging equipment, and for wound care. Alcohols, including ethanol and isopropanol, are capable of providing rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores.

For denatured alcohol, one or more denaturing agents are generally added to absolute or diluted ethanol for the purpose of making the resulting products unpalatable and therefore undesirable for human consumption. In addition to methanol, some of the more commonly used alcohol denaturants include 1–5 percent of isopropyl alcohol, acetone, methyl ethyl ketone, methyl isobutyl ketone, and denatonium. This attribute allows denatured alcohol to remain exempt from the duty requirements of beverage grade alcohol.

The majority of authorized denaturants are synthetic substances that are not included on the National List. Denaturing agents derived from natural sources could be used to generate denatured alcohol solutions for applications in organic livestock production. Authorized denaturing agents that are naturally derived include essential oils (Bergamot essential oil, cinnamon oil, clove oil, lavender oil, peppermint oil, pine oil, rosemary oil, sassafras oil, spearmint oil, thyme oil, and turpentine oil). Naturally derived substances and pure chemicals, such as camphor, eugenol, menthol, and vinegar, are also listed as authorized denaturants. In addition, the following synthetic substances authorized by FDA as denaturing additives are currently listed on various sections of the USDA National Organic Program's National List:

- **Iodine.** Approved for use in organic livestock production as a disinfectant, sanitizer, and medical treatment. May also be used as a topical treatment, external parasiticide or local anesthetic (7 CFR 205.603(a)(14) and (b)(3)).
- **Isopropanol.** Approved for use in organic crop production as an algicide, disinfectant, and sanitizer, including irrigation system cleaning systems (7 CFR 205.601(a)(1)(ii)). Also approved as a disinfectant only in organic livestock production (7 CFR 205.603(a)(1)(ii)).

- **Potassium Iodide.** Nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic” (7 CFR 205.605(a)).

During the first 2017 Sunset posting for this material, the LS sought feedback on the following questions:

1. Please provide any information regarding the denaturing material typically used in ethanol used in organic livestock production.
2. What are the most common uses of this material?

Public feedback was limited, but was overwhelmingly in favor of continued listing for ethanol. The most common uses listed were for disinfection of the teat end prior to testing for bacteria and for general disinfecting.

While there are several alternatives to this material, ethanol is relatively harmless and provides an additional means of disinfecting, thereby reducing the chances of development of resistant bacteria. The LS is supportive of continued listing of this material.

#### **Motion to Remove**

This proposal to remove ethanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of ethanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

#### **Vote in Subcommittee**

Motion to remove ethanol from §205.603(a)

Motion by: Tracy Favre

Seconded by: Jean Richardson

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

## **Alcohols – Isopropanol**

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

(1)(ii) Isopropanol-disinfectant only

**Technical Report:** 1995 TAP; 2014 TR Isopropanol

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

#### **Subcommittee Review**

The National Organic Standards Board (NOSB) reviewed isopropanol for livestock production in

accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(1)(ii). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Isopropanol meets all the evaluation criteria.

The framework for the recommendation for relisting is inclusive and consistent with the current information provided in the new isopropanol technical evaluation report (henceforth called TR) of February 3, 2014, the 2015 public written and oral comments, and NOSB 2010 action pertaining to this valuable and essential material. The TR states that the body of evidence indicates that fermentative methods using either natural or genetically modified microorganisms are not currently employed in the commercial production of isopropanol. No agricultural land grant agricultural extension publication repositories contained articles or reports related to the practice of using essential oils as disinfectants or any performance data for these oils relative to isopropanol. Thus, it is therefore uncertain whether essential oil mixtures could serve as viable, naturally derived alternatives to isopropanol-based products for equipment and surface disinfection in livestock production. Isopropanol is allowed by the international organic associations such as the International Federation of Organic Agricultural Movements (IFOAM) and Canadian General Standards Board (CGSB).

It was noted during the spring of 2015 written public comment period, 10 organizations and individuals commented. The dissenting views expressed concern about the environmental effect of isopropanol manufacturing process. The support for and against relisting isopropanol, was 80% and 20%, respectively. Those in support relisting isopropanol included the premier organic trade organization, consumer groups, certifying organizations, a premier food safety group, individuals, environmental, organic businesses, and farmer groups. Isopropanol is used as a disinfectant only. In addition, the recent 2014 TR for isopropanol showed that this material posed minimal risk. No report of the release of this material has been reported according to the 2015 TR on isopropanol as stated on lines 361-365, 475-476, and lines 478-484. No new scientific or sufficient information was presented that warrants removal of this material during the 2017 sunset. NOSB voted unanimously in 2010 to retain this critical and valuable material on the National List (NL). We encouraged new and/or scientific information that warranted consideration for subsequent sunset.

### **Motion to Remove**

This proposal to remove isopropanol from §205.603(a)(1)(ii) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont. The subcommittee proposes removal of isopropanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Impact on the environment.

### **Vote in Subcommittee**

Motion to remove Isopropanol from §205.603

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

## Aspirin

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(2) Aspirin-approved for health care use to reduce inflammation

**Technical Report:** 1995 TAP

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/15

### Subcommittee Review

Aspirin has been known and used in medicine for over 100 years. It is widely used as an anti-inflammatory, and to reduce fever and pain. Its half life is short in cattle and it is not as beneficial in reducing pain as flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency.

Aspirin is widely used and supported by stakeholders and should continue to be listed.

This material satisfies the OFPA Evaluation criteria.

### Motion to Remove

This proposal to remove Aspirin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

### Vote in Subcommittee

Motion to remove Aspirin from §205.603

Motion by: Jean Richardson

Seconded by: Tracy Favre

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

## 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 TR

**Petition(s):** 2002

**Past NOSB Actions:** 05/2003 NOSB recommendation; 04/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/24/17

### Subcommittee Review

Atropine is an anti-cholinergic derived from the plant atropa belladonna (deadly nightshade). For commercial veterinary uses it is synthetically derived. It is a highly controlled substance, administered under orders of a veterinarian; generally given orally as an antidote for organophosphate poisoning and as an antispasmodic. The TR describes it as a benign treatment without a holistic or natural alternative. The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI). Atropine is considered an essential treatment of nerve agent poisoning. Public comment indicates its continued listing.

### Motion to Remove

This proposal to remove Atropine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Atropine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

### Vote in Subcommittee

Motion to remove Atropine from 205.603

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

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

## Biologics - Vaccines

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

(4) Biologics – Vaccines.

**Technical Report:** 2014 TR (Aquaculture); 2011 TR (Vaccines from Excluded Methods)

**Petition(s):** 2012 Petition (Aquaculture)

**Past NOSB Actions:** 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation on Vaccines at §205.105; 04/2010 NOSB sunset recommendation; 10/2014 recommendation on Vaccines from Excluded Methods

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Vaccines – Biologics – have been reviewed by the NOSB at Sunset and on several occasions over the

years. Reference is made to the most recent Proposal and Recommendation to the NOP from the NOSB dated August 19, 2014.

The USDA organic regulations at 7 CFR part 205 contain several references that are relevant to the discussion on the use of vaccines in organic livestock production.

The first reference, under the “Livestock healthcare practice standard”, requires that “the producer must establish and maintain preventive healthcare practices, including... administration of vaccines and other biologics” (205.238(a)(6)).

The second reference on the National List of Allowed and Prohibited Substances allows the use of synthetic livestock vaccines as follows: “Biologics – Vaccines.” (205.603(a)(4)) (without annotation).

The third reference at section 205.672 deals with emergency pest or disease treatment which is defined in section 205.2 as a “mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease.” The OFPA Statute (7 U.S.C. 6506(b)(2)) refers to exemptions for organic “farms subject to a Federal or State emergency pest or disease treatment program,” suggesting that Congress did not intend to include locally declared programs. In the past, vaccines made with excluded methods have been required as part of disease eradication programs. It is unclear as to the effects of these eradication programs on organic livestock producers.

The fourth reference is found within section 205.105 of the USDA organic regulations, “Allowed and prohibited substances, methods, and ingredients in organic production and handling”:

To be sold or labeled as “100 percent organic”, “organic,” or “made with organic (specified ingredients or food groups)”, the product must be produced or handled without the use of...

(e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with 205.600(a).

Section 205.600(a), “Evaluation criteria for allowed and prohibited substances, methods and ingredients” specifies:

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

205.600(a) Synthetic and nonsynthetic substances considered for inclusion on, or deletion from, the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

Thus, under this section (205.105(e)), the use of excluded methods is prohibited in organic production. To date, the NOSB has not recommended any vaccines made with excluded methods be added to the National List.

Vaccines are critical for the prevention of disease and to prevent needless suffering of livestock. Organic

livestock cannot be treated with antibiotics and maintain their organic status.

Public Comment strongly supports continuing to re-list Biologics-vaccines.

### **Motion to Remove**

This proposal to remove Biologics-vaccines will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Satisfies OFPA criteria

### **Vote in Subcommittee**

Motion to remove Vaccines from §205.603

Motion by: Jean Richardson

Seconded by: Calvin Walker

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

## **Butorphanol**

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

(5) Butorphanol (CAS #-42408-82-2) - 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 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

**Technical Report:** 2002 TR

**Petition(s):** 2002 Petition

**Past NOSB Action :**s 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation

**Recent Regulatory Background:** National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### **Subcommittee Review**

The National Organic Standards Board (NOSB) reviewed butorphanol for use in livestock production as a pre-operative treatment of pain before surgery in accordance with criteria in the Organic Foods Production Act (OFPA), 7 Code of Federal Regulation (CFR) §205.603(a), the 2002 technical advisory panel (TAP), past NOSB actions, and 2015 public comments. No new nor scientific information has been received that warrants removal of this material from the national list (NL) at this time.

Impacts of manufacture of butorphanol are unknown (TAP p25.) Butorphanol is used by injection. Butorphanol and metabolites are not considered toxic if released. Although the fate of butorphanol in the environment is not known, the metabolites that are excreted via urine and bile are water-soluble which will not likely accumulate in the local environment. Butorphanol disposal in city water drainage/sewer systems is accepted practice (TAP pp19, 25). There is a potential for abuse of butorphanol. “Metabolites of the drug can cross the placenta and pass into the mammary gland and into milk” (TAP pp20, 25, 26, 28.)

As it relates to essentiality, the TAP states, “Butorphanol belongs to a general class of drugs known as opiate agonists. It is commonly used as an anesthetic used to treat patients prior to surgery. Other related drugs in this class include buprenorphine, fentanyl, meperidine, and morphine. Xylazine, acepromazine, and butorphanol serve similar functions but each has its own specific advantages that make it the preferred treatment at the time: acepromazine has no analgesic activity, it is only a sedative; xylazine has both analgesic and sedative properties; and butorphanol is a pain killer with no real sedative activity” (TAP p24.) Although, “there are non-synthetic opiates (refers to a group of drugs used for treating pain), butorphanol is preferred for several reasons: it is associated with fewer adverse effects for the animal; it has less abuse potential in humans thereby reducing unwanted consequences if the drug is “diverted” to illicit use.” Butorphanol is used for livestock to ease pain just prior to surgery.

Butorphanol has been FDA approved for use as an anesthetic in non-food animals. Its use in food animals is an extra-label use (ELU) governed by the Animal Medicinal Drug Use Clarification Act, which allows animal drugs to be used for ELUs when, “limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat.” The material must be administered by a licensed veterinarian. If all precautions are followed and the drug is administered appropriately, the NOSB judged that there will be no harm done to humans who consume the meats from these animals—and the livestock are able to tolerate surgery, recover quickly, and grant the farmer economic satisfaction, according to the 2002 TAP review of butorphanol.

The withdrawal periods for butorphanol in the organic regulations are twice those in the [Food Animal Residue Avoidance Databank](#) (FARAD). FARAD is a university-based national program that serves as the primary source for scientifically-based recommendations regarding safe withdrawal intervals of drugs and chemicals in food-producing animals. From the FARAD website (<http://www.farad.org/eldu/eldumain.asp>):

According to AMDUCA, veterinarians who treat food animals with drugs in an extra-label manner must use evidence “*...derived from food safety data or other scientific information...*” in order to determine an appropriate withdrawal interval (WDI) that allows for a conservative estimate of drug residue level in edible animal tissues. Based on published scientific reports and population-based pharmacokinetic modeling, FARAD has developed a [WDI Lookup Tool](#) that provides recommended WDI values for a limited number of approved food animal drugs used in an extra-label manner.

**IMPORTANT NOTE:** The withdrawal interval (WDI) is a scientifically-derived recommended withholding time for a drug following its extra-label use in a food animal. The WDI is distinct

from the official withdrawal time (WDT) for a drug. WDTs are established by the FDA for all approved (labeled) uses of food animal drugs and can be located in [VetGRAM](#) or at the [FDA Center for Veterinary Medicine](#).

The TAP states, “European Union: Butorphanol tartrate is included as an Annex II type drug (Reg. 1076/98). This means that it is permitted for use in veterinary medicine as of January 1, 2000.” (p. 17) However, it is listed for equine species (Commission Regulation (EU) No 37/2010), and EU law permits extra-label use (cascading use) only “provided that the medicinal product, where administered to animals whose flesh or products are intended for human consumption, contains only substances to be found in a veterinary medicinal product authorized for such animals in the Member State concerned and that in the case of food-producing animals the veterinarian responsible specifies an appropriate withdrawal period to ensure that food produced from the treated animals does not contain residues harmful to consumers.” (Council Directive 90/676/EEC).

The NOSB judged butorphanol to be consistent with consumer perceptions of organic products. The NOSB’s 2002 votes were 11 favored, 1 absent, and 2 abstained and the NOSB’s 2010 vote was unanimous to retain this material on the NL.

Comments received generally supported the continued listing of butorphanol. Two dairy organizations, one dairy cooperative, and one former NOSB member commented in favor of continued use. One organization requested that the LS determine the impacts of the metabolites of butorphanol in milk and when excreted; and determine the legality of the use under AMDUCA, since labels prohibit the use in food-use animals. With regard to the legality of the use and the presence of butorphanol and its metabolites in milk, USDA did determine that butorphanol is listed in the Food Animal Residue Avoidance Databank (FARAD), and the listed meat withdrawal and milk discard times are twice those listed in FARAD (2007 FR Notice). With regard to the impacts of the excreted metabolites, the TAP review did not consider them problematic.

However, reliance on AMDUCA’s exemption of ELUs can be problematic (Wren, 2008), and the Livestock Subcommittee encourages the Food and Drug Administration to address these uses directly through labeling.

### References Cited

NOSB, 2002. Summary of Minutes: National Organic Standards Board, September 17-19, 2002.

Washington, D.C.

TAP. 2002. Butorphanol (Livestock).

Geni Wren, 2008. Options for Pain Management. Bovine Veterinarian.

<https://ahdc.vet.cornell.edu/Sects/NYSCHAP/docs/BovineVetpain01-08.pdf>

USDA, 2007. National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Livestock). Federal Register Vol. 72, No. 238, Wednesday, December 12, 2007, pp.70479- 70486.

Council Directive 90/676/EEC Of 13 December 1990 amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31990L0676>

Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [http://ec.europa.eu/health/files/eudralex/vol-5/reg\\_2010\\_37/reg\\_2010\\_37\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf)

### Motion to Remove

This proposal to remove Butorphanol will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Butorphanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### Vote in Subcommittee

Motion to remove Butorphanol from §205.603

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

## Chlorhexidine

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

(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

**Technical Report:** 1999 TAP; 01/2010 TR; 2015 TR

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

**Past NOSB Actions:** 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### Subcommittee Review

In 2009, the NOSB recommended chlorhexidine be added to the National List as a teat dip for use when alternative teat dips have lost their effectiveness. Chlorhexidine kills bacterial cells by damaging cell membranes and precipitation of cytoplasmic proteins and macromolecules.

Chlorhexidine is mildly to moderately toxic to mammals in oral, dermal and inhalation exposure (2015 TR lines 314-315) and is an eye irritant (line 324) and pulmonary toxicant (line 318). However, “chlorhexidine teat dips are typically used in small amounts, at low concentrations (e.g., 0.5%) and under relatively controlled conditions” (TR lines 365-366), which limits exposure concentration.

For the first round of public comments, the subcommittee asked “Have you used chlorhexidine as a teat dip? If so, why did you need to use it?” No comments were received in answer to those questions. Several general comments were received recommending that chlorhexidine should remain on the National List. There were no comments suggesting that chlorhexidine be removed from the List.

### **Motion to Remove**

This proposal to remove chlorhexidine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of chlorhexidine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None given

### **Vote in Subcommittee**

Motion to remove Chlorhexidine from §205.603(a)

Motion by: Francis Thicke

Seconded by: Calvin Walker

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

## **Chlorine materials**

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

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

**Technical Report:** 2006 TR

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### **Subcommittee Review**

#### **Specific Uses of the Substance:**

##### *Sodium and Calcium Hypochlorite*

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems.

### *Chlorine Dioxide*

Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a).

Bleach materials are currently used for disinfection of livestock facilities.

#### **Approved Legal Uses of the Substance:**

With regard to organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. Similarly, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from all of these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 mg/L).

**Discussion:** The NOSB in its initial request for public comment asked:

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

The NOSB Livestock committee did not receive specific answers to the above questions. The majority of the comments about chlorine materials were form letters opposing any chlorine use in organic production and non-form letter comments were primarily related to the Crops and Handling Committees.

Several commenters opposed to the relisting stated:

- They are concerned about the NOP clarification on the use of chlorine, which allows for a higher concentration than allowed in the Safe Water Drinking Act to be used in wash tanks. They were especially concerned about organic food products that could absorb the higher concentration of chlorine into the food. They stated that poultry, eggs, leafy vegetables, root crops and more could absorb highly chlorinated water and the final effluent after the wash tank could still only contain the required 4 PPM. To address this concern, they suggested the annotation for chlorine be amended to the following: Chlorine materials, only as present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. They further went on to say that the use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the

wash water.

- There is a growing unease that we (commenters) share about the need to eliminate chlorine from organic disinfection processes because of concerns about its efficacy on the produce and about the environmental and health risks associated with the formation of carcinogenic halogenated disinfection by-products.

Several commenters in support of relisting stated:

- Calcium hypochlorite, chlorine dioxide, sodium hypochlorite: these materials are so basic to hygienic, sanitary livestock keeping that no further comment is needed. To do away with chlorine (as well as iodine, hydrogen peroxide and other germicides) would do permanent damage and harm to the organic livestock industry.
- Chlorine Materials (Calcium hypochlorite, sodium hypochlorite, chlorine dioxide): These chemicals are used in the industry for sanitization and their incorporation is required for food safety per the Pasteurized Milk Ordinance. Our partners in dairy production and in our member farms choose chlorine materials often as the preferred sanitizer for food contact surfaces. Disallowing sodium hypochlorite, calcium hypochlorite and chlorine dioxide would have a profound effect on the dairy industry. We support the continued listing of Chlorine Materials on the National List.
- Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite – The use of these products in disinfecting and sanitizing facilities and equipment is critical to the health of the animals and humans.
- Chlorine products are required by the Federal Government via the Pasteurized Milk Ordinance (PMO) that governs the cleaning of milkhouse equipment on dairy farms shipping milk. To sanitize and sterilize both calf feeding and milking equipment (bottles, nipples, buckets, milking pipeline, receiver jar, bulk tank, etc.)

While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation. There are also specific requirements to use chlorine above the 4ppm SDWA limit in several commodity specific industries. For example, The Pasteurized Milk Ordinance states that the product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of Chlorine Materials.

### **Motion to Remove**

This proposal to remove Chlorine Materials will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of these materials from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

**Vote in Subcommittee**

Motion to remove chlorine materials from (Calcium hypochlorite, Sodium hypochlorite, Chlorine dioxide) 205.603(a)

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Electrolytes

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

(8) Electrolytes—without antibiotics

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

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review**

The National Organic Standards Board (NOSB) has reviewed electrolytes for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(8) – without antibiotics. The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. It is the NOSB-LS view that electrolytes meet the above evaluation criteria and should not be removed from the National List.

Historically speaking, electrolytes have been recommended for relisting based on the material compatibility as recommended by the technical advisory panel (TAP) of October 1995 and the unanimous NOSB 2010 support of this material. Electrolytes are being used to prevent or treat dehydration with resulting loss of minerals. Also, electrolytes provide minerals and sugars lost in dehydration. The annotation for electrolytes is that it *must not* contain antibiotics. On April 29, 2010, NOSB voted 14 yes, 0 no, 0 abstain, and 1 absent for this material. The most recent Technical Evaluation Report (TR) on March 20, 2015 provided a detail overview of electrolytes use. Also, the 2010 OMRI Generic Material List, states that electrolytes are substances such as potassium, calcium, magnesium, and sodium that are essential to metabolic functioning. Electrolytes are important in the care of animals to prevent dehydration and animals suffering from diarrhea, anorexia or the inability to absorb fluids from the digestive tract (OMRI 2010). In essence, electrolytes are only to be used when preventive practices and veterinary biologics are inadequate these type of conditions or illnesses. They may not be used in the absence of an illness.

The 2015 public comments are overwhelmingly in support the relisting of this material. No new scientific or meritorious information has been brought forth since the last 2010 sunset review to warrant the

removal of this material. During the last sunset review by NOSB in 2010, the material was unanimously supported for relisting on the national list (NL) without any annotation or change, except that any electrolytes must not contain any antibiotics.

During the spring of 2015 public comment period, eight organizations and individuals (67%) supported the relisting, three were neutral (25%), and one individual did not support (8%) the relisting of electrolytes. Those in support included a food safety organization, consumer groups, a cooperative, individuals, etc. The one that was against did not support electrolytes due to the material being a synthetic. The three organizations remain neutral on the material. Thus, in the final analysis, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

#### References

1. [http://www.omri.org/sites/default/files/Newsletter\\_Summer\\_2010.pdf](http://www.omri.org/sites/default/files/Newsletter_Summer_2010.pdf)

#### **Motion to Remove**

This proposal to remove Electrolytes will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Electrolytes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

#### **Vote in Subcommittee**

Motion to remove Electrolytes from 205.603(d)(8)

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

## Flunixin

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

(9) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA

**Technical Report:** 2007 TAP Report

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

**Past NOSB Actions:** 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation

**Recent Regulatory Background:** National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

## Subcommittee Review

### Specific Uses of the Substance:

Flunixin is used mostly for veterinary purposes as an analgesic and an anti-inflammatory drug. It persists in inflammatory tissues and is associated with anti-inflammatory properties which extend beyond the period associated with plasma drug concentrations. This has to do primarily with flunixin's counterclockwise spin of light absorption.

Flunixin meglumine, in its drug form, exists for intravenous or intramuscular use in horses and for intravenous use in beef and dairy cattle. Flunixin has been used to rapidly reduce the fever and lung inflammation that typically accompany bovine respiratory disease (BRD). As a result of usage, cattle feel better faster and have fewer lung lesions in comparison to treatment with other remedies. Additionally, flunixin has been used to reduce inflammation associated with endotoxemia.

### Approved Legal Uses of the Substance:

OFPA states in Sec. 6509(d):

#### (d) Health Care.

(1) **Prohibited Practices.** For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not

- (A) use subtherapeutic doses of antibiotics;
- (B) use synthetic internal paracitocides on a routine basis; or
- (C) administer medication, other than vaccinations, in the absence of illness.

Flunixin is often used by veterinarians to treat inflammation and pain.

**Discussion:** The NOSB in its initial request for public comment asked:

In the event the NOSB votes to remove flunixin from the National List, would aspirin serve as a replacement? If not, why not?

Several commenters in support of relisting stated:

- This is an NSAID (non-steroidal anti-inflammatory drug) related to aspirin, but about 100 times as strong. It is injected and can bring pain relief, fever reduction and keep inflammation in check within a very short time. Often times animals will start to eat again within 30 minutes – this is good for if an animal will start to eat again, it often can “eat its way” out of a problem. It is a critically important material in veterinary medicine. Aspirin would not come close to replacing it. Flunixin is far superior in relieving abdominal pain due to colic and other digestive disturbances.
- Specific comments describing the use of this substance on organic farms: On rare occasions, prescribed by a vet for an acute situation with one of our cows. Specific comments regarding the availability and efficacy of alternatives: Most potent anti-inflammatory available for organic livestock. Don't know of any other available as powerful.
- Flunixin is a nonsteroidal anti-inflammatory (NSAID) drug used for the treatment of pain, inflammation, and pyrexia (fever). This drug contributes significantly to the comfort and welfare of ill or injured animals. It remains an important analgesic with properties different from those of other available drugs. We support the continued listing of Flunixin on the National List.

There were no comments received opposing the relisting of flunixin. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of flunixin.

### **Motion to Remove**

This proposal to remove flunixin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of flunixin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### **Vote in Subcommittee**

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 0 No: 4 Abstain: 1 Absent: 1 Recuse: 0

## **Furosemide**

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable (10) Furosemide (CAS #-54-31-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA

**Technical Report:** 2003 TR

**Petition(s):** 2002 Petition

**Past NOSB Actions:** 05/2003 NOSB recommendation for addition to the National List; 10/2010 sunset recommendation

**Recent Regulatory Background:** National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### **Subcommittee Review**

#### **Specific Uses of the Substance:**

“Furosemide is a diuretic. It has been used extensively since 1964 in the treatment of edema and hypertension.” “This medicine is used to rid the body of excess fluid (salt and water). Patients who frequently have this problem are ones with weakened hearts (congestive heart failure), poor kidney function, or poor liver function. It can be used to reduce blood pressure in these patients.” (2003 TR, pg. 4.)

#### **Clinical Uses:**

- Major uses: acute pulmonary edema, acute hypercalcemia, management of edema
- Other uses: reduction of intracranial pressure, hyperkalemia: loop diuretics increase potassium

excretion and effect increased by concurrent administration of NaCl and water, acute renal failure: may increase rate of urine flow and increase potassium excretion, may convert oligouric to non-oligouric failure {easier clinical management}and renal failure duration -- not affected, anion overload: bromide, chloride, iodide: all reabsorbed by the thick ascending loop: systemic toxicity may be reduced by decreasing reabsorption, concurrent administration of sodium chloride and fluid is required to prevent volume depletion

**International:**

**IFOAM:** not specifically mentioned in approved list

**JAPAN:** not specifically mentioned in approved list

**EUROPEAN UNION:** not specifically mentioned in approved list

**Discussion:** The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on furosemide.

Comments in support of relisting stated:

- Furosemide is used for the treatment of physiological parturient edema of the mammary gland and associated structures. A diuretic-saluretic for prompt relief of edema. This product is important to the humane treatment of organic animals.

Comments opposed to relisting stated:

- This is a compound which could be sunsetted. Its use is very limited and there are other natural compounds that can off-set it, such as coffee, as far as being a diuretic (stimulates urination). I submitted this material in the original "batch" in 2002 but no longer think it is necessary – in contrast to butorphanol, flunixin, xylazine, and tolazoline which are vital to provide humane care and to relieve pain and suffering in the livestock that are part of the organic sector.

The subcommittee is planning to remove furosemide at the fall meeting unless we receive public or written comments from stakeholders why alternatives could not be a suitable alternative for furosemide.

**Motion to Remove**

This proposal to remove furosemide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of furosemide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

**Vote in Subcommittee**

Motion to remove furosemide from 205.60()

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 5 No: 1 Abstain: 0 Absent: 0 Recuse: 0

## Glucose

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

(11) Glucose

**Technical Report:** 1995 TAP

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; [10/2010 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### Subcommittee Review

The National Organic Standards Board (NOSB) reviewed glucose for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(11). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Glucose meets the above evaluation criteria.

Glucose is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995, the 2015 public written comments, the unanimous NOSB 2010 support of this material, and no new information. Glucose is a synthetic substance allowed in organic livestock production for medical treatment of ketosis. For animal health purpose, glucose is used as an aid in the treatment of primarily ketosis in cattle. In the treatment of hypoglycemia, glucose is used as needed energy source and must bear a veterinarian's prescription. It is critical if used for the aforementioned purposes. The use of glucose provides a more rapid recovery to livestock in a hypoglycemia state. There is no current annotation for glucose. During the last sunset review by NOSB in 2010, the Board unanimously supported the relisting of glucose on the National List (NL) without any annotation or change. During the spring of 2015 public comment period, 11 organizations and individuals (73%) supported the relisting, two were neutral (18%), and one individual did not support (9%) the relisting of glucose. Those that were neutral did not give a reason for their neutrality. Those in support included a premier food safety organization, consumer groups, a cooperative, individuals, etc. Conversely, there was no new scientific or sufficient information presented since the last sunset to warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

### Motion to Remove

This proposal to remove glucose from §205.603(a)(11) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of glucose from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

**Vote in Subcommittee**

Motion to remove Glucose from §205.603(a)

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

## Glycerin

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(12) Glycerin - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

**Technical Report:** 1995 TAP (Livestock); 2010 TAP (Livestock)

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

**Past NOSB Actions:** 1997 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review**

Glycerin has a wide variety of uses, including use as a food additive, flavor and coloring carrier and humectant.

Glycerin—produced by hydrolysis of fats and oils, is listed at 7 CFR section 205.603, synthetic substances allowed for use in organic livestock production, as a livestock teat dip.

Glycerin has excellent anti-bacterial, anti-fungal, and anti-viral properties. Glycerin is readily biodegradable and will partition into the water phase. Glycerin is readily degraded by microorganism under both aerobic and anaerobic conditions. Glycerin is not expected to bioaccumulate.

Public comment was heavily in favor of the continued listing of this material, as glycerin is the main component in many teat dips and provides unique emollient properties which prevent chapping and damage to udders, especially in winter.

The Livestock subcommittee recommends continued listing of Glycerin.

**Motion to Remove**

This proposal to remove Glycerin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Glycerin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

**Vote in Subcommittee**

Motion to remove Glycerin from §205.605(a)

Motion by: Tracy Favre

Seconded by: Ashley Swaffar

Yes: 0 No: 5 Abstain: 1 Absent: 2 Recuse: 0

## Hydrogen peroxide

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

**Technical Report:** 1995 TAP (Crops); 2015 TR (Crops)

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

**Past NOSB Actions:** 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review**

The National Organic Standards Board (NOSB) reviewed hydrogen peroxide for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) § 205.603(a)(13). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. Hydrogen peroxide meets the above evaluation criteria.

Hydrogen peroxide is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995 (Crops), the 2015 public written comments, the unanimous NOSB 2010 support of this material, and no new scientific or meritorious information. Hydrogen peroxide is a synthetic substance allowed in organic livestock production for medical treatment. It is used as a readily available disinfectant and broad spectrum germicide. It is an important cleaning agent for use on contact surfaces, such as equipment, calf pails, bottles, and utensils. The material is used to clean wounds. The use of chlorine dioxide and soap and water diluted with iodine are alternatives. There is no annotation needed. During the last sunset review by NOSB in 2010, the material was unanimously supported for relisting on the National List (NL) without any annotation or change.

During the spring of 2015 public comment period, 25 organizations and individuals (93%) supported the relisting, two (2) were against (7%). Those in support included a premier food safety organization, a premier organic trade group, a premier environmentalist group, various consumer groups, a cooperative, a premier farm group, organic food businesses, individuals, etc. Those against did not support hydrogen peroxide due to the material being a synthetic. However, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset.

**Motion to Remove:**

This proposal to remove hydrogen peroxide from §205.603(a)(13) is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of hydrogen peroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

**Vote in Subcommittee**

Motion to remove Hydrogen peroxide from §205.603(a)

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

**Iodine**

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

(14) Iodine

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

(3) Iodine

**Technical Report:** 1995 TAP; 2014 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review**

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 anti-microbial teat dips, used 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. 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 a number of other ingredients in iodine based teat dips, some

of which may be excipients.

One of the nonionic surfactants used is nonylphenol polyethylene glycol ether (NPE). NPEs are known to have negative environmental impacts, even at low levels, notably in aquatic systems, and a Technical Report for NPEs was requested and received by the NOSB Crops Subcommittee and reviewed as part of this analysis.

**The Livestock Subcommittee requested additional information during the first posting for iodine, posing the following questions:**

1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comment indicates that iodine is critical to organic livestock production and that it is widely used. Scientific research suggests that the use of NPEs in complexing iodine for use in organic livestock production should be rapidly phased out, and public comment clearly indicates that the dairy industry, starting in Fall 2014, began moving quickly to eliminate NPEs from iodine based livestock teat dips and disinfectants. Iodine based teat dips are now available labeled “NPE-free”. Some milk buying companies require dairy producers to stop using teat dips containing NPEs.

It is recommended that dairy producers check with their teat dip suppliers to make sure that from now on their farm’s teat dip and other iodine uses will be one of the many formulations with no NPEs.

The Livestock Subcommittee does not recommend removal of iodine from the National List but the Livestock Subcommittee will propose a separate annotation requiring the use of iodine made without NPEs.

**Motion to Remove**

This proposal to remove iodine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of iodine from the National List.

**Vote in Subcommittee**

Motion to remove iodine from 205.603(a)(14) and 205.603(b)(2)

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## Magnesium hydroxide

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable (15) Magnesium hydroxide (CAS #-1309-42-8)—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 use by or on the lawful written order of a licensed veterinarian.

**Technical Report:** 2007 TR

**Petition(s):** 2002 Petition

**Past NOSB Actions:** 2002 NOSB recommendation; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### Subcommittee Review

#### Specific Uses of the Substance:

Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Organic farmers historically use magnesium hydroxide, for cattle, particularly, with digestive problems. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. Magnesium hydroxide is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid. Magnesium hydroxide is also used as a fertilizer (in the form of lime) as a substitute for more expensive chemical fertilizers.

**Discussion:** The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on magnesium hydroxide.

Comments in support of relisting stated:

- This is a compound which helps correct grass tetany (low magnesium in the blood stream) which occurs in the lush growing times of spring pasture. It is also a good antacid for possible rumen acidosis
- We use for the extremely occasional cow with bowel function problems.

There were no comments received opposing the relisting of magnesium hydroxide. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of magnesium hydroxide.

### Motion to Remove

This proposal to remove magnesium hydroxide will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of magnesium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
Compatibility

**Vote in Subcommittee**

Motion to remove Magnesium hydroxide from §205.603

Motion by: AS

Seconded by: CW

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Magnesium sulfate

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable (16) Magnesium sulfate

**Technical Report:** 1995 TAP; 2011 TR

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review****Specific Uses of the Substance:**

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 (Dodman, 2010).

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 (Organic Livestock Research Group, 2000) (2011 TR Line 87). 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 (Epsom Salt Council, 2009).

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 (Champness, 2007). If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously (Papich, 2007).

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 (Harris, 2005).

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 (Epsom Salt Council, 2009).

#### **International:**

The Canada Food Inspection Agency, Food and Drug Regulations (last modified in 2009) permit the use of magnesium sulfate as a soil amendment and crop nutrient when a soil deficiency has been documented. Acceptable forms of magnesium sulfate include mined kieserite and natural or synthetic Epsom salt. Mined sources of magnesium sulfate are permitted for use in healthcare products and production aids. Nonsynthetic sources of magnesium sulfate are classified as a food additive. Sulfates produced using sulfuric acid are prohibited (Canadian General Standards Board, 2009).

The European Economic Community (EEC) Council Regulation permits the use of non-synthetic magnesium sulfate (kieserite) as a fertilizer and soil conditioner (Annex I, EC No. 889/2008). Non-synthetic magnesium sulfate is also permitted as a feed material of mineral origin (Annex V, EC No. 889/2008). Magnesium sulfate is not listed as an approved organic processing agent.

International Federation of Organic Agriculture Movements (IFOAM) lists magnesium sulfate as a permissible mineral for use as a fertilizer and soil amendment agent (KRAV, 2001). Approved mineral fertilizers can only be applied in their natural form (i.e., without any further processing to increase solubility, with the exception of grinding).

#### **Discussion:**

The NOSB in its initial request for public comment had no specific questions for comments. Very few comments were received on Magnesium Sulfate.

Comments in support of relisting stated:

- This is a good natural laxative.
- We use Epsom salts to occasionally soak sore or infected feet on cows.

There were no comments received opposing the relisting of Magnesium Sulfate. This material satisfies the OFPA Evaluation criteria and the Handling committee supports the relisting of Magnesium Sulfate.

#### **Motion to Remove**

This proposal to remove Magnesium Sulfate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Magnesium Sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
Compatibility

#### **Vote in Subcommittee**

Motion to remove Magnesium sulfate from §205.603

Motion by: Ashley Swaffar

Seconded by: Calvin Walker

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Oxytocin

**Reference:** 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable  
(17) Oxytocin -use in post parturition therapeutic applications

**Technical Report:** 1995 TAP; 2005 TR

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### Subcommittee Review

The National Organic Standards Board (NOSB) conducted a review of oxytocin for use in livestock production in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(a)(17). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment.

For 20 years (since 1995), oxytocin has been recommended for relisting to the National List (NL). The technical advisory panel (TAP) of October, 1995 and the unanimous approval by the 2010 NOSB 2010 were to relist of the material. The relisting vote on April 29, 2010 was 14 yes, 0 no, 0 abstain, and 1 absent. Oxytocin is currently included on the NL of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic livestock production 7 CFR §205.603 (a)(17). The use of oxytocin is limited to “use in post parturition therapeutic applications.” The uses are not specifically defined, but presumably do not include prolonged use to promote milk production. According to the TAP of 1995, there are no well explored or acceptable alternative practices or materials for the substitution of the injection of synthetic oxytocin in “certain health cases” in livestock production. Homeopathic herbs or acupuncture may alleviate some symptoms and conditions associated with stress at parturition.

During the spring of 2015 public comment period, six (6) organizations and individuals (67%) supported the relisting, two (2) were neutral (22%), and one (1) individual did not support (8%) the relisting of material. Those in support included a premier food safety organization, consumer groups, a cooperative, individuals, etc. The one individual that was against did not support material due to the material being a synthetic. Thus, in the final analysis, no new scientific or sufficient information was presented that warrant removal of this material during the 2017 sunset. We encouraged new and/or scientific information that warrants consideration for subsequent sunset review of the material.

Oxytocin is used in post parturition therapeutic applications in organic livestock production. Oxytocin is important in some cases when it is necessary to use for relaxing the pelvic bone of the female during birthing to help save the life of the offspring(s) coming through the birth canal and reduce the stress on the female during this critical time of birthing.

**Motion to Remove**

This proposal to remove Oxytocin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Oxytocin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

**Vote in Subcommittee**

Motion to remove Oxytocin from 205.603(a)17

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

## Parasiticides, Fenbendazole

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

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only

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

**Petition(s):** [2007 Fenbendazole](#)

**Past NOSB Actions:** [2008 NOSB recommendation](#)

**Recent Regulatory Background:** Added to National List, effective May 16, 2012 ([77 FR 28472](#))

**Sunset Date:** 5/16/2017

**Subcommittee Review**

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of parasiticides, and regulate of the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
- (1) Selection of species and types of livestock with regard to suitability for site-specific

conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided that such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

**In October 1999**, the NOSB voted on three parasiticides for inclusion on the National List. Only Ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In May 2008, Fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when Fenbendazole was added to the National List, Ivermectin (and possibly Moxidectin) should come off the List.

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): “If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than

two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan.”

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

For conventional livestock production, no milk withdrawal time is required for either Fenbendazole<sup>1,2</sup> or Moxidectin.<sup>3,4</sup> Ivermectin is not labeled for use in dairy animals, and no milk withdrawal time has been established for Ivermectin.<sup>5,6</sup> However it is used under veterinary supervision under provisions of AMDUCA.

Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. (TR 2015)

In its initial request for public comment, the Livestock Subcommittee asked the public “Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?”

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common comment received was that Ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and Ivermectin are both in one class of parasiticides and Fenbendazole is in a

<sup>1</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf>

<sup>2</sup> <http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf>

<sup>3</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf>

<sup>4</sup>[http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com\\_EN/product\\_files/cydectin-pour/Cydectin\\_Pour\\_On\\_label.pdf](http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf)

<sup>5</sup><http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=128-409>

<sup>6</sup> <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162>

separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the National List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas Ivermectin and Moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelmintic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

1. Fenbendazole, which is considered the most environmentally benign, is annotated to require the "written order of a licensed veterinarian. Ivermectin and Moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticides for convenience.
2. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and Moxidectin have no milk withdrawal time for use in conventional production.

The Livestock Subcommittee will be preparing a proposal to modify Sections 205.603 and 205.238 as they apply to use of fenbenzadole, including reduction in Withholding Period. The Livestock subcommittee may also propose to allow sheep wool to be sold as "organic" after a withholding period.

### **Motion to Remove**

This proposal to remove Fenbendazole will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Fenbendazole from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

**Vote in Subcommittee**

Motion to remove Fenbendazole from §205.603

Motion by: Francis Thicke

Seconded by: Jean Richardson

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

## Parasiticides, Ivermectin

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

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

**Technical Report:** 1999 TAP (Fenbendazole, Ivermectin); 2015 Technical Evaluation Report

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

**Past NOSB Actions:** 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

**Subcommittee Review**

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of parasiticides and regulate the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (c) The producer must establish and maintain preventive livestock health care practices, including:
  - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
  - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
  - (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (d) When preventive practices and veterinary biologics are inadequate to prevent sickness, a

producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation “for control of internal parasites only” was included for moxidectin for the given reason that, “There is much less chance of any kind of contamination if it is used for internal parasites versus external.” According to the meeting notes, “It was the committee’s opinion, that (moxidectin) failed on Criteria 1, and that was the reason for the proposed annotation because of concern about the half-life of the material and impact on soil organisms.” However, the board noted then that moxidectin “is also less problematic” than ivermectin. Further, it should be noted that just before the NOSB vote on moxidectin, a board member corrected an error that had been part of the discussion leading to the annotation: it was brought up that the 2003 TAP review indicated the half-life of moxidectin in soil to be two months, not six months as had been reported in the evaluation criteria document (which had led to support for the annotation).

The 2015 TR indicates that “The half-life for degradation of moxidectin in the environment may be up to 130 days,” and the half-life of ivermectin to be “127 days in soil.” However, other sources indicate that the half-life of these materials can be quite variable, depending on temperature and soil conditions. For example, the half-life of ivermectin in a soil/feces mixture was found to be 91 to 217 days during winter weather conditions and 7 to 14 days during the summer period.<sup>7</sup>

Although the NOSB approved the addition of moxidectin to the National List in 2004, the US Agriculture

<sup>7</sup> Fate of Pharmaceuticals in the Environment and in Water Treatment Systems. 2008. Diana S. Aga ed., p. 128. CRC Press.

Secretary did not initially accept NOSB's recommendation because moxidectin was labeled as a macrolide antibiotic. However, subsequent clarification found that moxidectin belongs to the polyene class of macrolides, "which unlike their erythromycin counterparts do not possess antibiotic properties" (2015 TR lines 100 – 111). Moxidectin was then added to the National List.

In May 2008, fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when fenbendazole was added to the List, ivermectin (and possibly moxidectin) should come off the List (meeting notes, page 207).

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): "If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan."

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

For conventional livestock production no milk withdrawal time is required for either fenbendazole<sup>8,9</sup> or moxidectin.<sup>10,11</sup> Ivermectin is not approved for use in dairy animals, and no milk withdrawal time has been established for ivermectin.<sup>12,13</sup>

<sup>8</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf>

<sup>9</sup> <http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf>

<sup>10</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf>

<sup>11</sup>[http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com\\_EN/product\\_files/cydectin-pour/Cydectin\\_Pour\\_On\\_label.pdf](http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf)

Ivermectin is considered to be the most harmful to soil life. From the 2015 TR: “Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. Excreted ivermectin does delay the disappearance of dung pats, but does not affect earthworm populations or health. The delay in ivermectin treated soils may be the result of its toxicity to insects” (2015 TR lines 580 – 583). Ivermectin is more toxic to dung-dwelling insects than moxidectin: “The macrocyclic lactones (the class of parasiticides to which ivermectin and moxidectin belong) can be ranked in decreasing order of toxicity to dung-dwelling insects as abamectin>doramectin ≥ ivermectin > eprinomectin>>moxidectin” (TR Table 7).

The NOP standards prohibit the use of parasiticides in slaughter stock. Although ivermectin is not labeled for use in dairy animals of breeding age, it may be used under veterinary order under provisions of AMDUCA (TR line 321).

In its initial request for public comment, the Livestock Subcommittee asked the public “Are the three parasiticides (ivermectin, moxidectin and fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?”

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common comment received was that ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and ivermectin are both in one class of parasiticides and fenbendazole is in a separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas ivermectin and moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelmintic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite

<sup>12</sup><http://www.accessdata.fda.gov/scripts/animaldrugatfda/details.cfm?dn=128-409>

<sup>13</sup> <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162>

control systems in the future.

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

3. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian. Ivermectin and moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticide for convenience.
4. Moxidectin is annotated “for control of internal parasites only.” However, moxidectin is widely used as a pour-on, and when used in that form for control of internal parasites it is also a *de facto* control for external parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
5. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and moxidectin have no milk withdrawal time for use in conventional production.

#### **Motion to Remove**

This proposal to remove ivermectin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ivermectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Harmful to human health and the environment.

#### **Vote in Subcommittee**

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 5 No: 1 Abstain: 0 Absent: 2 Recuse: 0

### **Parasiticides, Moxidectin**

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

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

**Technical Report:** 2003 TAP (Moxidectin); 2015 Technical Evaluation Report

**Petition(s):** Moxidectin

**Past NOSB Actions:** 2004 NOSB recommendation

**Recent Regulatory Background:** Added to National List , effective May 16, 2012 ([77 FR 28472](#))

**Sunset Date:** 5/16/2017

### Subcommittee Review

The USDA organic regulations at 7 CFR part 205 provides guidance on livestock production practices to prevent the need for the use of parasiticides, and on regulation of the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (e) The producer must establish and maintain preventive livestock health care practices, including:
  - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
  - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
  - (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (f) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
  - (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
  - (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

In October 1999, the NOSB voted on three parasiticides for inclusion on the National List. Only

Ivermectin had sufficient votes be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add moxidectin to the National List by a vote of 11-1-1-1. The annotation “for control of internal parasites only” was included for moxidectin for the given reason that “There is much less chance of any kind of contamination if it is used for internal parasites versus external.” According to the meeting notes, “It was the committee’s opinion, that (moxidectin) failed on Criteria 1, and that was the reason for the proposed annotation because of concern about the half-life of the material and impact on soil organisms.” However, the board noted then that moxidectin “is also less problematic” than ivermectin. Further, it should be noted that just before the NOSB vote on moxidectin, a board member corrected an error that had been part of the discussion leading to the annotation: it was brought up that the 2003 TAP review indicated the half-life of moxidectin in soil to be two months, not six months as had been reported in the evaluation criteria document (which had led to support for the annotation).

The 2015 TR indicates that “The half-life for degradation of moxidectin in the environment may be up to 130 days,” and the half-life of ivermectin to be “127 days in soil.” However, other sources indicate that the half-life of these materials can be quite variable, depending on temperature and soil conditions. For example, the half-life of ivermectin in a soil/feces mixture was found to be 91 to 217 days during winter weather conditions and 7 to 14 days during the summer period.<sup>14</sup>

Although the NOSB approved the addition of moxidectin to the National List in 2004, the US Agriculture Secretary did not initially accept NOSB’s recommendation because Moxidectin was labeled as a macrolide antibiotic. However, subsequent clarification found that Moxidectin belongs to the polyene class of macrolides, “which unlike their erythromycin counterparts do not possess antibiotic properties” (2015 TR lines 100 – 111). Moxidectin was then added to the National List.

In May 2008, fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0. The stated intention of the Livestock Committee at that time was that when Fenbendazole was added to the List, ivermectin (and possibly moxidectin) should come off the List (meeting notes, page 207).

The organic standards of Canada prohibit the use of parasiticides with exceptions (2015 TR): “If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued. The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than

<sup>14</sup> Fate of Pharmaceuticals in the Environment and in Water Treatment Systems. 2008. Diana S. Aga ed., p. 128. CRC Press.

two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan.”

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

For conventional livestock production no milk withdrawal time is required for either fenbendazole<sup>15,16</sup> or moxidectin.<sup>17,18</sup> Ivermectin is not approved for use in dairy animals, and no milk withdrawal time has been established for ivermectin.<sup>19,20</sup>

Ivermectin is considered to be the most harmful to soil life. From the 2015 TR: “Fenbendazole does not appear to hinder rapid disappearance and mineralization of cattle dung pats in pastures and does not appear to affect the role that earthworms play in this process. Excreted ivermectin does delay the disappearance of dung pats, but does not affect earthworm populations or health. The delay in ivermectin treated soils may be the result of its toxicity to insects” (2015 TR lines 580 – 583). Ivermectin is more toxic to dung-dwelling insects than moxidectin: “The macrocyclic lactones (the class of parasiticides to which ivermectin and moxidectin belong) can be ranked in decreasing order of toxicity to dung-dwelling insects as abamectin>doramectin ≥ ivermectin > eprinomectin>>moxidectin” (TR Table 7).

Considering that the NOP standards prohibit the use of parasiticides in slaughter stock and that ivermectin is not labeled for use in dairy animals of breeding age, there seems to be little opportunity for the use of ivermectin in organic production. The only opportunity for use of Ivermectin would be in breeder stock, before the last third of gestation for progeny to be sold as organic.

In its initial request for public comment, the Livestock Subcommittee asked the public “Are the three parasiticides (ivermectin, moxidectin and fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?”

In the public comments received from those questions, and from additional comments from veterinarians and producers queried by members of the Livestock Subcommittee, the most common

<sup>15</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm069880.pdf>

<sup>16</sup> <http://www.asp-inc.com/products/documents/prodinfo/s/safeguard20spec.pdf>

<sup>17</sup><http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm117119.pdf>

<sup>18</sup>[http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com\\_EN/product\\_files/cydectin-pour/Cydectin\\_Pour\\_On\\_label.pdf](http://www.bi-vetmedica.com/content/dam/internet/ah/vetmedica/com_EN/product_files/cydectin-pour/Cydectin_Pour_On_label.pdf)

<sup>19</sup><http://www.accessdata.fda.gov/scripts/animaldrugatfda/details.cfm?dn=128-409>

<sup>20</sup> <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=11162>

comment received was that ivermectin should be removed from the National List, primarily because of its toxic effects on dung beetle larvae.

Parasiticides fall into five anthelmintic drug classes differentiated by their chemical structures (TR line 151–152). Moxidectin and ivermectin are both in one class of parasiticides and fenbendazole is in a separate class, relative to modes of action, so some commenters suggested that it may be beneficial to keep one parasiticide from each class on the List to allow rotation of parasiticides to prevent the development of resistance and to have an alternative in cases where resistance develops. Also, different synthetic parasiticides allow different modes of use (i.e., oral administration, subcutaneous, and pour-on). Fenbendazole is restricted to use by oral administration only, whereas ivermectin and moxidectin are both approved for topical, subcutaneous and oral administration.

Fenbendazole is approved by FDA for use in cattle, swine, sheep, turkeys, goats, and deer. Ivermectin is approved for use in swine, sheep, cattle, goats, bison, deer and reindeer. Moxidectin is approved for use in cattle and sheep.

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelmintic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

6. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian. Ivermectin and Moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticide for convenience.
7. Moxidectin is annotated “for control of internal parasites only.” However, moxidectin is widely used as a pour-on, and when used in that form for control of internal parasites it is also a *de facto* control for external parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only: was apparently written based on incorrect information on the half-life of moxidectin in the soil.
8. §205.603(a)(18) requires a 90-day withholding period for milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) that is considered an excessive withdrawal time for food safety. Fenbendazole and Moxidectin have no milk withdrawal time for use in conventional production.
9. Ivermectin is not allowed for use in slaughter stock under the NOP, and it is not allowed for use in dairy animals of breeding age by the FDA, leaving the only legal use of ivermectin to be on breeder stock before the last third of gestation for progeny to be sold as organic.

### **Motion to Remove**

This proposal to remove moxidectin will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of moxidectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: This material satisfies the OFPA Criteria.

### Vote in Subcommittee

Motion to remove Moxidectin from §205.603

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 4 No: 2 Abstain: 0 Absent: 2 Recuse: 0

## Peroxyacetic/peracetic acid

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

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

**Technical Report:** [2000 TAP](#)

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

**Past NOSB Actions:** [11/2000 NOSB recommendation](#); [10/2010 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

### Subcommittee Review

Peracetic acid (PAA) is a relatively recent development, but has been used to clean stalls and to disinfect livestock, particularly dairy cattle. Acetic acid and hydrogen peroxide both have a longer history of use in livestock production than commercial preparations of peracetic acid, but the substance has, in effect, been used by farmers who combine vinegar and peroxide in a cleaning solution. The primary mode of action is oxidation. PAA works synergistically with hydrogen peroxide, decreasing the amount of hydrogen peroxide needed to reduce microorganisms (Lambert et al., 1999). Under normal use and disposal conditions, PAA decomposes into acetic acid, oxygen, and water. Peracetic acid is produced by reacting acetic acid and hydrogen peroxide. (Tap Review, November 3, 2000).

Peracetic acid is an irritant of the skin, eyes, mucous membranes and respiratory tract (NTP, 2000; Budavari, 1996; Lenga, 1985). When heated to decomposition it emits acrid smoke and toxic fumes of carbon monoxide and carbon dioxide. The vapor is heavier than air and can travel a considerable distance to a source of ignition and flash back (NTP, 2000). Misuse at the processing level would cause a bleaching out effect on the color of meat and poultry, resulting in loss of quality that could be visually detected.

Direct consequences of misuse of concentrated solutions could be catastrophic; i.e., burns and explosions. Indirect consequences are minimal, as breakdown into acetic acid and water happens rapidly. Proper use should have minimum consequences, due to the dilute nature of the solutions, although the possibility of irritation of mucous membranes and skin is possible. Therefore, good chemical practices should be followed when using PAA. Alternatives include hydrogen peroxide, chlorine, chlorhexidine solutions. Broad-spectrum synthetic biocides are generally considered incompatible with sustainable agriculture. However, proper farm sanitation and the protection of the public health from food-borne pathogens merits special consideration. Substances are needed to clean milking machines and keep livestock facilities from harboring food-borne pathogens. While sustainable systems should minimize the use of such substances, they should not be eliminated unless and until suitable alternatives are found.

(TAP Review, November 3, 2000).

The 2000 Tap reviewers unanimously agreed that while there were potential issues with PPA, the material is critical to ensure proper sanitation of farm and/or processing facilities.

Public comment was overwhelmingly in support of relisting Peracetic Acid, noting that the material is more effective with longer efficacy than chlorine and is critical to proper sanitation and human and animal health. One commenter did ask that when the NOSB reviews the material to determine whether it is still necessary.

#### **Motion to Remove**

This proposal to remove Peracetic Acid will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Peracetic Acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

#### **Vote in Subcommittee**

Motion to remove Peracetic acid from 205.603

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

### **Phosphoric acid**

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs

**Technical Report:** 2003 TAP (Handling)

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

**Past NOSB Actions:** 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

#### Specific Uses of the Substance:

Phosphoric acid is used in cleaning operations to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining of stainless steel, lime and scale from heat exchangers and in Clean In Place (CIP) cleaning operations, especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

**Discussion:** The NOSB in its initial request for public comment asked if the material is used in livestock production and if there were alternative materials. Public comment indicates widespread use of phosphoric acid and public did not indicate alternatives.

This material satisfies the OFPA Evaluation Criteria.

### Motion to Remove

The Subcommittee proposes removal of Phosphoric Acid from the National List.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Satisfies OFPA criteria

### Vote in Subcommittee

Motion to remove Phosphoric acid from §205.603

Motion by: Jean Richardson

Seconded by: Francis Thicke

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

## Poloxalene

**Reference: 205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable (21) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat

**Technical Report:** 2001 TAP

**Petition(s):** 2000 Petition

**Past NOSB Actions:** 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Poloxalene is a fast-acting synthetic material approved for emergency treatment of bloat. In the 2001 TAP review, all three reviewers agreed that there are natural alternatives to poloxalene, such as vegetable oils. However, two of the reviewers recommended approval of poloxalene because it is faster-acting than oils in relief of bloat. The third reviewer argued that when rumen bloat becomes acute enough that oils will not stop the bloat and poloxalene is required, a rumenotomy (surgical opening of the rumen) is probably required anyway, so poloxalene is not essential to organic production.

In the first round of public comments for the 2017 sunset, two brief comments were received recommending that poloxalene remain on the National List. Also, one commenter (a veterinarian) suggested that poloxalene is not essential because olive oil and other oils would substitute.

### Motion to Remove

This proposal to remove poloxalene will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of poloxalene from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

### Vote in Subcommittee

Motion to remove Poloxalene from §205.603(a)

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

## Tolazoline

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

(22) 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;
- (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

**Petition(s):** 2002 Petition

**Past NOSB Actions:** 09/2002 NOSB recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Tolazoline is used in conjunction with xylazine. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine.

For the first round of public comments, the Livestock Subcommittee asked two questions:

1. Are there alternative materials that should be petitioned for use?
2. What alternative practices are available?

No comments were received specifically answering those questions. However, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list. One commenter questioned the legality of the use of xylazine/tolazoline in food-producing animals. However, off-label use of xylazine/tolazoline was cleared with FDA when they were added to the National List in 2002.

### Motion to Remove

This proposal to remove tolazoline will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of tolazoline from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### Vote in Subcommittee

Motion to remove Tolazoline from §205.603

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 1 Absent: 0 Recuse: 0

## Xylazine

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

(23) 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;
- (ii) The existence of an emergency; 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

**Petition(s):** 2002 Petition

**Past NOSB Actions:** 09/2002 NOSB recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Xylazine is used in conjunction with tolazoline. Tolazoline is used to reverse the effects of xylazine.

For the first round of public comments, the Livestock Subcommittee asked two questions:

Are there alternative materials that should be petitioned for use?

What alternative practices are available?

No comments were received specifically answering those questions. However, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list. One commenter questioned the legality of the use of xylazine/tolazoline in food-producing animals. However, off-label use of xylazine/tolazoline was cleared with FDA when they were added to the National List in 2007 (see proposed rule [71 FR 40624](#)).

### Motion to Remove

This proposal to remove xylazine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of xylazine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Compatibility**

### Vote in Subcommittee

Motion to remove from §205.603

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

## Copper sulfate

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable (1) Copper sulfate.

**Technical Report:** 1995 TAP; 2015 TR

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

**Specific Use:** Walk-through footbaths are used to help control and prevent hoof related diseases in dairy cattle and sheep. A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes. Spent solution is mixed with manure waste and ultimately disposed by land application.

The popularity of copper sulfate footbaths can be attributed to both its relatively low cost per footbath and that it effectively controls the infectious lesions. Research has shown that using copper sulfate footbaths decreases both the incidence and severity of foot lesions over time.

Concerns with using copper sulfate include metal corrosion and disposal of the copper sulfate solution. On the farm, discarding the diluted copper sulfate solution with manure (and placed in wastewater lagoon) is a normal practice. It is fairly common practice for lagoon water and lagoon solids to be applied to farmland. The environmental effect of this copper depends on the volume of footbath solution disposed (a function of the number of animals and intensity of footbath use), concentration of copper sulfate, and the land area of application. Without careful attention, maximum soil copper loading rates may be exceeded in relatively short times (5 to 30 years) (Epperson et al., 2007).

Although the soil rarely produces excessive amounts of copper on its own, copper toxicity can occur from over application of the micronutrient in agricultural production. Neutralizing copper soil toxicity is extremely difficult once the problem occurs. Copper has low solubility, which enables it to persist in the soil for years.

According to the Technical Review commissioned by the Livestock subcommittee, there are no natural (non-synthetic) products available that can be used as a management strategy to treat hoof related diseases and lameness in dairy cattle and sheep operations. However, there are various management tools available that could help reduce the cost of treatment and prevent hoof related diseases. These include the use of additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices (Maas 2009).

The Livestock Subcommittee had put forth the following questions for public comment:

Zinc sulfate has recently been petitioned for use as a footbath treatment. In the event that the NOSB votes to add zinc sulfate to the National List, how likely are you to use this material instead of copper sulfate?

The NOSB did receive public response to the question posed above, with most respondents stating the addition of zinc sulfate to the National List would likely reduce their reliance solely on copper sulfate. Additional public comments voiced concerns regarding accumulation of copper in soils due to disposal of copper sulfate baths in lagoon water, but generally acknowledged the necessity of this material, and proposed an annotation requiring soil testing to monitor for copper accumulation. Comment was also

received refuting the TR's statement that there are no non-synthetic alternatives to copper sulfate. In particular, hydrated lime was put forth as an alternative to control fungal diseases in cows and sheep.

The Livestock subcommittee feels that copper sulfate, used after appropriate management practices and disposed of properly, provides an important tool to livestock producers and recommends this material stay on the National List.

### **Motion to Remove**

This proposal to remove copper sulfate will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of copper sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:

### **Environmental Impacts**

### **Vote in Subcommittee**

Motion to remove Copper Sulfate from §205.603(b)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

## **Formic acid**

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable  
(2) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives

**Technical Report:** 2011 TR

**Petition(s):** 2010 Petition

**Past NOSB Actions:** 2010 NOSB recommendation

**Recent Regulatory Background:** Added to National List, effective August 3, 2012 [[77 FR 45903](#)]

**Sunset Date:** 8/3/2017

### **Subcommittee Review**

The National Organic Standards Board (NOSB) reviewed formic acid for use as a pesticide solely within honeybee hives according based on the evaluation criteria in the Organic Foods Production Act (OFPA), 7 Code of Federal Regulation (CFR) §205.603(b), the 2011 technical report (TR), past NOSB actions, and 2015 public comments. Formic acid is used to control varroa and tracheal mites in honeybees. It is less toxic and less hazardous than conventional miticides, but it is a synthetic that poses some hazards to beekeepers. Available alternatives include management practices, nonsynthetic materials, and a synthetic soap on the National List. When the NOSB approved formic acid in 2010, a technical review was not available, and the Livestock Subcommittee evaluated the petition based on information in the petition, but said it, "will reevaluate the recommendation when the TR becomes available." Thus, the technical review and checklist based on it should be considered new information.

Formic acid is found naturally in small amounts in some fruits and nectars and is a natural component of honey, with formic acid being present in a natural state in stinging nettles. It is also present as a defense mechanism in the stings and bites of many insects, including bees and ants. Synthetic formic acid used by beekeepers is produced as a by-product in the manufacture of acetic acid. However, the industrial demand for formic acid is higher than can be made from this route, so dedicated production routes have been developed. One method combines methanol and carbon monoxide in the presence of a strong base, such as sodium methoxide, to produce methyl formate. Other uses of formic acid include use as a preservative and antibacterial agent; in textile dyeing and finishing, leather tanning, nickel plating baths, electroplating, coagulating rubber latex, regenerating old rubber, and de-hairing and plumping hides, and in some commercial paint strippers. It is used: in the manufacture of metal salts, including nickel, cadmium, and potassium formates; as a solvent for perfumes; in the manufacture of lacquers, glass, vinyl resin plasticizers, and formate esters for flavor and fragrance; and in the synthesis of the artificial sweetener aspartame.

Natural formic acid is not available in adequate amount for commercial use. The 2011 TR further states that, "formic acid can serve as an effective treatment for mite infestations because it harms mites but generally not bees. During treatment, formic acid vapors diffuse through the hive and then dissipate to background levels at the end of the treatment."

Formic acid is applied as a fumigant to the interior of the beehive and is unlikely to affect biological or chemical interactions in the agro-ecosystem. If released to water as a result of accident during manufacturing, formic acid is expected to volatilize from the surface of water and is not expected to absorb sediment and suspended solid.

There are management alternatives to formic acid fumigation - use of a screened bottom board and drone-brood trapping. In addition, bees resistant to the mites because of grooming behavior or a trait that prevents mites from reproducing are now available.

The fungus *Metarhizium anisopliae* is highly pathogenic to varroa mites and does not cause harm to honeybees or affect reproduction.<sup>21</sup> Although beekeepers may use it for this purpose, it is not a registered use.<sup>22</sup> Use of wintergreen-salt grease patties is a natural treatment of varroa and tracheal mites used by many beekeepers. However, the prepared grease patties are not commercially available and are created by beekeepers for personal use, and wintergreen is considered a synthetic and is not on the National List. Neem oil and inert dusts are other nonsynthetic alternatives. Sucrose octanoate ester is listed on §205.601 for this use.

<sup>21</sup> NPIRS (National Pesticide Information Retrieval System), 2015. *Metarhizium anisopliae* strain F52 spores, <http://ppis.ceris.purdue.edu>

<sup>22</sup> Kanga, L. H., Jones, W. A., & Gracia, C. (2006). Efficacy of strips coated with *Metarhizium anisopliae* for control of Varroa destructor (Acari: Varroidae) in honey bee colonies in Texas and Florida. *Experimental & applied acarology*, 40(3-4), 249-258.

Two questions were put forth seeking public input upon the first stage of sunset listing review. These were:

1. Do the alternatives documented in the TR control varroa and tracheal mites?
2. Are the alternatives discussed in the TR available for organic beekeepers?
- 3.

During the 2015 public comment period, there were few comments regarding the listing of formic acid and, unfortunately, no beekeepers. Neither OTA nor MOSA reported any responses to their surveys concerning formic acid. One livestock organization supported formic acid, and one environmental organization urged the NOSB Livestock Subcommittee to get input from beekeepers.

Communication directly with a beekeeper who is well established (fourth generation), and significant producer of organic honey, stated that at this time, without formic acid, their 4,000-hive operation would no longer be certified organic.

Specifically, the hives are kept stronger via use of formic acid, and without use of formic acid the hives often or regularly develop hive beetle problems. With use of formic acid, hives also have not been affected by deformed wing virus. Systems management and maintenance of hives means that for at least some organic beekeepers, there is not an effective alternative at this time.

#### **Motion to Remove**

The motion to remove Formic Acid from 205.603 as “Synthetic substances allowed for use in organic livestock production” will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

#### **Vote in Subcommittee**

Motion to remove Formic Acid from §205.603

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

### **Iodine**

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

(14) Iodine

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

(3) Iodine

**Technical Report:** 1995 TAP; 2014 TR

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

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

sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 06/27/17

### **Subcommittee Review**

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 anti-microbial teat dips, used 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. 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 a number of other ingredients in iodine based teat dips, some of which may be excipients.

One of the nonionic surfactants used is nonylphenol polyethylene glycol ether (NPE). NPEs are known to have negative environmental impacts, even at low levels, notably in aquatic systems, and a Technical Report for NPEs was requested and received by the NOSB Crops Subcommittee and reviewed as part of this analysis.

### **The Livestock Subcommittee requested additional information during the first posting for iodine, posing the following questions:**

1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comment indicates that iodine is critical to organic livestock production and that it is widely used. Scientific research suggests that the use of NPEs in complexing iodine for use in organic livestock production should be rapidly phased out, and public comment clearly indicates that the dairy industry, starting in Fall 2014, began moving quickly to eliminate NPEs from iodine based livestock teat dips and disinfectants. Iodine based teat dips are now available labeled “NPE-free”. Some milk buying companies require dairy producers to stop using teat dips containing NPEs.

It is recommended that dairy producers check with their teat dip suppliers to make sure that from now on their farm’s teat dip and other iodine uses will be one of the many formulations with no NPEs.

The Livestock Subcommittee does not recommend removal of iodine from the National List but the

Livestock Subcommittee will propose a separate annotation requiring the use of iodine made without NPEs.

### **Motion to Remove**

This proposal to remove iodine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of iodine from the National List.

### **Vote in Subcommittee**

Motion to remove iodine from 205.603(a)(14) and 205.603(b)(2)

Motion by: Jean Richardson

Seconded by: Harold Austin

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

## **Lidocaine**

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable (4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

**Technical Report:** None

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Lidocaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on.

Lidocaine is used for example to humanely de-bud horns on calves, and for minor surgery on mature animals.

The NOSB in its initial request for public comment asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a very short withholding period would be scientifically acceptable.

The Livestock subcommittee cannot make an annotation at Sunset review but will seek further public

comment through a Discussion Document, and depending on public comment and the requested Technical Report, a subsequent proposal to change the withholding period for slaughter stock may be proposed.

There was widespread stakeholder support for continuing to list lidocaine.

### **Motion to Remove**

This proposal to remove lidocaine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lidocaine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

### **Vote in Subcommittee**

Motion to remove Lidocaine from §205.603

Motion by: Jean Richardson

Seconded by: Calvin Walker

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

## **Lime, hydrated**

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable  
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes

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

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

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Hydrated lime is produced by heating calcium carbonate, which results in quicklime. Quicklime is then mixed with water to create hydrated lime. This is a caustic solution which can be used for a variety of reasons, but the material is restricted in organic production to an external parasiticide. The NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle and other livestock. Mange caused by parasitic mites is highly irritating for animals, and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (TR lines 61-64). Hydrated lime scattered in yards and pens is also effective for control of bacteria that causes foot rot. For this purpose, the substance is typically placed in and around areas where sheep congregate such as watering areas, feed bunks or salt and mineral sources. (TR lines 83-86) Hydrated lime and other lime products have a long history of use in agricultural and non-agricultural settings. (TR lines 146-147)

Direct application of large amounts of hydrated lime to soils can cause compaction, a rapid rise in soil pH, and rapid oxidation of soil nutrients. However, per the 1995 TAP review, small amounts reaching the soil from application to livestock may have a beneficial effect on soil calcium.

Hydrated lime can be caustic if inhaled. Respiratory protection should be used during application.

Public comment, while limited in quantity, did support the re-listing of hydrated lime, citing the essentiality of the material for control of external parasites and for control of foot/hoof infections.

### **Motion to Remove**

This proposal to remove Lime, hydrated will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Lime, hydrated from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Essentiality

### **Vote in Subcommittee**

Motion to remove Hydrated Lime from §205.603(b)

Motion by: Tracy Favre

Seconded by: Calvin Walker

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

## **Mineral oil**

**Reference:** **§205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable (6) Mineral oil - for topical use and as a lubricant

**Technical Report:** 2002 TAP; 2015 TR

**Petition(s):** 2002 Petition

**Past NOSB Actions:** 10/1995 NOSB minutes and vote; 2003 NOSB recommendation, 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

In 1995, mineral oil was approved by the National Organic Standards Board for use in organic livestock production for topical use and as a lubricant.

Mineral oil occurs naturally in the form of pitch, tar, or bitumen and has been used as a sealing and building material or for medicinal purposes for thousands of years. Mineral oil and natural gas are formed by the accumulation of the decomposing remains of large quantities of marine micro-

organisms. To obtain mineral oil, gasoline and kerosene are removed from the crude petroleum by heating, in a method called functional distillation. By using sulphuric acid, applying absorbents, and washing with solvents and alkalis, hydrocarbons and chemicals are removed.

([http://www.essentiallyoils.com/Newsletters/April\\_1997\\_Newsletter/april\\_1997\\_newsletter.html](http://www.essentiallyoils.com/Newsletters/April_1997_Newsletter/april_1997_newsletter.html) )(TAP Review, August 12, 2002). Mineral oil can interfere with the absorption of some medications and vitamins, including Vitamin K, which can lead to anticoagulant affects. Mineral oil is considered relatively non-toxic (TAP Review, August 12, 2002).

Public comment was limited but generally supportive of relisting, citing mineral oil's importance in fly control. The Livestock Subcommittee supports continued listing of mineral oil.

### **Motion to Remove**

This proposal to remove mineral oil will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of mineral oil from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

### **Vote in Subcommittee**

Motion to remove Mineral oil from 205.603(b)(6)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 1 No: 3 Abstain: 1 Absent: 1 Recuse: 0

## **Procaine**

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

(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

**Technical Report:** N/A

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

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

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on.

Procaine may be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

The NOSB in its initial request for public comment asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a very short withholding period would be scientifically acceptable.

The Livestock subcommittee cannot make an annotation change at Sunset review but will seek further public comment through a Discussion Document, and depending on public comment and the requested Technical report, a subsequent proposal to change the withholding period for slaughter stock may be proposed.

Public comment indicates procaine is not readily available in the United States and does not appear to be widely used. Procaine may not be essential and may not need to continue to be listed.

#### **Motion to Remove**

This proposal to remove procaine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of procaine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Compatibility

#### **Vote in Subcommittee**

Motion to remove Procaine from §205.603(b)

Motion by: Jean Richardson

Seconded by: Calvin Walker

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

### **Sucrose octanoate esters**

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable  
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling

**Technical Report:** 2005 TR

**Petition(s):** 2004 Petition; 05/2004 petition amendment; 09/2004 petition amendment

**Past NOSB Actions:** 08/2005 NOSB recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Background from Subcommittee**

Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

### **Subcommittee Review**

Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

SOEs seem to be fairly benign for health and the environment: “SOEs are rapidly biodegradable, and do not persist or accumulate in the environment” (TR line 298). “EPA has not identified any subchronic, chronic, immune, endocrine, dietary, or non-dietary exposure issues for SOEs in children or the general U.S. population” (TR lines 303-304).

In the first round of public comments, one comment was received on SOEs, recommending that it remain on the National List.

SOEs are used to control mites in honey bee colonies. Given the difficulty bee keepers are experiencing maintaining the health of honey bee colonies in recent times, the subcommittee thought it essential for SOEs to remain on the National List.

### **Motion to Remove**

This proposal to remove sucrose octanoate esters will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of sucrose octanoate esters from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable:  
None given.

### **Vote in Subcommittee**

Motion to remove Sucrose octanoate esters from §205.603(b)

Motion by: Francis Thicke

Seconded by: Jean Richardson

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

## 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 maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry - 3 pounds.

**Technical Report:** 2001 TAP; 2011 TR

**Petition(s):** 2005 Methionine; 2007 Methionine; 2009 Methionine; 2011 Methionine

**Past NOSB Actions:** 10/2001 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation through October 2012; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 10/02/17

### Subcommittee Review

Methionine is classified as an essential amino acid because it is required in the diet for cell growth, but cannot be biologically produced. Of the 22 amino acids found in body proteins, the National Research Council (NRC) lists 13 as essential in poultry diets, and these must be consumed in feed: arginine, glycine, histidine, isoleucine, leucine, lysine, methionine, cysteine, phenylalanine, proline, threonine, tryptophan, and valine (NRC, 1994). (2011 TR, Lines 104-108). Poultry feed made of corn and soybean does not supply enough methionine to prevent deficiency symptoms that include curled toes, bare spots, and improper feathering (Hungerford, 2007). In addition, amino acids like methionine improve the efficiency of the production of animal protein. (TR Lines 112-144)

The nonsynthetic amino acid methionine is found naturally in foods such as: rice; rapeseed; soybean meal; sunflower, safflower, and sesame seeds; flax; alfalfa; grass; corn; wheat; and peas (Fanatico, 2010). Levels of methionine vary by food. For example, corn has only 0.17% methionine while soybean meal has 0.64% methionine. Methionine is also found naturally in animal protein from insects, fish, and dairy products, which are permitted in organic agriculture. Thus, natural methionine can be obtained from high-methionine foods; however, these foods are also high in protein. High protein diets are not physiologically healthy for birds due to excess excretion of uric acid, which is broken down into water and ammonia in the environment (Fanatico, 2010). (TR, lines 267-274)

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. (TR, lines 279-283)

It is unlikely that the use of methionine and its breakdown products will cause harm to the environment. Methionine supplementation can reduce environmental pollution from nitrogen-rich manure, a significant concern in poultry production. (TR, lines 334-336, Lines 386-389). However, feeding systems

that reduce levels of protein fed using amino acid supplementation are not the only means identified to reduce nitrogen pollution from animal manure. Other potential solutions include lower animal densities; more frequent rotations; better manure storage, handling, and application techniques; use of enzymes; improved processing of the feed; and selection of more appropriate land and locations to graze and shelter animals (Archer and Nicholson, 1992; Tamminga, 1992; Tamminga and Verstegen, 1992). (TR, Lines 391-396).

The most likely source of possible environmental contamination associated with synthetic methionine is through waste streams from its production. Methionine is manufactured using a number of toxic intermediates including methyl mercaptan and acrolein. However, it is unlikely that the use of methionine and its breakdown products will cause harm to the environment. (TR, lines 404-407).

There are reports of herbal supplements that mimic methionine activity and which are made up of methionine-rich herbs such as *Cicer arietinum*, *Triticum sativum*, *Phaseolus mungo*, *Mucuna puriens*, and *Allium cepa*; however, the efficacy and commercial availability of these products is unclear. Another way to supplement natural methionine is through consumption of additional plant and animal proteins. Raising chickens with access to pasture is considered a possible alternative to synthetic methionine supplementation. Some sources indicate that they can adequately raise chickens without synthetic methionine as long as the birds have adequate access to pasture (Hungerford, 2007). Forage provides low to moderate levels of methionine and allows birds to obtain high-quality protein from insects and worms (Fanatico, 2010). However, foraging conditions change by season, affecting the pasture's ability to supplement the diet. During certain times of the year, it is difficult for methionine needs to be met from forage alone (Rack et al., 2009). (TR, Lines 439-442 and Lines 460-467).

As of the November 2011 Technical Report, research indicates that the organic poultry industry has not been able to develop a commercially viable, nonsynthetic form of methionine extract for use in organic poultry diets. While methionine can be extracted from intact proteins or proteins partially hydrolyzed to isolate it, there are still no commercially available forms of naturally extracted methionine (Fanatico, 2010). (TR, Lines 474-477).

Public comments regarding the continued listing of synthetic methionine have been extensive, heated and divided. Generally, those in favor of continued listing indicate that synthetic methionine is still critical to production of organic poultry and cite issues around animal welfare, including feather pecking and cannibalism. Those against continued listing of methionine express deep concerns around the continued and routine use of a synthetic ingredient in organic animal feed and predict erosion of public trust if synthetics remain in organic poultry production. To further complicate the issue, the NOSB recommendations for Animal Welfare Standards, and their requirements for outdoor access for poultry (December, 2011), are generally seen by many in the industry as a key component in helping to resolve the continued need for synthetic methionine. Those Standards have not yet been implemented as part of the National Organic Program.

### Spring 2015 NOSB Meeting

At the Spring 2015 NOSB meeting in La Jolla, CA, the NOSB voted on and approved the proposal from the Livestock Subcommittee, which addressed a petition from the Methionine Task Force to modify the annotation for methionine. With this vote the annotation for methionine will be changed to read as follows:

*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% Methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.*

Detailed history of the evolution of synthetic methionine in organic poultry production, including arguments both for and against, was included in the [proposal for the annotation change](#).

The Livestock Subcommittee believes that it is important to the long-term public trust in the organic seal that the organic industry strives for continuous improvement. As part of the proposal for annotation change, the NOSB adopted the following resolution:

*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.*

It is the intent of the Livestock Subcommittee to bring forth at the Fall 2015 NOSB meeting targeted and specific research priorities to address the urgent need for further development of synthetic methionine alternatives.

Due to the timing of this annotation change recommendation and the fact that methionine sunsets in 2017, the Livestock Subcommittee has moved forward with this sunset review in parallel with the recommendation for annotation change. The Livestock Subcommittee is recommending relisting of methionine, while urging the organic industry to move forward with urgency to develop alternatives.

### Motion to Remove

This proposal to remove methionine will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of methionine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

**Vote in Subcommittee**

Motion to remove Methionine from §205.603

Motion by: Tracy Favre

Seconded by: Colehour Bondera

Yes: 1 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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

**Past NOSB Actions:** 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

**Subcommittee Review**

From the Livestock Committee's October 1995 recommendations: "Producers often may not be able to control the quantity of vitamins and minerals naturally occurring in feedstuffs. Non-synthetic vitamins and minerals should be used if available, but synthetics are allowed...Synthetic vitamins and minerals should be used in keeping with the recommendations of the National Research Council and the Association of Animal Feed Control Officials, Inc. specific to each species."

In June 2013, the Livestock Subcommittee received a Technical Report (TR) for Trace Minerals for aquaculture, which also addressed issues around mineral supplementation of terrestrial livestock. Trace mineral elements, whether naturally occurring in the diet or provided in supplements, are important for the maintenance, growth, and reproduction in the healthy production of beef cattle, swine, and poultry. In beef cattle production, minerals needed in larger amounts include calcium, phosphorus, magnesium, potassium, sodium, chlorine, and sulfur, while iron, zinc, manganese, copper, cobalt, and selenium are needed only in trace amounts (2013 TR Line 178). Forages and grains are good sources of calcium and phosphorus, respectively. However, the bioavailability of minerals in forage may vary depending on the mineral content of the soil and the level of pasture fertilization. Mineral premixes are therefore widely used for livestock feed fortification to ensure the adequate intake of minerals (Hale, 2001). Likewise, poultry and swine production uses dietary supplementation of trace mineral compounds (Richards, 2010). (TR lines 173-180). The NOP has issued a guidance document for the use of minerals in livestock feed, which 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.

Public comments weighed heavily in favor of continued listing of trace minerals, citing the essentiality of minerals to ensure animal welfare and to offset variables in forage nutrition due to seasonality.

**Motion to Remove**

This proposal to remove trace minerals will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of trace minerals from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Essentiality**

**Vote in Subcommittee**

Motion to remove trace minerals from §205.603(e)

Motion by: Tracy Favre

Seconded by: Jean Richardson/Calvin Walker

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

## Vitamins

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

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

**Technical Report:** 2015 TR

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

**Past NOSB Actions:** 1995 NOSB recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

**Subcommittee Review**

The National Organic Standards Board (NOSB) reviewed vitamins for livestock in accordance to the Organic Foods Production Act (OFPA) and 7 Code of Federal Regulation (CFR) §205.603(d)(3). The evaluation criteria used were: (1) compatibility and consistency with organic production, (2) essentiality and availability, and (3) impact on human and the environment. The synthetic vitamins reviewed are currently allowed for use in organic livestock production for enrichment and fortification. These vitamins are consistent with those defined as “required nutrients” by the National Research Council (NRC).

The NOSB Livestock Subcommittee received a technical evaluation report (TER) on March 5, 2015. The TER helped to provide the framework and essence for our recommendation of vitamins in synthetic form to be retained on the National List (NL). Vitamins meet all of the above criteria for a material to remain on the NL. Vitamins supplied in the diet are essential for good animal nutrition and health. Vitamins are one of six basic nutrients that must be considered in making rations for livestock such as swine, dairy, beef, and poultry. Without these six basic nutrients (vitamins, minerals, carbohydrate, protein, fat, and water) in the right amount animal welfare and production issues will generally become evident. Synthetic vitamins are allowed by various organic associations such as International Federation of Organic Agricultural Movements (IFOAM), European Union (EU), Canadian General Standards Board (CGSB), United Kingdom Soil Association, Japan Ministry of Agriculture, Forestry, and Fisheries, and

CODEX, when natural sources are not available in adequate amount.

The written public comment showed overwhelming support for retaining synthetic vitamins on the NL. The support for, against and neutral, was 71%, 14%, and 14%, respectively. The use of green forages and pastures are alternatives. However, concerns were expressed regarding the availability of sufficient year-round quantity. Also, support was expressed for the approval of use of injectable vitamins, which was passed by a previous NOSB. No new or sufficient information has been submitted to warrant removal of this critical basic feed nutrient from organic livestock ration is warranted at this time. We encouraged new and/or scientific information that warrants otherwise.

### **Motion to Remove**

This proposal to remove vitamins is being considered by the NOSB at the fall 2015 biannual meeting in Stowe, Vermont.

The subcommittee proposes removal of vitamins from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Essentiality.

### **Vote in Subcommittee**

Motion to remove Vitamins from §205.603(d)

Motion by: Calvin Walker

Seconded by: Jean Richardson

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

## **EPA List 4—Inerts of Minimal Concern**

**Reference:** 205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 -Inerts of Minimal Concern

**Technical Report:** 2015 TR Nonylphenol Ethoxylates (NPEs) (one group only of List 4 inerts)

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

**Past NOSB Actions:** 02/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### **Subcommittee Review**

Used for a wide range of applications including surfactants and adjuvants in pesticide, herbicide and fungicide formulations.

The Inerts Working Group (IWG) was established in June 2010 and reports to the Crops Subcommittee. The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting. The NOSB and the IWG are

working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the Safer Choice Program (SCP) Program of the EPA.

Earlier this year, a Technical Report (TR) requested by the Crops subcommittee was completed on the class of inerts known as Nonylphenol Ethoxylates (NPEs). The Livestock subcommittee has also reviewed this TR as part of the 2017 Sunset review of the EPA List 4 Inerts of Minimal Concern listed at 205.603. As highlighted in the TR, the US EPA is encouraging industry to eliminate the use of NPE (TR 2015, line 137) because of toxicity concerns and persistence in the environment. It is unlikely that the NPEs would pass favorably through the SCP screening process. The Crops and Livestock Subcommittees are considering removing NPEs through an annotation, while maintaining the general listing for EPA List 4 at sunset while the new SCP review program starts up.

Because of concerns about the adverse health and environmental effects of NPEs, SCP recently completed an alternatives assessment for synthetic surfactants, like NPEs, that are not endocrine disrupting chemicals. SCP's goal is to assist in the voluntary phase-out of NPEs used in industrial detergents. The SCP assessment for NPEs reviewed several alternatives to NPE surfactants that are comparable in cost, readily available, and rapidly biodegrade to non-polluting, lower hazard compounds in aquatic environments.

The Crops Subcommittee has crafted a proposal that outlines the steps for implementation of the Safer Choice Program for inert review. Once it begins, inert manufacturers will have to submit their products to Safer Choice to be reviewed. A long implementation phase will be proposed, so that industry and manufacturers have enough time for submittal of inerts for screening and any required formulation change. Both the Livestock and Crops Subcommittees believe that some inerts currently in use in organic products will likely not fare well in this review, and strongly encourage manufacturers to consider the likelihood of the need for reformulation.

Public comments weighed heavily in favor of robust review of inert ingredients, due in large part to the fact that the original listing of inerts relied upon an EPA screening process which does not take into account the OFPA criteria. Additionally, public comments indicate significant concern that, while inerts are not listed as active ingredients in many pesticide, herbicide and fungicide formulations, they nevertheless exert significant impact on the environment, terrestrial and aquatic ecosystems and human health.

The Livestock subcommittee recognizes the public's deep concerns regarding these materials, while also acknowledging the significant impact that wholesale removal of EPA List 4 Inerts from the National List would have on the Organic industry. Given this dilemma, the Livestock subcommittee proposes re-listing of EPA List 4 – Inerts of Minimal Concern, while working closely with the IWG and Crops Subcommittee to craft a proposed annotation change which would subject inerts to screening through the SCP program.

### Motion to Remove

This proposal to remove EPA List 4 Inerts of Minimal Concern will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of EPA List 4 - Inerts of Minimal Concern from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: **Compatibility**

### Vote in Subcommittee

Motion to remove EPA List 4 - Inerts of Minimal Concern

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 1 No: 4 Abstain: 1 Absent: 2 Recuse: 0

## Excipients

**Reference:** **205.603(f)** Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application

**Technical Report:** [2015 TR](#)

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

**Past NOSB Actions:** 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

### Subcommittee Review

Excipients are ingredients added to livestock medications but which do not exert a therapeutic or diagnostic effect although they may improve drug delivery. They include such substances as dilutants, wetting agents, and absorption enhancers.

There are about 8000 substances that qualify as Excipients. However, most chemicals used as excipients in organic livestock production are recognized by the U.S. Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS), identified in the Everything Added to Food in the United States (EAFUS) database, or found in the FDA's Inactive Ingredient Search for Approved Drug Products database. There is not a comprehensive list of excipients.

Public Comment supports continued Listing.

**Motion to Remove**

This proposal to remove excipients will be considered by the NOSB at its public meeting. The Subcommittee proposes removal of Excipients from the National List.

**Vote in Subcommittee**

Motion to remove Excipients from 205.603(f)

Motion by: Jean Richardson

Seconded by: Calvin Walker

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

## Strychnine

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

The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine

**Technical Report:** None

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

**Past NOSB Actions:** 04/1995 NOSB minutes and vote (crops only); 11/2005 sunset recommendation; 10/2010 sunset recommendation

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017

**Subcommittee Review**

Strychnine is a prohibited substance and public comment continues to support that it be on the National List as a prohibited substance.

**Motion to Remove**

The Subcommittee proposes removal of Strychnine (as a prohibited Substance ) from the National List

The Subcommittee proposes removal of this material from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: Fails OFPA criteria

**Vote in Subcommittee**

Motion to remove strychnine from §205.604

Motion by: Jean Richardson

Seconded by: Calvin Walker

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



**National Organic Standards Board  
Livestock Subcommittee  
Discussion Document  
Annotation Change for Lidocaine and Procaine Use in Livestock Production  
July 31, 2015**

## **I INTRODUCTION**

Lidocaine and Procaine are local anesthetics. They are used to reduce or prevent pain during de-budding horns in calves, or general minor surgery on mature cows. They numb only the area to be worked on. Humane treatment of animals is critically important and the public expects high standards of animal welfare for organic livestock. A lengthy withholding may result in animals not being treated in a timely manner, or not treated at all. Based on new information received during Sunset Review of these materials the Livestock subcommittee requested a Technical Report on Lidocaine and Procaine for use in organic livestock production, and seeks public comment on a possible annotation change to reduce the withholding period from 90 days to 8 days for slaughter stock.

## **II BACKGROUND**

When added to the National List in 1995 there was no scientific rationale for the 90 day withholding, and the NOSB analysis in their document entitled “Local Anesthetics” provided very little information. The NOSB had not requested a Technical Report on these materials until this summer.

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double FARAD times (when appropriate), on a number of livestock materials.

As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank (FARAD). The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide “withholding period” (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP–DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB. USDA agrees with the position...

Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly, USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this

determination was not based on scientific research or risk assessments. The decision to extend the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. ([72 FR 70479](#))

### III RELEVANT AREAS OF THE RULE

Section 205.238 Livestock healthcare practice standard.

(a) The producer must establish and maintain preventive livestock healthcare practices, including:

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress;

...

(c) The producer of an organic livestock operation must not:

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled or represented as organically produced.

Lidocaine: §205.603(b) as topical treatment, external parasiticide or local anesthetic as applicable

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

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

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

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

(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

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

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

### IV DISCUSSION

During the present Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary ([72 FR 70479](#)) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

In FARAD the recommended withdrawal interval for lidocaine in cattle is listed as 1 day for meat and 24 hours for milk after epidural use of lidocaine, and for subcutaneous use of lidocaine it is 4 days for meat and 72 hours for milk.

FARAD provides information on procaine only as it relates to procaine combined with an antibiotic and thus it would not be used in organic production. Procaine on its own is apparently not readily available in the US and public comment from veterinarians only suggests a similarity with lidocaine. Further information on procaine is needed.

During Review of these materials the NOSB in its initial request for public comment asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives, did not provide any scientific rationale for the lengthy withholding period, and recommendations were received suggesting that a very short withholding period, such as 5 days would be scientifically acceptable.

In contrast to butorphanol, which is a systemic anesthetic, lidocaine and procaine numb only the area to be worked on. Science indicates that the half-life of lidocaine and procaine in all animals studied is very short—typically less than one hour.

There appears to be public support to reduce the Withholding period in order to ensure humane treatment of animals. The 90 day withholding period is far in excess of the withholding period used in conventional livestock production.

The Livestock subcommittee has requested a Technical Report on lidocaine and procaine used in livestock production. Following receipt of public comment in response to this Discussion Document, and the findings presented in the Technical Report, the NOSB may develop a Proposal to amend the withholding period of lidocaine and procaine.

## **V REQUEST FOR PUBLIC COMMENT**

1. Is Lidocaine widely used; under what circumstances is it used; how is it administered; should the withholding period be the same in all animal species?
2. Is Procaine used; under what circumstances; how is it administered; should the withholding period be the same in all animal species?
3. Should the annotation for Lidocaine at 205.603(b) be amended as follows?

Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

4. Should the annotation for Procaine at 205.603(b) be amended as follows?

Procaine—as a local anesthetic, use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

Motion to change annotations for lidocaine and procaine on §205.603

Motion: Jean Richardson

Seconded by: Francis Thicke

Yes: 4 No: 0 Abstain: 0 Absent: 2 Recuse: 0

**National Organic Standards Board**  
**Livestock Subcommittee**  
**Discussion Document: Use of Parasiticides in Organic Livestock Production**  
**August 18, 2015**

**I. INTRODUCTION:**

The use of synthetic parasiticides in organic production is strictly confined to emergencies. Synthetic parasiticides cannot be used routinely, but sick animals must be treated. Typically farmers bring clean animals into their herds or flocks, select breeds which have high resistance to parasites, and manage their land, especially pastures, in a manner which reduces the likelihood of parasite infection. If an increased parasite load is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, the farmer, working with the veterinarian, may need to use one of the synthetic parasiticides on the National List.

At the present time, there are three (3) substances on the National List which are approved for use as parasiticides for organic livestock: Ivermectin, Moxidectin and Fenbendazole. All three of these materials are presently being reviewed as part of the regular five-year Sunset process. All three materials have annotations and other language limiting usage. Such language was developed when Ivermectin was first added to the National List. Recent data and information indicates that if Moxidectin and Fenbendazole remain on the National List, milk withholding and other restrictions could be modified in a manner which would be beneficial to the sick animal in emergency situations, without jeopardizing the quality of the organic product. In conventional milk production there is no withholding for fenbendazole or moxidectin, but for organic milk there is a 90-day withholding period. Organic slaughter stock may never be treated with synthetic parasiticides.

Public comment is requested to guide the NOSB in determining if a proposal is needed to modify the withholding period, especially for milk, and/or allow the skin and fleece of animals treated with a parasiticide to be sold as organic.

**II BACKGROUND:**

In October 1999 the NOSB voted on three parasiticides for inclusion on the National List. Only Ivermectin had sufficient votes to be added to the List. The votes were: Ivermectin 8-3-0, Fenbendazole 5-6-0, and Levamisole 0-11-0.

In April 2004, the NOSB voted to add Moxidectin to the National List by a vote of 11-1-1. The annotation “for control of internal parasites only” was included for Moxidectin for the given reason that “there is much less chance of any kind of contamination if it is used for internal parasites versus external.” Moxidectin was added to the National List in 2012 (77 FR 28742).

Each of the parasiticides was added to the National List with the annotation of a 90-day Withholding period.

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double FARAD times (when appropriate), for a number of livestock materials.

As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that

USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank (FARAD). The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide “withholding period” (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP–DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB. USDA agrees with the position...

Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly, USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. (72 FR 70479)

In May 2008, Fenbendazole was approved by the NOSB for addition to the National List by a vote of 14-0 and added to the National List in 2012 (77 FR 28472).

Three technical reports have been prepared on synthetic parasiticides: a [1999 Technical Advisory Panel \(TAP\) Report](#) on Fenbendazole and Ivermectin; a [2003 TAP Report](#) of Moxidectin; and a [2015 Technical Evaluation Report](#) on all three parasiticides (Fenbenzadole, Ivermectin and Moxidectin) that was requested by this Livestock subcommittee for our Sunset Review of parasiticides.

### III RELEVANT AREAS OF THE RULE:

The USDA organic regulations at 7 CFR part 205 provide guidance on livestock production practices to prevent the need for the use of synthetic parasiticides, and on regulation of the use of parasiticides in organic livestock production:

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
  - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions

- and resistance to prevalent diseases and parasites;
- (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, That, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

§205.603 Synthetic substances allowed for use in organic livestock production.

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
- (18) 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. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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.
- (i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
- (ii) Ivermectin (CAS #70288-86-7).
- (iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

**IV DISCUSSION:**

Parasiticide Uses:

***Fenbendazole:***

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit oral administration of fenbendazole in dairy cattle for the removal and control of lungworm (*Dictyocaulus viviparus*); brown stomach worm (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*) and nodular worm (*Oesophagostomum radiatum*); in beef cattle (beef) for the removal and control of stomach worm (*Ostertagia ostertagi*) and tapeworm (*Moniezia benedeni*); in goats for the removal and control of stomach worms (*Haemonchus contortus* and *Teladorsagia circumcincta*); in swine for the removal and control of lungworms (*Metastrongylus apri* and *M. pudendotectus*), roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*), small stomach worms (*Hyoststrongylus rubidus*), whipworms (*Trichuris suis*) and kidney worms (*Stephanurus dentatus*) and in turkeys for the removal and control of round worms (*Ascaridia dissimilis*) and cecal worms (*Heterakis gallinarum*). Currently, fenbendazole is sold by Merck Animal Health as Panacur® and Safe-Guard®. It is available in liquid suspension, as granules, as a paste and in blocks. Products are dispensed both by veterinarian's prescription and over the counter, but must be used in organic production only under veterinary supervision. For swine, turkeys, and wild sheep the NADA (141-144, 140-954, 136-116, 131-675) for fenbendazole is for use in medicated feed only. Other 300 uses for these animals are extralabel. Furthermore, the use of fenbendazole in medicated feed for domestic 301 sheep in food production is not

permitted by the FDA (TR 2015 284-302).

***Ivermectin:***

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of ivermectin in cattle for the treatment and control of gastrointestinal nematodes: *Haemonchus placei*, *Ostertagia ostertagi*, *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, *N. spathiger*, *Bunostomum phlebotomum*, lungworms: *Dictyocaulus viviparus*, grubs *Hypoderma bovis*, *H. lineatum*, sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, mites: *Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*, in reindeer for treatment and control of warbles (*Oedemagena tarandi*), in swine for treatment and control of gastrointestinal roundworms: *Ascaris suum*; red stomach worm, *Hyostrongylus rubidus*; nodular worm, *Oesophagostomum* species; threadworm, *Strongyloides ransomi*, somatic roundworm larvae-threadworm, *Strongyloides ransomi*, lungworms: *Metastrongylus* species, lice: *Haematopinus suis*, mites: *Sarcoptes scabiei* var. *suis* and ear mites: *Otodectes cynotis*, in american bison for the treatment and control of grubs: *Hypoderma bovis* and in sheep for treatment and control gastrointestinal roundworms: *Haemonchus contortus*, *H. placei*, *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. spathiger*, *S. papillosus* *Chabertia*, *Trichuris ovis*, lungworms: *Dictyocaulus filaria* and all larval stages of the nasal bot *Oestrus ovis*. Ivermectin is marketed by Merial, Inc. and other companies under a number of pharmaceutical labels. It is available as a drench, in liquid solution, for medicated feed, as a sustained release bolus and as a paste. Products are dispensed both by veterinarian's prescription and over the counter (TR 2015, 303-321).

***Moxidectin:***

The US Food and Drug Administration Center for Veterinary Medicine and the US Department of Agriculture National Organic Program permit topical, subcutaneous and oral administration of moxidectin in cattle for treatment and control of internal and external parasites, gastrointestinal roundworms: *Ostertagia ostertagi*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. pectinata*, *C. punctata*, *C. spatulata*, *C. surnabada*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Nematodirus helvetianus*, lungworms: *Dictyocaulus viviparus*, cattle grubs: *Hypoderma bovis*, *H. lineatum*, mites: *Chorioptes bovis*, *Psoroptes ovis*, *P. communis* var. *bovis*, lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola*(*Damalinia*) *bovis* and horn flies: *Haematobia irritans* and in sheep for the treatment and control of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*. Moxidectin is sold by Boehringer Ingelheim Vetmedica, Inc. as Cydectin. It is available in liquid solution. Products are dispensed over the counter (TR 2015, 322-332).

Regulated approvals:

The use of fenbendazole for food animals is approved under six FDA new animal drug applications (TR 2015, Table 3). It is dispensed over the counter. The use of ivermectin for food animals is approved under nineteen FDA new animal drug applications. It is dispensed both by veterinary prescription and over the counter. The use of moxidectin is approved under three new drug approval applications. It is available over the counter (TR 2015, 243-248).

Once a NADA is approved, the FDA, under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), can permit the use of the approved drug under specific conditions outside the designated or intended label use, e.g. use in species not listed in the labeling, use for indications (disease or other

conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses (FDA, 1994). This “off-label” or extralabel use is only permitted in the context of a valid veterinarian-client-patient relationship and is limited to treatments when the health of an animal is threatened or suffering or death may result from failure to treat. A valid veterinarian-client-patient relationship is one in which: (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian; (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) The practicing veterinarian is readily available for follow up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept (TR 2015, 249-266)

For example, there is not an FDA approved use for fenbendazole in domestic sheep; however, it is used under veterinary supervision for this purpose. Furthermore, the National List permits the use of fenbendazole only under veterinary supervision (§ 205.603(a)(18)(i)). There are some limitations for the AMDUCA including extralabel use of an approved new animal or human drug by a lay person (except when supervised by a veterinarian). (TR 2015, 266-268).

#### International Use and Restrictions - TR 2015, 432-507:

The organic standards of Canada prohibit the use of parasiticides with exceptions: If no alternative treatment exists a parasiticide may be administered under veterinary supervision as directed by the standard and mandated by law. Treated livestock with a withdrawal period equivalent to double the label requirement or 14 days, whichever is longer is still considered organic. Organic status for chronically infected animals is discontinued.

The Canadian Organic Standard requires organic livestock operations to have a comprehensive plan to minimize parasite problems in livestock, including monitoring and emergency measures. Normally, parasiticides cannot be administered to meat, dairy or laying animals, but in emergencies, production operations can use them: (1) if parasites are detected, (2) under veterinary instructions, (3) with double the label withdrawal time or 14 days whichever is longer, (4) with one treatment for slaughter animals under one year and two treatments for older animals (requiring more treatments will lose organic status), (5) but dairy animals requiring more than two treatments lose organic status and require a 12 month transition, (6) but dairy animals cannot be organic for slaughter, (7) and a dam may be treated during gestation, (8) and poultry flocks can be treated, but laying hens with more than one treatment per 12 months lose organic status and (9) the operator must provide a written action plan with amendments to the parasite control plan.

The organic standards of CODEX Alimentarius, the European Economic Community, Japan, and IFOAM also do not allow routine use of parasiticides, but they allow some provisions for emergency uses of parasiticides if preventative animal husbandry practices and natural remedies have been used and not found to be effective.

Like the Canadian standards, IFOAM organic standards require that when livestock are treated with synthetic parasiticides the required withdrawal time is not less than double the withdrawal period required

by legislation, or a minimum of 14 days, whichever is longer. The organic standards of Japan and CODEX Alimentarius both require a withdrawal period of double the period required by legislation or a minimum of 48 hours.

#### Alternatives:

There are many natural alternative parasiticides being used in organic livestock production today. Natural parasiticides include homeopathic remedies, diatomaceous earth and many herbs with anthelmintic properties. Table 10 of the 2015 TR lists over 50 botanical and alternative de-wormers. The efficacy of most of these natural alternatives is not well documented, and more research is needed. However, there does seem to be a lot of potential for the development of effective natural parasite control systems in the future.

#### Confusion in present annotation language:

There are some inherent contradictions and problems in the way the three parasiticides are listed and annotated on the National List:

1. Fenbendazole, which is considered the most environmentally benign, is annotated to require the “written order of a licensed veterinarian”. Ivermectin and Moxidectin have no such requirement. That may lead producers to choose a more environmentally detrimental parasiticide for convenience.
2. Moxidectin is annotated “for control of internal parasites only.” However, Moxidectin is widely used as a pour-on, and when used in that form for control of internal parasites it is also a de facto control for external parasites. Moreover, as mentioned above, the annotation “for control of internal parasites only” was apparently written based on incorrect information on the half-life of Moxidectin in the soil.
3. §205.603(a)(18) requires a 90-day withholding period for organic milk or milk products from a treated animal. There seems to be wide consensus that 90 days is much too long of a withholding period, because 1) it may motivate a producer to withhold needed treatment of an animal because of the severe consequences of a 90-day withdrawal, and 2) Fenbendazole and Moxidectin have no milk withdrawal time for use in conventional production. There is no scientific rationale for the 90-day withholding. The 90 days reflects a desire to assure consumers that organic standards exceed conventional use of restricted materials.

## **V REQUEST FOR PUBLIC COMMENT**

1. Should the milk withholding period be modified for any or all of the parasiticides? If so, how many days for Moxidectin, Fenbenzadole and Ivermectin?
2. Should minimal use of parasiticides be allowed in organic slaughter stock such as is permitted under Canadian Organic standards with one treatment for slaughter animals under one year old and two treatments for older animals (requiring more treatments will lose organic status)?

3. Should sheep fleece and wool be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life?
4. Should use of moxidectin be changed to allow both internal and external use?
5. Should use of parasiticides be allowed only under veterinarian advice?

**Vote in Subcommittee**

Motion to accept the discussion document on annotation changes for paraciticides

Motion by: Jean Richardson

Seconded by: Francis Thicke

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



**National Organic Standards Board  
Materials Subcommittee  
Proposal: Research Priorities for 2015  
August 24, 2015**

**Introduction**

A Recommendation for a Framework to set Research Priorities was approved at the National Organic Standards Board (NOSB) meeting in May 2012. Part of that recommendation was that the research priorities from the previous year of NOSB deliberations would be presented at each fall meeting. Additional information about the background and NOSB Research prioritization can be found in the previous Materials Subcommittee papers from fall 2011 and spring 2012.

**Background**

The reasons for encouraging research into organic production systems are well discussed in the previous two Materials Subcommittee papers from fall 2011 and spring 2012.

The recommendation that was passed recommends that potential topics be prioritized. The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but will be evaluated by the Materials Subcommittee in selecting the top research needs.

Criteria for research topics are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear).  
For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

In 2012, the NOSB adopted research priorities and identified topics for future review. In 2013, the Materials Subcommittee proposed research priorities and identified topics for future review; however they were not adopted by the NOSB until spring of 2014 because the fall 2013 meeting was cancelled due to a government shut down. Each fall, after a recommendation is finalized by the NOSB, the Chair of the Board will make sure it is sent to the primary organic research funders and stakeholders.

The NOSB requests the collaboration of national laboratories, foundations, organizations, federal agencies, land-grant institutions, non-land grant colleges, individuals, organic farmers, and the organic community in carrying out research, education, and training activities related to facilitating the development of organic agriculture, handling, processing, and organic foods.

The following research priorities seek to solve critical organic agricultural challenges and problems. The issues are often interrelated and should be viewed through an organic whole farm integrated approach as determined through the criterion of the organic system plan. All of the 2015 research topics are priorities.

**The NOSB encourages organic agricultural integrated research in the following areas:**

**Research Priorities 2015**

**2015 Materials and GMO ad Hoc Research Priorities**

Prevention of GMO Contamination: Evaluation of effectiveness

Last year we posed the research topic to find out how contaminated organic at-risk crops are from different sources; i.e. whether there is more contamination coming in from seed, from drift, or from handling practices.

While this is still badly needed, we also would like to see some data of how well some of the Prevention Strategies proposed by the NOSB work at keeping GMOs out of organic crops. For instance, how wide (or how many rows) of buffer are needed for corn? As a follow up to that, 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 reduce contamination using typical protocols for organic cleaning, whether siting at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen.

Lastly there needs to be research on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent GMO drift and impact on organic and identity preserved crops. This is policy research rather than field research but is equally as important.

**2015 Livestock Subcommittee Research Priorities**

Organic Agriculture is a systems based certification program. Systems research is complex. It takes time, perhaps 20 years or more, and is not easily replicable. It takes into account the “confounding variables” and tries to understand the synergy in a system and the impact of internal and external factors. Without a quick clear result, funding for such systems research is hard to obtain.

By contrast the traditional, academic, funded research is to pose a narrow, clearly defined question, usually as a null hypothesis, and develop a research protocol which will allow an answer to the question in as short a time as possible. Results must be replicable in order to have peer reviewed acceptance and satisfy the funder. Such research specifically tries to eliminate the confounding variables, like the context of the farm field, in order to obtain the highest level of accuracy in answering the narrow question posed. Such basic research is typically laboratory based. Basic research provides critical detail and indicates topics for further research.

Over the last 25 years organic agriculture has become a well-established agriculture system and the research questions can now be posed within the context of established farms in various geographic regions of the country. This need for systems research is very clear when looking at trends in organic livestock production.

Asking the Right Question! We need both basic research and systems research, but the emphasis for livestock research priorities for 2015 is a systems approach to questions which the NOSB has raised in various forms in the past, and which continue to be of issue.

### 1. 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 are 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, it is clear that parasite immunity to chemical control will inevitably occur. Thus prevention of parasites is critical.

So the research question on prevention and management of parasites must be systems based. What farm systems, animal breeds, herd or flock management systems have shown the best results with parasite control over the last 20 years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic or other alternative treatments which have proven to work over time? What are the parasite resistant breeds? Are there plant species in pastures and scrub lands that could be incorporated into the annual grazing system to reduce 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 which include plants known to prevent parasites in various breeds?

### 2. Herd and Flock Health

In previous years the Livestock subcommittee has suggested basic research priorities on prevention and treatment of such topics as pneumonia and mastitis. The consumer expects all organic livestock to be treated well and be healthy. Animal welfare is of critical importance to the consumer. Consumers expect to be able to observe that their meat, wool and egg producing organic livestock are in good health.

In 2015 we suggest that the research priorities on herd and flock health should move to a systems review of successful models of livestock production nationwide. Which breeds are doing best being managed under organic management? Are we selecting the most appropriate breeds to be able to have high levels of herd and flock health? Which grazing management systems are producing the highest quality organic product from the healthiest flocks and herds? What factors on case studied farms appear to be contributing to healthy livestock? What internal and external factors contribute to the healthiest herds and flocks?

### 3. Evaluation of on Methionine in the Context of a System Approach in Organic Poultry Production

Continued research on the use of synthetic methionine in the context of a system approach (nutrition, genetic selection, management practices, etc.) is consistent with the National Organic Standards Board (NOSB) unanimous resolution passed at the La Jolla, California, spring 2015 full board meeting. Methionine is an essential amino acid in poultry diets. A system approach that includes industry and independent research by USDA/ARS, on-farms, and agricultural land grant universities is needed for (1) evaluation of merits of natural alternatives source of methionine such as herbal methionine, high methionine corn, corn gluten meal in organic poultry production systems, (2) 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, and (3) assessment of management practices for improving existing organic poultry animal welfare under different conditions. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and research wherein applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution. However, an aggressive and/or heightened research focus could lead to positive findings that can positively impact the organic poultry industry and the organic brand. The continued methionine focus *in globo* with a system approach is imperative and necessary.

## 2015 Handling Subcommittee Research Priorities

### Chlorine Materials

The three chlorine materials on the National List are widely used in farming and handling to clean and disinfect equipment, surfaces and produce. There is compelling and building evidence that these materials are harmful to the environment and to humans when they form trihalomethanes and other toxic compounds. Yet the new regulations on food safety and best management practices for cleaning in handling operations both require a suitable level of cleanliness to prevent pathogens from entering the food supply. The organic industry needs better information on alternatives for specific situations to determine if moving away from chlorine compounds can be implemented in the future.

The following points are particular areas for research activities:

- Alternatives that work in some situations include citric acid, hydrogen peroxide, ethanol and isopropanol, peracetic acid, and ozone. Which specific situations will these materials be able to substitute for chlorine?
- Which specific applications will the above materials NOT be able to substitute for chlorine?
- Are there practices which can reduce the formation of trihalomethanes in situations where chlorine must be used?
- Would rotating the choice of materials used for cleaning help lower the risks from the chlorine materials while still being effective against pathogens?
- Can chlorine be taken up by produce from the amount being used in wash tanks and the amount of time of exposure? If so, how much and how harmful is this if consumed?
- Is there a maximum level of chlorine that should be adopted by the NOSB as well as a residual level in rinse water, to prevent absorption by produce or other harmful effects?

## 2015 Crops Subcommittee Research Priorities

### Alternatives to Copper for disease and algae control

Copper has been used for more than a century to control serious diseases in crops such as late blight in tomatoes and fire blight in pears. Because the copper products degrade to elemental copper, the continued use over time can cause copper to accumulate in soil. If used improperly or to excess, copper can be toxic to aquatic life and wildlife.

Alternative materials are not yet available to address the many diseases and crops on which copper is used. Targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. The Crops Subcommittee does not feel that a Technical Report (TR) alone will be able to get specific enough about alternatives for each disease in each crop and more research is needed on many of the crop/disease combinations.

Some avenues for research:

- 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.
- Breeding plants that are resistant to the diseases that copper is necessary for.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced from current formulations.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating nutritional strategies to mitigate the impacts of plant diseases.
- Particular research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.

### Previous Years Research Priorities

These research priorities are listed to inform institutions and our organic stakeholders of the need for continued relevant research in these critical areas that impact every day organic agriculture, production and management:

#### 1. Organic Whole Farm Systems

a) Whole farm systems and impact on diversity of habitat, cropping systems, biological life, pest and disease resistance, the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests, the need for diverse ecological systems, food safety and sustainable organic farming systems, etc.

b) Alternatives to antibiotics (tetracycline and streptomycin) for fire blight. The studies should examine location, planting density, choice of varieties of cultivar and rootstock, soil improvement practices, pruning practices and general sanitation, groundcovers or intercrops, pollinator management, dormant copper sprays, bloom thinning/lime sulfur, early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment, surveys for fire blight activity, and other cultural and preventative techniques is critical.

c) Plant disease management practices and alternative materials, particularly for the humid areas of the country, that decrease reliance on copper or other substances that might have a

negative impact on the soil and health of workers. Assessment of pathogens including, but are not limited to: *Alternaria*, *Erwinia*, *Pseudomonas*, *Xanthomonas*, *Cercospora*, *Colletotrichum*, *Cladosporium*, powdery mildew, downy mildew, *Phytophthora*, *Pythium*, *Mycosphaerella*, *Phomopsis*, *Taphrina*, *Elsinoe*, *Gnomonia*, *Fusicladium*, *Nectria*, *Phyllosticta*, *Diplocarpon*, *Albugo*, *Guignardia*, *Botrytis*, *Exobasidium*, *Entomosporium*, *Exobasidium*, *Pestalotia*, *Phoma*, *Cristulariella*, and *Monilinia fruticosa*.

d) Citrus greening, caused by the bacterium *Candidatus Liberibacter*, and spread by a disease infected Asian citrus psyllid, is an emerging problem. Promising avenues of research include examining disease-resistant varieties, predators and parasites and how they interact with approved materials, nutrition (calcium, boron, and nitrogen have been identified), and botanical oils.

e) Biological control of plant diseases and bio-pesticides. Plant diseases caused by bacteria and fungi can often be prevented by the application of a non-pathogenic microorganism before infection occurs. Although much basic research has been done to identify microbial biological control agents, there is still a need for commercial development, field testing, and adoption by growers. Biological controls have been researched for late blight of potato and tomato (*Phytophthora infestans*), several diseases caused by *Botrytis cinerea*, and powdery mildew (several species), controlled by mites, fungi, and bacteria.

f) Nonsynthetic practices and materials that build soil health and accelerate development of organic matter in the soil, i.e. humates.

g) Evaluating organic no-till practices as a subset of the whole farm systems. Studies that examine the relationship of biodiversity and pest and disease resistance, the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests, and research into organic no-till should address practices that lead to effective weed control with minimum interference with the crop.

## **2. Genetically Modified Organisms (GMOs)**

a) The fate of genetically engineered plant material in organic compost. Studies that evaluate the microbial ecology of compost. Is there trait expression of BT (*Bacillus thuringiensis*) after composting? The impact of residues of pesticides in compost material. Because of the importance of compost to organic management systems, the types of mitigation measures that are efficacious, identification of problematic feedstock (e.g. cotton-based materials and yard waste), types of corrective action, and if thresholds for allowable residues are established, testing guidelines are required.

b) Reduction of genetically modified content of breeding lines.

c) Seed purity. Research evaluating how much crop contamination is occurring from seeds as a vector compared to drift or handling practices.

d) Breeding lines, foundation seed and ways to mitigate small amounts of genetic presence in breeding lines. Evaluates public germplasm collections that house at-risk crops for contamination. 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 researched.

e) Risk reduction from off-target exposure to non-permitted materials. Successful coexistence suggests that organic farms can exist without harm, consistent with consumer and farmer choice to avoid or minimize contamination. Avoidance or minimization may be achieved through users of GMOs and pesticides adopting practices that prevent non-permitted materials in OSPs from causing involuntary exposure by moving off their target site. Research efforts are needed that examine alternative strategies that can a) develop and examine management practices that enhance public and farmer awareness of at-risk organic farms, b) identify effective practices and standards that will prevent non-target impacts of materials used on farms not certified organic, and c) best methodologies to provide information and training. Are there strategies in place or that could be put in place that can provide information, training, to enhance public awareness of at-risk organic farms? Which methodologies are successful in ensuring risk reduction from materials not permitted under organic standards?

### **3. Organic livestock production and management systems**

a) Preventative organic practices to improve organic livestock health are critical and of high importance. These include general animal health as it relates to diseases prevention, uterine infections in peri-parturient animals, growth, and identification of vaccine types, nutrition, and production systems. It thus encompasses some of the more specific issues and is also related to the 2012 and 2013 priority of whole farm systems research.

b) Pastured poultry and salmonella. The assessment of preventive organic practices to improve organic livestock health is critical and of high importance. Research that could lead practitioners to better prevention strategies, that would improve health and management practices that minimize health issues are all important topics. Research examining where Salmonella infections can be introduced from, whether the pasture system has some inherent buffering capacity against pathogens getting a foothold, and the risk involved in raising organic poultry on pasture are key research topics.

c) Ways to find materials for the control of internal and external parasites in organic livestock operations. Research is needed that considers the efficacy of organic treatments used by, recommended to, and available to organic producers.

d) Methods to reduce mastitis. Mastitis is a disease that results in inflammation of the mammary gland. It is generally associated with dairy animals. It can be caused by bacteria, physical injury, etc. Mastitis is one of the most common and expensive diseases of dairy cattle. It can result in reduced milk production, discarded milk, treatment, and veterinary expenses. An urgent need exist for looking at ways to reduce mastitis in dairy herds. The research needs include the areas of herbal treatment of mastitis and management practices, and consider the efficacy of organic treatments used by, recommended to, and available to organic producers. Internal and external parasites control is important to animal welfare, growth, reproduction, and production.

e) Efficacy of organic treatments used by, recommended to, and available to organic producers. Pneumonia in a herd or flock means animals are not performing up to their maximum potential, production costs are higher, labor is increased, and food product quality is compromised.

Responsible animal caretakers know it is their duty and responsibility to address animal welfare concerns and ensure a safe and healthy environment for their animals.

f) Plant extracts to organically control methane producing bacteria in livestock. Plant extracts that could be environmentally and economically beneficial to organically control methane producing bacteria in the animal could lead to practices that reduce methane. Reduced methane results in more energy going to the animal from a given amount of feed. This reduces total feed required to meet nutritional needs and particularly helps grazing animals which have high protein availability.

g) Genetically modified (GMO) vaccines for livestock: A need exists for research and/or outreach on easier ways to determine the types of vaccines. A better way of identifying the types of vaccines is critically important to our stakeholders, especially livestock producers. The testing of products that could be alternatives to GMO vaccines in livestock production is a top priority.

#### **Organic Aquaculture**

a) Whole system evaluation of organic aquaculture - closed and open systems. Evaluation of the use patterns of synthetic materials permitted on the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which few synthetics are added.

b) Impact of fish waste water on the environment, feed and other supplements such as trace minerals that may have synthetic sources, fish health (diseases and parasites), and fish escapes in open and closed systems. The subcommittee also requests research into defining “organic aquaculture” in a framework that is consistent with OFPA and supportive of materials decisions.

c) Aquatic biodiversity. Organic farmers promote biodiversity in cultivated and uncultivated areas, and are expected to maintain areas like hedgerows, woodlands, wetlands, and wildlife corridors to promote non-crop biodiversity on the farm. Evaluation of terrestrial inputs derived from aquatic environments need to be based on an understanding of impacts.

d) Nutrient and mineral cycling in various aquatic systems, the structure of aquatic food webs, the movement of pollutants in various aquatic systems, bioaccumulation and bioconcentration in aquatic organisms, and the status and impacts of overharvesting and other stresses on aquatic/marine plants and animals. Board members, certifiers, and aquaculture operators all need to know how biodiversity conservation measures should be implemented in aquaculture systems and materials decisions.

#### **4) Public health and risk**

a) Impact of the use of the food additive carrageenan on human health.

b) Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products including organic tomatoes, beans, and soups.

#### **5) Commercial availability Assessments**

Research is requested that examines resources that indicate commercial availability.

The NOSB must make assessments of commercial availability or organic sources every time there is a petition or a sunset review for substances on §205.606 in particular (agricultural substances that may be used from non-organic sources). The NOSB requests research that indicates national and global commercial availability and how data was developed.

#### **6) Organic Consumer studies**

Research is needed that examines organic consumers and consumer demand. The NOSB requests research indicating the relationship of consumer buying habits and their belief about organic products in the market place. This could include evaluation of national organic consumer preferences and expectations beyond sales of organic products.

The NOSB values the support and hopes that this information will be useful for researchers in many fields to defend and solicit funds for research that benefits organic agriculture and organic food.

#### **Subcommittee Vote**

Motion to adopt the proposal on NOSB Research Priorities for 2015

Motion by: Jennifer Taylor

Seconded by: Harold Austin

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by C. Reuben (Calvin) Walker, Subcommittee Chair, to transmit to NOSB August 25, 2015**



**National Organic Standards Board**  
**Materials Subcommittee**  
**Proposal: Prevention Strategy Guidance for Excluded Methods**  
**August 11, 2015**

On April 24, 2014, the National Organic Program sent a memorandum to the NOSB titled “Improved Guidance on Preventing GMO Presence in Organic Products.” The memorandum asked the NOSB to provide recommendations regarding best management practices for prevention of unintended GMO presence. In response, the Materials Subcommittee prepared the following proposal.

## **I INTRODUCTION**

In an environment where GMOs are widely distributed throughout the food chain, it is imperative that organic producers and handlers have strategies and plans to prevent GMO contamination. A key tenet of "co-existence" is a shared responsibility for the exclusion of the methods and products of genetic engineering. The organic part of this shared responsibility is practiced extensively already, but it would be a stronger point in future policy statements and efforts against GMO contamination of organic products if it were spelled out thoroughly in guidance from the National Organic Program.

Many prevention strategies already exist in the organic and non-GMO community. These sources are being utilized to create a comprehensive set of steps and considerations that organic producers and handlers can use in their own operations and Accredited Certifying Agents (ACAs) can use to verify compliance with the contamination avoidance clause in the rule as it relates to GMOs.

## **II BACKGROUND**

The Organic Foods Production Act (OFPA) of 1990 does not mention biotechnology, genetic engineering or genetically modified organisms, but OFPA prohibits synthetics unless they are on the National List. The first NOP proposed rule (1997) did not prohibit GMOs, resulting in a huge public outcry against GMOs being considered for use in organic production and handling. The proposed rule was withdrawn and the second NOP proposed rule (2000) excluded the use of GMOs in organic production and handling.

The NOP regulations prohibit the use of GMOs as “excluded methods” under 7 CFR § 205.105: “Allowed and prohibited substances, methods, and ingredients in organic production and handling.” Excluded methods are defined as:

A variety of methods to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture (7 CFR § 205.2-Terms defined)

Compliance with the organic Standards requires that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, the presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The organic Standards make allowances for “Unavoidable residual environmental contamination,” which is defined (§ 205.2) as “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.”

The NOP relies on organic certifiers and producers to determine preventive practices that most effectively avoid contact with GMOs on an organic operation.

### III RELEVANT AREAS OF THE RULE AND NOP GUIDANCE/POLICY

#### Rule 7 CFR

#### **§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.**

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, that, the vaccines are approved in accordance with §205.600(a);

#### **§205.201 Organic production and handling system plan.**

(a)...An organic production or handling system plan must include:

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances;

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

#### **§205.272 Commingling and contact with prohibited substance prevention practice standard.**

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

#### **§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.**

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

**§205.670 Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”**

(a) All agricultural products that are to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

*NOP Guidance*

- NOP 5025 Commingling and Contamination Prevention in Organic Production and Handling (Effective date: 7/22/2011)

*NOP Policy Memo*

- Policy Memo 11-13 Genetically modified organisms (Issue date: 4/15/11)

*NOP Fact Sheets*

- Can GMOs be used in Organic Products? (Published May 2013)

**IV DISCUSSION**

Education is needed for organic farmers and handlers and their employees on the specific opportunities for cross contamination in their operations and regions. Education could be provided through extension services, webinars, self-assessment tools, etc. Part of the best management for every organic operation is to stay informed on GMO issues and the best management practices.

**Organic System Plan (OSP)**

Production and handling operations should identify and address their GMO prevention strategies and organic control points in their OSP. The producer and handler's OSP should include a description of management practices established to prevent contact of organic crops and products with GMOs, and a

description of the monitoring practices performed to verify that such measures are effectively implemented.

Certifying agents should evaluate the preventive practices to determine if they are adequate to avoid contact with GMOs. The preventive practices described in the OSP should be based on information collected through an “at-risk” assessment of crops/products and possible sources of GMO contact. The inclusion of this information should be consistent with other guidance documents NOP has released to industry and Accredited Certifying Agencies (ACAs).

### **Best Management Practices**

Because GMOs are widely used in conventional food and feed systems, they are nearly ubiquitous in our environment, and there are many potential opportunities for GMOs to contaminate organic food and feed. The following is a summary of management practices recommended to help prevent GMO contamination, drawn from the references listed at the end of this document, public comment on the draft discussion document on this subject put forward for spring 2015, and other sources.

#### Best Management Practices for seed and crop production

- Assess farm site and crops to be grown for potential sources of contamination.
- Identify at-risk crops<sup>1</sup> and potential points of contamination for each, including knowing what GMO crops are expected to be grown in the area.
- Communicate with neighboring farmers about what at-risk crops you will grow, if they will grow GMO varieties of those crops, and what might be done to help reduce the GMO contamination potential on your farm.
- Be certain that non-organic seeds that are used come with non-GMO verification from seed supplier.
- Seed growers and seed companies supplying organic seed to the organic community should follow protocols designed to intercept GE-contaminants and to deal with potential sources of contamination.
- Test at-risk seed, or get verification of clean seed from supplier, before planting.
- Avoid using bee pollinators that have been used in proximity to GMO fields and determine if neighboring feral hives exist that could carry GMO pollen to your farm.
- Know the life cycles of crops being planted, if the crops are self- or cross-pollinating, if the pollen is transported by wind or insects, etc.
- Isolate at-risk organic crops from GMO crops with suitable distances and/or planting timing, conferring with neighbors as needed.
- Control plants that could contaminate your crops, including volunteers, feral populations and wild relatives in proximity to your fields.
- Verify that all inputs, such as fertility and pest control materials, are non-GMO.
- Clean all equipment and facilities prior to use.
- Document equipment cleanout and keep records of all practices used to limit contamination.
- Inspect and clean storage facilities and be sure they are isolated from GMO storage.
- Avoid mixing during harvest, cleaning, storage, transport and sales.
- Be aware that GMO-laden dust from neighboring fields may require more thorough cleaning and

<sup>1</sup> High risk crops include alfalfa, canola, corn, cotton, soy, sugar beets, zucchini and yellow summer squash.

protection of organic products than just removing GMO seeds from equipment.

- Know the organic regulations for excluding GMOs and know your certifier's requirements
- Know your buyers' GMO requirements and testing protocols.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation are available from farm to buyer.

#### Best Management Practices for livestock

- Assess farm site and facilities for potential sources of contamination.
- Maintain separate, isolated facilities for feed storage of organic and GMO feeds (if a split operation).
- Inspect and clean storage facilities before use.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.
- Thoroughly clean and purge feed processing and handling equipment if used for GMO products.
- Document and maintain records of cleanout of equipment and facilities used for GMO products.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation are available from farm to buyer.

#### Best Management Practices for handling

- Assess the site, facilities and organic products/inputs for possible sources of GMO contact.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.
- All inputs must be traceable and must be of non-GMO source, even the nonorganic inputs contained in "made with organic" products.
- Organic and non-GMO materials must be strictly segregated from any GMO materials.
- Equipment must be thoroughly cleaned and purged if used for processing and handling GMO materials.
- Know which ingredients pose a GMO-contamination risk and what, if any, contamination levels are present in them.
- Determine minimum thresholds of GMO contamination for rejecting inputs in at-risk inputs.
- Create quality assurance and quality control procedures and practices for traceability, segregation, sampling and testing lots of inputs for GMO content, with adequate training of personnel to assure routine adherence to those procedures and practices.
- Utilize "Identity Preservation" systems as part of quality control system.
- Transportation: Clean and inspect trucks and trailers (including tarps and trailer covers). Require and keep verification records/affidavits. Know where product is coming from and where it is going, and ensure that transportation is clean and that records to support clean transportation

are available from farm to buyer.

### **The Role of ACAs and Oversight**

- On-site inspections (observation), review of the OSP and records, and periodic testing verify that farmers and handlers are following their organic system plan and that the measures described are effective.
- Role of testing (by ACAs) as a tool for verifying adequate contact prevention measures
  - Certifying agents may conduct residue testing to determine if these preventive practices are adequate to avoid contact with substances such as prohibited pesticides, antibiotics, and GMOs
  - If GMOs are suspected or detected, certifiers must conduct an investigation to determine if a violation of organic farming or processing standards occurred.
  - Note: Certifiers may need additional guidance from NOP on GMO testing (sampling procedures, testing options, choosing labs). Guidance is also needed to address positive results given that there aren't specific threshold levels in the USDA organic regulations. See Appendix A
- Any certified organic operation found to use GMOs may face enforcement actions, including loss of certification and financial penalties.

### **Subcommittee Vote:**

Motion to accept the Prevention Strategy Guidance for Excluded Methods in Crops and Handling Proposal

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Additional Discussion: none

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

### **Sources/References**

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Non-GMO Project Standard, 2013. Non GMO

Project. [http://www.nongmoproject.org/?attachment\\_id=8561](http://www.nongmoproject.org/?attachment_id=8561)

USDA National Organic Program - <http://www.ams.usda.gov/AMSv1.0/nop>

Blue River Hybrids - [www.blueriverorgseed.com/docs/PuraMaize-Fact Sheet.pdf](http://www.blueriverorgseed.com/docs/PuraMaize-Fact Sheet.pdf)

The Organic Center - <http://www.organic-center.org>

USDA/APHIS Biotech Regulatory Services (BRS) - <http://www.aphis.usda.gov/biotechnology/>

## **Appendix A**

### ***Guidance and training for ACAs on GMO testing***

On November 9, 2012, NOP published a Final Rule on Periodic Residue Testing. The rule clarifies a provision of the Organic Foods Production Act (OFPA) of 1990 and the regulations issued that require periodic residue testing of organically produced agricultural products by ACAs. NOP received several comments regarding types of residues that would be considered acceptable targets for testing under the rule. Four commenters requested clarification on testing for GMOs.

NOP responded by saying that it does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. Under the existing regulations, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and GMOs.

Given the regulatory requirements and NOP clarification, ACAs are required to test if there is reason to believe that an organic product has come into contact with GMOs. ACAs may also test for GMOs under the periodic residue testing requirements. To date, however, NOP has not issued any instruction or guidance on GMO testing.

The Materials/GMO Subcommittee could draft a recommendation to NOP to create guidance and provide training to ACAs on conducting GMO sampling and testing under the residue-testing rule. Providing NOP with a recommendation that includes further guidance on testing falls directly under the specific responsibilities outlined in the OFPA starting at section 2119(k):

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.

Although NOP guidance on pesticide residue testing is available and USDA resources for GMO testing in organic feed do exist, further guidance on GMO testing of other crops for human consumption is greatly needed. It is extremely important that guidance offer clear and consistent sampling and testing protocols so ACAs may accurately assess the efficacy of an organic operation's system for ensuring that GMOs do not come in contact with organic product. Testing is one of the most definite and effective tools ACAs can use to evaluate whether an organic operation has adequate measures in place to prevent commingling with non-organic GMO crops as well as intentional or unintentional contact with GMOs.

**Approved by C. Reuben (Calvin) Walker, Subcommittee Chair, to transmit to NOSB August 25, 2015**



## UPDATE

from the Policy Development Subcommittee  
August 11, 2015

The PDS collaborated with the NOP to draft revisions to the NOSB Policy and Procedures Manual. The goal is to update and streamline the document. This draft is presented for public comment and further NOSB review. There will be no vote on this document at the October 2015 meeting of the NOSB.

## NATIONAL ORGANIC STANDARDS BOARD

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# POLICY AND PROCEDURES MANUAL

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**DRAFT August 11, 2015**

# 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. New NOSB members are encouraged to review this manual in depth as well as to become familiar with the [Organic Foods Production Act](#) (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 accepting 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 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;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- 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 ACS, circulates that record to NOSB members for approval

- Assists with the annual election of NOSB officers
- 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 DFO/ACS. This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference once or twice a month on an as-needed basis, to be determined by the Administrative Team.

#### **E. NOSB-NOP COLLABORATION**

The Organic Foods Production Act (7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board 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. In Section 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution responsible for this and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture.

Maintaining, enhancing, and promoting integrity of organic principles and products is accomplished through team work and collaboration of the NOSB and the NOP, as well as others in the organic community. 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 ES 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.

Several factors to keep in mind with regard to the working relationship between the NOP and the NOSB:

- The NOSB is a FACA advisory committee, and as such, 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. 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 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.

#### **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 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 Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP approves NOSB work agenda.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., petitions, 5-year sunset review)
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 meeting 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 handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available

for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. 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 invests in transcripts to support the transparency of NOSB 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.

- 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 are subject to these requests, with some exemptions. Some 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 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:

- Don’t accept improper gifts (from those seeking actions from the Board).
- Don’t use board appointments for private gain.
- Don’t misuse internal non-public government information.
- Use government property and time properly.
- Don’t accept compensation for teaching, speaking, and writing related to your board duties.
- Don’t 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 nonpublic information with the public. Nonpublic information is 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.
- 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 fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he 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**

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.

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 NOP associate deputy administrator 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 NOP associate deputy administrator 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 associate deputy administrator 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 (etcetera).”
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 SUBCOMMITTEES**

The current standing Subcommittees are:

- Executive (ES)
- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

##### **Executive Subcommittee (ES)**

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 guidance, clarification or proposed standards on NOSB operations, policies, and procedures as needed, in collaboration with the NOP.

**B. AD HOC SUBCOMMITTEES**

At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee 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 plan 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 plans in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Subcommittee 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 plans
- 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**

Immediately after the election, on the final day of the NOSB meeting, the new 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.

#### **4. 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.

#### **5. Review of Subcommittee Files**

New Subcommittee Chairs should review all work plan items and active files involving Subcommittee work

#### **6. 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.

#### **7. 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.

#### **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 Subcommittee.

#### **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**

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 Subcommittees 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 recommendation;
- Will be included as a separate section at the end of the 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**

(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 petitions, sunset reviews, annotation changes, or classification changes.
- Proposals for policy or procedure changes
- Discussion documents

### **3. Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings**

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, and the other a motion to 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, and it cannot be acted upon unless there is a motion to substitute it for the report of the Subcommittee.

#### 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 (currently January 18, 2007 [72 FR 2167]).

##### 1. 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 if a Technical Review (TR) is needed.
3. Technical Report is completed and sent to the Subcommittee for review.
4. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
5. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
6. The NOSB members analyze comments and votes on the proposal at the public meeting.

7. 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 petitioner

### **Step 2: Determine whether a Third Party Technical Review is Required**

During this phase, 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?
- 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 the 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 3: 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 4: 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 TR, that the TR is sufficient. If the TR is not found sufficient, 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 Technical Reports are deemed sufficient, the NOP will post on the NOP website.

#### **Step 5: 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 Review, personal knowledge, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, 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 6: 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, listen to public comments, 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.

## **2. Changes to annotations 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 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 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.

## **3. 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 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 makes a determination on the completeness of the petition and whether a Technical Review is needed.
- The decision to define 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.

#### 4. Definitions

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.

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 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 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.

### **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 List Summary** for posting which may include requests for specific information. The NOP posts the list 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 may include 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**.

**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.

**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

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 may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

##### **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 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.

### **Oral Comments**

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings 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. Such electronic 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 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 names and affiliations 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 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 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.

### **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 Subcommittee 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 after each officer nomination and the Chair will verify the results
- The candidate receiving the greatest number of votes will be elected
- 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 or may be given the opportunity to withdraw at their discretion
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.

### **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.

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 Subcommittee 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. 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 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
  - 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 invests in transcripts 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:  
<http://www.gsa.gov/portal/content/100916>

**Note: the following sections have been removed from the PPM, and will be added to the NOSB Member Guide:**

- A. NOP COI MEMO
- B. PARLIAMENTARY PROCEDURES AT A GLANCE
- C. BASIC CHEMISTRY
- D. FORMS AND TEMPLATES