

**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](#)

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[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