

**Sunset 2019**  
**Meeting 1 - Request for Public Comment**  
**Handling Substances §§205.605(a), 205.605(b), 205.606**  
**April 2017**

**Introduction**

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

**Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at [www.regulations.gov](http://www.regulations.gov) by March 30, 2017 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

**Guidance on Submitting Your Comments**

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

**For Comments That Support Substances Under Review:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;

- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic handling.

**For Comments That Do Not Support Substances Under Review:**

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

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with handling.

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

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

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

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

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through March 30, 2017 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

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**Note:** The materials included in this list are undergoing early sunset review as part of November 18, 2016 [NOSB recommendation](#) on efficient workload re-organization.

**Reference: 7 CFR 205.605** *Nonagricultural* (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

**§205.605(a) Nonsynthetics allowed:**

[Attapulgite](#)

[Bentonite](#)

[Diatomaceous earth](#)

[Nitrogen](#)

[Sodium carbonate](#)

**§205.605(b) Synthetics allowed:**

[Acidified sodium chlorite](#)

[Carbon dioxide](#)

[Chlorine Materials: calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Magnesium chloride](#)

[Potassium acid tartrate](#)

[Sodium phosphates](#)

**Reference: 7 CFR §205.606** Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

[Casings](#)

[Konjac flour](#)

[Pectin \(non-amidated forms only\)](#)

## Attapulgit

**Reference:** 205.605(a) – as a processing aid in the handling of plant and animal oils.

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

**Petition(s):** [2009 Attapulgit](#)

**Past NOSB Actions:** [04/2011 NOSB recommendation](#); [10/2015 sunset review](#)

**Recent Regulatory Background:** Added to National List effective 08/03/2012 [[77 FR 45903](#)]

**Sunset Date:** 08/03/17 (NOP renewal pending)

### **Background:**

The original petition (2009) is a 158 page document with literature review. The petition also included information regarding the use of attapulgit in animal feed. In 2011 the NOSB recommended addition of attapulgit to §205.605 with the annotation “allowed as a processing aid in the handling of plant and animal oils”.

Attapulgit is characterized as a natural clay most often composed of a complex of magnesium (Mg) aluminum (Al) silicates that creates an open-channel structure with a large surface area and cation-exchange capacity that is important to its function to absorb, adsorb and filter substances (TR lines 19-21, 28-30,44-46, 75-83). In bleaching of oils/fats, the clay adsorbs color and other impurities to create the finished oils (TR lines 87-89). Common names for the substance include Fullers Earth, Palygorskite and Hormite (2009 Petition pg. 2).

Attapulgit (Doc. No. 1943) is listed under Everything 64 Added to Food in the United States (EAFUS) and referred to in 21 CFR Part 582 -- Substances Generally 65 Recognized as Safe (GRAS), §582.99 Adjuvants for pesticide chemicals (TR lines 63-65). The material is also listed by EPA as an inert ingredient in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) pesticide products applied 69 to food use site (e.g., food crops, animals used for food) and nonfood use site (e.g., ornamental plants, 70 highway right-of-ways, rodent control). In addition, attapulgit can be used, under 40 CFR §180.910 Inert 71 Ingredients, during pre- and post-harvest. It is exempted from the requirement of a tolerance. (TR lines 67-71)

Modern extraction is by open-pit mining where clay is removed and sent for processing of drying, milling, sieving, and possible acid activation (sulfuric, hydrochloric) to increase inherent attapulgit properties (TR 143-146, 148-151, 224-227). There is an adverse environmental impact due to mining and dust byproduct; environmental and mining regulations are in place to return disturbed earth and control dust output, minimizing overall net environmental impact (TR 233-244). Worker safety from dust concern is addressed through worker protective equipment and monitored through OSHA (TR 239-244). Material meets OFPA criteria.

This material was reviewed by the Board for Sunset during 2015: 3 Yes to remove, 11 No votes to maintain listing.

### **Additional information requested by NOSB**

None requested.

## Bentonite

**Reference:** 205.605(a)

**Technical Report:** [1995 TAP Kaolin Clay and Bentonite](#)

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

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/17 (NOP renewal pending)

**Background:**

Bentonite/Kaolin is a natural clay composed of alumina, silica and water derived from volcanic ash or tuff (1995 TAP pg. 1, 2). Clays have functional properties of large surface area with adsorptive properties that make them useful for filtering and purification functions with no function in finished food products (1995 TAP pg. 1, 2).

Bentonite is a mined substance obtained through open pit mining. Environmental impacts are monitored and subject to environmental regulations by other agencies to minimize long term impacts.

During Sunset Review in 2015 the Subcommittee sought public comment to specifically address the ongoing need for bentonite/kaolin and received clear indication from a range of stakeholders that it continues to be necessary. There was no public comment in opposition. Material meets OFPA criteria.

**Additional information requested by NOSB**

None requested.

## Diatomaceous earth

**Reference:** 205.605(a) - food filtering aid only

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

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

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 10/21/17 (NOP renewal pending)

**Background:**

The NOSB reviewed diatomaceous earth (DE) in November 2005, April 2010, most recently in October 2015, and recommended relisting each time.

Diatomaceous earth is comprised of accumulated shells of hydrous silica secreted by diatoms and is used as a filter aid in production of syrups, juices, beer, beverages and other products (1995 TAP pg. 4).

Diatomaceous earth does not exist within the final organic product, and is classified as a processing aid and not an ingredient.

Diatomaceous earth is a mined substance and processors must adhere to environmental regulations for removal and production purposes. Dust produced during processing can be a human health concern for workers and would be subject to OSHA requirements (1995 TAP pg. 5). Waste material can, in some states, be considered a hazardous waste requiring special disposal requirements (1995 TAP pg. 5).

The 1995 Technical Advisory Panel was made up of 3-people. . One reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify “food grade” quality of DE. DE is also used in swimming pool filters, which is not a food grade form. Diatomaceous earth satisfies the OFPA criteria

Public comment indicates a widespread use of diatomaceous earth as a filter aid.

**Additional information requested by NOSB**

None requested.

## Nitrogen

**Reference:** 205.605(a) - oil-free grades.

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

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

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 10/21/17 (NOP renewal pending)

**Background:**

Use: Nitrogen is used to displace oxygen and thereby reduce oxidation of product during processing, storage and packaging. It can be used in the flash freezing of foods. It also functions as a propellant when used under pressure, and doesn't have ozone-depleting properties.

Manufacture: Nitrogen is a colorless, odorless gas. Cryogenic distillation, where air is compressed, cooled, and then filtered, is the most economic and highest purity method for separating nitrogen from air.

International: The use of Nitrogen is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Nitrogen satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

**Additional information requested by NOSB:**

None requested.

## Sodium carbonate

**Reference:** 205.605(a)

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

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

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 10/21/17 (NOP renewal pending)

### Background :

Use: Used as a raising (leavening) agent. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a stabilizer, as well as a neutralizer for butter, cream, fluid milk, and ice cream. Sodium carbonate is the material used to give pretzels and lye rolls their brown crust without burning. Sodium carbonate is also used in the processing of olives prior to canning, in the making of ramen noodles, and in cocoa products.

Manufacture: Sodium carbonate is produced in North America from natural deposits of trona ore (sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then concentrated by evaporation to crystallization. This is considered to be the most sustainable form of producing sodium carbonate. Also, in California, sodium carbonate can be produced from a similar method using natural brine (Searles Lake).

International: The use of Sodium carbonate is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Sodium chlorite satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

### Additional information requested by NOSB:

None requested.

## 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](#), [2013 TR for Livestock](#)

**Petition(s):** [2006 Sodium Chlorite, Acidified](#)

**Past NOSB Actions:** [2009 NOSB recommendation](#); [10/2015 sunset review](#)

**Recent Regulatory Background:** Added to NL effective 03/15/2012 ([77 FR 8089](#))

**Sunset Date:** 03/15/17 (NOP renewal pending)

**Background:**

Specific Uses of the Substance:

Acidified Sodium Chlorite (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

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: Previous public comments asked for a comprehensive review of all sanitizers but the Subcommittee feels that a review of that scope is beyond the sunset review process.

**Additional information requested by NOSB**

1. Is the substance essential for organic food production and handling?
2. 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.
3. Provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.



## Carbon dioxide

**Reference:** 205.605(b)

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

**Petition(s):** [2005 Carbon Dioxide](#)

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [2007 NOSB Committee recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/2017 (NOP renewal pending)

### Background:

Use: Carbon dioxide is used in modified atmospheric packaging, modified atmospheric storage, the freezing of foods, beverage carbonation, as an extracting agent, processing aid, and for pest control in grain and produce storage.

Manufacture: 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.

International: The use of carbon dioxide is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances: None

Carbon dioxide satisfies the OFPA evaluation criteria.

This material was reviewed by the NOSB during 2015 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

### Additional information requested by NOSB:

None requested.

## 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](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/2017 (NOP renewal pending)

**Background:**

## Specific Uses of the Substance:

## Sodium and Calcium Hypochlorite

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals. These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems.

## Chlorine Dioxide

Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies. 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:

Regarding 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 these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L or 4ppm).

Discussion: Previous public comments asked for a comprehensive review of all sanitizers but the Subcommittee feels that a review of that scope is beyond the sunset review process.

**Additional information requested by NOSB**

The NOSB in its initial request for public comment asks:

1. Is the substance essential for organic food production and handling?
2. 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.

**Magnesium chloride**

**Reference:** 205.605(b) – derived from sea water.

**Technical Report:** [1995 TAP](#); [2016 TR](#)

**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](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/2017 (NOP renewal pending)

**Background:**

Use: Magnesium chloride is used in organic food processing as a processing aid, and as a coagulant/firming agent in tofu production. It can also be used to dress cotton fibers, or as a color retention agent and as a source of essential mineral magnesium in infant formula.

The EPA regulates magnesium chloride as a pesticide on List D, pesticides of less concern (EPA 1998). Magnesium chloride has also been used to treat bovine hypomagnesemia (low blood magnesium levels).

Magnesium chloride is currently allowed under the National Organic Program regulations at 7 CFR 205.605(b) as a nonagricultural synthetic substance for use as an ingredient in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).” The current annotation reads, “derived from sea water”.

During the 2015 Sunset Review, 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”.

In its initial review in 2015 the Handling Subcommittee 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.

Following the 2015 Sunset Review this material was recommended for continued listing but issues related to classification were raised and a Technical Report (TR) was requested. The TR, dated November 30, 2016 was utilized by the subcommittee in this initial Sunset 2019 Review.

**Manufacture:** Natural commercial sources of magnesium chloride can be classified as (a) sea water; (b) terminal lake brines; (c) subsurface brine deposits; and (d) mineral ore deposits. Magnesium chloride produced from each of these natural sources is the product of a brine comprising soluble ions of various mineral elements, primarily sodium, potassium, magnesium, calcium, chloride and sulfate (TR 2016, 186-189).

*(a) Sea Water*

Sea water is processed in solar ponds to produce concentrated brines from which specific minerals crystallize and are recovered. These specific minerals, called “evaporites,” crystallize in a sequence based on the concentrations of anions and cations in the brine and their innate solubility in water (TR 192-194).

*(b) Terminal lake brines*

A terminal lake is a lake where water is flowing in but no water flows out, so that the dissolved salts concentrate and form brine as the water evaporates. The Great Salt Lake in Utah is a familiar example.

Great Salt Lake brine is the primary source of magnesium chloride in North America. The Great Salt Lake contains sodium-magnesium-chloride-sulfate brine with low alkalinity (Domagalski, Orem, and Eugester 1989). Like solarization of seawater, the first evaporite of Great Salt Lake brine to form is halite (sodium chloride), followed by schoenite (magnesium-potassium sulfate), kainite (potassium chloride-magnesium sulfate double salt), and carnallite (potassium-magnesium chloride), resulting in a magnesium chloride brine (Neitzel 1971 ). Evaporating the water in this magnesium chloride brine creates crude solid magnesium chloride (TR 2016, 221-234).

*(c) Subsurface brine deposits*

Brine deposits in Midland, Michigan, have been a source of magnesium chloride since the 1890s. The Dow company originally obtained its bromine, chlorine, sodium, calcium and magnesium from the brine of ancient seas under Midland (TR 2016, 264-266).

*(d) Mined mineral deposits*

The two major mined mineral sources of magnesium chloride are bischofite and carnallite, both of which were formed during prehistoric solar evaporation of sea water (Butts 2004). Solution mining of these ore bodies creates a brine that is processed on the surface. Water is pumped into the ore body to dissolve these soluble minerals, forming a brine which is pumped to the surface. Most of the patented processes for purification and concentration of these brines rely on water and evaporation, without any additional chemicals. However, because magnesium chloride is soluble in alcohol while potassium chloride is not, several patented processes for separating pure magnesium chloride from carnallite employ a low molecular weight alcohol, such as methanol, to recover pure magnesium chloride (TR 2016, 291-297).

Synthesis of magnesium chloride by the reaction of a magnesium compound such as the oxide, hydroxide, or carbonate with hydrochloric acid is a chemical process, which involves chemical reaction of an acid and an alkali to form a salt. (TR 2016, 340-342).

GRAS: Magnesium chloride hexahydrate is affirmed by the FDA as Generally Recognized As Safe (GRAS) as a food ingredient (21 CFR 184.1426). It is allowed by the FDA as a flavoring agent, adjuvant, nutrient supplement, and may be used in infant formula (TR 2016, 94-96).

Ancillary substances: Magnesium chloride hexahydrate is commercially available as colorless, odorless flakes, crystals, granules or lumps. Both JECFA and FCC require that the material assays at 99% to 105%  $MgCl_2 \cdot 6H_2O$ . Commercial sources contain no additional or ancillary ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents or other materials) (TR 2016, 110-113).

International: International Organic food processing standards allow use of magnesium chloride – see TR 2016 for scope of specifications (TR 2016, 156-181). EU standards include use of term nigari. Nigari consists of the natural components of sea water including magnesium chloride, magnesium sulfate and other elements of sea water that remain after sodium chloride crystallizes from solar brine (TR 2016, 120-122).

Classification: During initial Review in 2015 the subcommittee requested public comment on whether or not this material should be re-classified as non-synthetic because it is simply derived from sea water by brine drying, with no ancillary substances. Public comment supports that this material should be re-classified as non-synthetic and moved from a listing at 205.605 (b) to 205.605 (a). However, information provided in the TR 2016 indicates that this material can be produced both synthetically and non-synthetically, and the annotation “derived from seawater” can apply to both synthetic and non-synthetic.

Magnesium chloride produced by reacting a magnesium compound or mineral with hydrochloric acid is considered synthetic. This is because the substance undergoes a chemical change so that it is chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-354)

Natural sources of magnesium chloride can be extracted by various means which may affect the classification of the final substance as synthetic or non-synthetic. Evaporation and crystallization are physical processes which do not result in chemical change. Magnesium chloride extracted from brine by the two-step process involving calcium hydroxide and carbon dioxide is not chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-361)

#### **Additional information requested by NOSB**

1. Are any producers/handlers using synthetic magnesium chloride? If yes, would they be able to switch to a non-synthetic version?
2. What impact on producers/handlers would result, if any, if magnesium chloride was removed from 205.605 (b) and added to 205.605(a)?
3. Besides a coagulant in making tofu, are there any other uses of magnesium chloride in organic processing/handling?

## **Potassium acid tartrate**

**Reference:** 205.605(b)

**Technical Report:** [1995 TAP](#); [2017 TR](#)

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

**Past NOSB Actions** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/2017 (NOP renewal pending)

#### **Background:**

Potassium acid tartrate is a by-product of wine making. It is commonly known as Cream of Tartar. It is used in baked goods, a component of baking powder, and can be used to stabilize egg whites or other food uses. No public comment opposing continued listing of this material was received during the 2015 Sunset Review.

Potassium acid tartrate is currently allowed under the National Organic Program (NOP) regulations at 7CFR 205.605(b) as a **“nonagricultural, synthetic substance** for use as an ingredient in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).” The FDA authorizes use of potassium acid tartrate in a variety of applications as a direct food substance, including as a leavening agent, a pH control agent, and an antimicrobial agent.

History: During its 2015 Sunset review, the NOSB noted a number of inconsistencies in the historical documents about this material, confusion with specific names of similar sounding materials, and confusion in classification of this material. However, until the NOSB received an updated TR, it recommended continued listing of potassium acid tartrate. . A new TR, dated January 11, 2017, was received and is utilized for this Sunset 2019 review. A detailed discussion of the historical documents relevant to potassium acid tartrate is provided in the 2017 TR.

Manufacture: During the winemaking process, sediments must be removed to produce a clear wine. “Lees” is the name of the sediment consisting of dead yeast cells, grape pulp, seed, and other grape matter that accumulates during fermentation. “Argol” and “tartar” are synonyms used to describe the crust that builds up in wine vats and casks. Argol is defined as crude potassium hydrogen tartrate, deposited as a crust on the sides of wine vats. Tartar is defined as a substance consisting essentially of cream of tartar that is derived from the juice of grapes and deposited in wine casks together with yeast and other suspended matter as a pale or dark reddish crust or sediment. Tartar consists of about 80% potassium acid tartrate. Potassium acid tartrate is only slightly soluble in cold water but highly soluble in hot water (6.1g/100 mL at 100°C). Extracting wine lees with hot water dissolves the potassium acid tartrate. When the filtered extraction solution is cooled, potassium acid tartrate precipitates as very pure crystals (>99.5% pure). No other reagents or solvents are involved in the extraction. (TR 2017, 58-69).

GRAS: Potassium acid tartrate is Generally Recognized as Safe (GRAS) (TR 2017, 350).

Ancillary substances: There are no ancillary substances associated with potassium acid tartrate.

International: International guidance and regulations include the use of potassium acid tartrate (INS 336i) in organic processing, generally consistent with the limited uses described by FDA at 21 CFR 184.1077(c). The European-focused regulations and guidance – CODEX, IFOAM and the EU – additionally include potassium tartrate (dipotassium tartrate) (INS 336ii) as an allowed potassium tartrate. (TR 2017, 184-187).

Classification: Potassium acid tartrate is present in grape juice and wine; it is extracted from natural sources: press cake, lees, and sediment recovered from winemaking. It is extracted with potable water and undergoes no chemical change during extraction or crystallization. Based on the decision tree in Draft Guidance NOP-5033-1, this manufacturing process could be considered nonsynthetic, although it is currently classified as a synthetic substance at §205.605(b) (TR 2017, 339-343).

The FDA defines “potassium acid tartrate” at 21 CFR 184.1077(a): “Potassium acid tartrate (C<sub>4</sub>H<sub>5</sub>KO<sub>6</sub>, CASReg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture” (TR 2017, 368-371).

No method of manufacture other than as a by-product of wine manufacture is encompassed by this regulation. The FDA definition of potassium acid tartrate would appear to require an agricultural source. Grapes and wine are agricultural products. The by-products that naturally settle out of grape juice and fermenting wine are used to make this food ingredient, with minimal processing (hot water extraction). However, the NOP regulation classifies potassium acid tartrate as nonagricultural at 7 CFR 205.605.

Interestingly, potassium acid tartrate is a precursor to tartaric acid, which is another substance on the National List. Tartaric acid, with the annotation “made from grape wine,” is listed at §205.605(a) as an allowed *non-synthetic*, nonagricultural (nonorganic) substance. This classification came from a 1995 NOSB vote. Thus, tartaric acid from grape wine is classified as non-synthetic, while the precursor, potassium acid tartrate from grape wine, is classified as synthetic.

This material appears to meet the OFPA criteria but it may be inaccurately classified as non-agricultural and synthetic as opposed to agricultural and non-synthetic.

#### **Additional information requested by NOSB**

Should this material be re-classified as agricultural or non-synthetic and therefore be listed at §205.606 or §205.605(a)?

## **Sodium phosphates**

**Reference:** 205.605(b) - for use only in dairy foods.

**Technical Report:** [2001 TAP](#); [2016 Phosphates](#)

**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](#); [10/2015 sunset review](#)

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

**Sunset Date:** 06/27/2017 (NOP renewal pending)

#### **Background:**

The material was added to the National List 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 soy processing was not added to the permitted uses 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.

The technical advisory panel (TAP) report, 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. They also noted low calcium reported in susceptible individuals (p 6).

The relationship between sodium phosphate and calcium sequestration raises issues of concern given that 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 are not listed in the following organic standards: EU, CODEX, IFOAM or JAS.

Public comment: Industry supports the listing 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 requested a new Technical Report (TR) which it received in 2016. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long term cumulative impacts are not fully understood.

**Additional Information requested.**

Given that this material is not allowed in organic foods produced in Europe, what alternatives are used?

## Casings

**Reference:** 205.606(a) casings, from processed intestines

**Technical Report:** N/A

**Petition(s):** [2006 Petition](#)

**Past NOSB Actions:** [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 sunset review](#)

**Recent Regulatory Background:** Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017 (NOP renewal pending)

**Background:**

Uses: The intestines of beef, lamb and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

Manufacture: Intestines are washed in pure water with no chemicals, and salted in NaCl salt and water. No other ingredients or processing aids are used. Animal intestines used may be from organic or non-organic animals. Slaughterhouses do not separate certified organic and non-organic offal. Certified organic intestines from certified animals are not available commercially.

History: On 4/21/2007 the NOSB found that "...no processor with the equipment or technology to process slaughter by-products into casings, from processed intestines, has organic certification and /or

is unwilling to use their equipment for a batch so small as size as would be needed to fulfill current organic requirements.”

In 2007 there were no public comments specifically opposing the listing of casings from processed intestines.

In 2015 the NOSB requested additional information during first posting of this material:

1. Are there companies manufacturing casings made from certified organic livestock?
2. Are casings from intestines of organic animals commercially available in the US or international?
3. What chemicals, other than salt, are used to process animal intestines into casings?

Public Comment during review in 2015:

Although more organic animals are being slaughtered than in 2007, no public comment provided any new information as to manufacture process or possible availability of certified organic intestines.

Industry strongly supports continued listing and no commenter asked for removal.

#### **Additional information requested by NOSB**

No additional information requested

## Konjac flour

**Reference:** 205.606(n) Konjac flour (CAS # 37220-17-0).

**Technical Report:** None

**Petition(s):** [2001 Petition](#)

**Past NOSB Actions:** [05/2002 NOSB minutes \(determined to be agricultural\)](#); [10/2010 NOSB sunset recommendation](#); [10/2015 sunset review](#)

**Recent Regulatory Background:** 2007 Interim Rule ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017 (NOP renewal pending)

#### **Background :**

Konjac flour is derived from tubers of the elephant yam, *Amorphophallus konjac*, and is primarily grown in tropical and subtropical regions of Asia. It is also called glucomannan. It is a soluble dietary fiber that's been used in traditional foods in Asia such as shirataki noodles and konjac curd (konnyaku). Shirataki noodles are marketed as a zero calorie, zero carbohydrate alternative to pasta and rice.

Konjac is also used as a binder, gelling agent, thickener and stabilizer. Konjac flour is unique in its ability to absorb up to 50 times its weight in water. It is widely used in weight loss supplements because it promotes a sense of fullness and pushes more calories through the colon instead of letting them be absorbed. It is one of the few fibers that are tolerated by diabetics and helps lower serum cholesterol and blood glucose.

Because of konjac's ability to quickly absorb water, there is some concern regarding the potential for capsule supplements or shirataki noodles to block the esophagus. However it appears this is largely avoided by consuming capsules with plenty of water and sufficient chewing of the noodles.

An internet search found several commercially available organic konjac products, including alternatives to [rice](#) and several forms of [pasta](#) (spaghetti, fettucine, etc.) made from organic konjac flour.

History: Konjac flour was reviewed at the Fall 2015 NOSB meeting. There was no new information regarding the OFPA criteria, and no sources of organic konjac flour were identified in public comment. One trade association indicated that it was still important, particularly for use with meat products like sausages and in fruit gels. Other starches and gums do not produce the unique combination of functions that konjac flour has.

#### **Additional information requested by NOSB:**

There appears to be increased availability of organic konjac sources, particularly for gluten-free alternatives to pasta & rice products. With sources seemingly more available, the Subcommittee is interested in the following questions:

1. In addition to alternative pasta & rice products, are the sources of this organic konjac sufficient to provide manufacturers with the form and function required for organic products such as sausages, fruit gels and supplement powder?
2. Do you make an organic product using konjac flour?

## **Pectin**

**Reference:** 205.606(s) Pectin (non-amidated forms only).

**Technical Report:** [1995 TAP](#); [2009 TR](#); [2010 supplemental TR](#); [2015 TR](#) (limited scope)

**Petition(s):** [2005 Petition – low methoxy pectins](#)

**Past NOSB Actions:** [04/1995 minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 NOSB recommendation](#); [10/2015 sunset review](#)

**Recent Regulatory Background:** Sunset Review effective 06/27/12 ([77 FR 33290](#))

**Sunset Date:** 6/27/2017 (NOP renewal pending)

#### **Background:**

Use: Pectin is extracted from citrus and pome fruits but so far there is no organic source of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. The excess sugar has the potential for more negative human health effects than pectin.

Manufacturing: The most common production of non-amidated pectin is the treatment of pectin containing byproducts (pome fruit cores, citrus peels) with acidified water. Insoluble materials are filtered and removed and the pectin is precipitated out with alcohol.

International: A review of international standards showed pectin was compliant with the Canadian organic standards (both high and low methoxy allowed), the IFOAM organic standards (unmodified

forms only), the EU standards (Pectin allowed in all products but meat based products), Japanese organic standards (Pectin allowed in all products but meat based products) and Codex (Pectin allowed in all products but meat based products, in dairy products pectin must be unmodified).

Ancillary Substances: Ancillary substances used in pectin include sugar and dextrose for standardizing products, and trisodium citrate (or other salt buffers described in the 2015 TR).

Discussion: In 2015, pectin was widely supported in public comment from its users. No negative comments were received with substantive information on why pectin would not meet the OFPA criteria.

**Questions:**

1. Have organic sources of pectin become available since the last review in 2015?

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
L-Methionine**

**January 17, 2017**

**Summary of Petition**

Nature's One has petitioned for L-Methionine to be added to §605.205(b) as a synthetic, non-agricultural substance, allowed in or on nutritionally complete enteral pediatric formulas labeled "organic" or "made with organic (specific ingredients)" with the annotation, "for use in nutritionally complete pediatric enteral formulas based on soy protein".

**Summary of Review:**

L-Methionine is an essential amino acid, which cannot be synthesized by the human body. The material exists as a clear or white powder.

L-Methionine exists in a category around which there has been much controversy, specifically, the addition of synthetic nutrient vitamins and minerals and accessory nutrients on the National List.

In 1995, the National Organic Standards Board (NOSB) made the following recommendation in "The Use of Nutrient Supplementation in Organic Foods" (USDA, 2011) *Upon implementation of the National Organic Program, 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.* (2012 TR, lines 162-167)

Since that recommendation, the National Organic Program (NOP) published a proposed rule that clarifies a previous reference to FDA's 21 CFR 104.20 for nutrient vitamins and minerals, which indicates that L-Methionine would not be allowed under that provision. Hence the separate petition for its inclusion on the National List.

Nature's One has petitioned for the addition of L-Methionine to the National List at §205.605(b) with a very narrow annotation. The material was petitioned so that organic soy-based enteral products may meet the nutritional requirements for protein. While the FDA does not have specific requirements for enteral products, a sister agency, The Centers for Medicaid and Medicare, has defined nutritionally complete pediatric enteral formulas through the Healthcare Common Procedure Coding System (HCPCS). B4159 is the HCPCS for nutritionally complete pediatric enteral formulas based on soy protein.

**Category 1: Classification**

1. Substance is for:  **Handling**
  
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance  **Agricultural** or  **Non-Agricultural**?  
Describe reasoning for this decision using NOP 5033-2 as a guide: