

Sunset 2019
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
November 2017

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.

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 crop production.

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

Attapulgite

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

Technical Report: [2010 TR](#)

Petition(s): [2009 Attapulgite](#)

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

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

Background:

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

Attapulgite 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).

Attapulgite (Doc. No. 1943) is found in the Everything Added to Food in the United States (EAFUS) inventory, as it is referred to in 21 CFR Part 582—Substances Generally Recognized as Safe (GRAS)—at §582.99 when used as an adjuvant with pesticides (TR lines 63-65). The substance is also listed by EPA as an inert ingredient in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 25(b) pesticide products applied to food use sites (e.g., food crops, animals used for food) and nonfood use sites (e.g., ornamental plants, highway right-of-ways, rodent control). In addition, attapulgite can be used, under 40 CFR 180.910 Inert 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 (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). The substance meets OFPA criteria.

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

At the Spring 2017 NOSB meeting there was public support for re-listing due to active use of the material by certified operators. A couple comments were made that, overall, the material does not appear to be

in widespread use and may not be necessary for the industry. The Handling Subcommittee supports continued listing of attapulgite on the National List.

Additional information requested by NOSB: None requested.

Subcommittee vote:

Motion to remove attapulgite from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Joelle Mosso

Seconded by: Ashley Swaffar

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

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 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

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.

At the Spring 2017 NOSB meeting public comment was received in strong support from the organic wine industry of relisting bentonite on the National List. A couple comments were made suggesting need to review the impact of mining activities in the production of this material; no new information was provided regarding that mining concern.

Bentonite satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports continued listing of attapulgite on the National List.

Additional information requested by NOSB

None requested.

Subcommittee vote:

Motion to remove bentonite from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Joelle Mosso

Seconded by: Ashley Swaffar

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

Diatomaceous earth

Reference: 205.605(a) - food filtering aid only

Technical Report: [1995 TAP](#)

Petition(s): N/A

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

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

Background:

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

Diatomaceous earth (DE) 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 three 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. At the Spring 2017 NOSB meeting, public comment was received in strong support from numerous stakeholders for the relisting of DE on the National List. A couple comments were made suggesting need to review the impact of mining activities; no new information was provided regarding the mining concern.

Diatomaceous earth satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports continued listing of the substance on the National List.

Additional information requested by NOSB: None requested.

Subcommittee vote:

Motion to remove diatomaceous earth (DE) from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Joelle Mosso

Seconded by: Ashley Swaffar

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

Nitrogen

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

Technical Report: [1995 TAP](#)

Petition(s): N/A

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

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

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

At the spring 2017 NOSB meeting there were a large number of public comments submitted in support of nitrogen remaining on the National List, and none in opposition.

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.

Subcommittee vote:

Motion to remove nitrogen from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

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

Sodium carbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

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

Recent Regulatory Background: Sunset renewal 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

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

Public comment from the spring 2017 NOSB meeting stated sodium carbonate is essential for use as a leavening agent, neutralizer in baked goods, frozen desserts, and soy base extraction. It is also used as a pH adjuster in organic laundry detergents. One certifier commented that it is used to clean fruit and remove mold. Overall public comment was in support of sodium carbonate remaining on the National List. There was one commenter that requested a technical report to examine possible hazards during mining and manufacturing, need, and alternatives. One commenter requested clarification regarding which manufacturing processes are considered non-synthetic and permitted under the current listing.

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.

Sodium carbonate satisfies the OFPA evaluation criteria, and the Handling Subcommittee supports its continued listing.

Additional information requested by NOSB: none

Subcommittee vote:

Motion to remove sodium carbonate from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

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

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: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

Background:

Acidified sodium chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitations for using in direct food contact and as an indirect food additive:

- Direct Food Contact (Secondary Direct Food Additive, 21 CFR 173.325) – 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 Food Additive (Sanitizing solutions, 21 CFR 178.1010) – Food-processing equipment and utensils, and other food-contact articles

Manufacture:

ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with citric acid. Sodium chlorite and citric acid 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, 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 annotation on the National List specifies that only citric acid may be used to acidify sodium chlorite.

Discussion:

At the spring meeting we received comments both supporting and opposing relisting of ASC.

Comments in support of relisting stated:

- This is an essential tool in the fight against food borne pathogens
- Comments opposed to relisting stated:

- NOSB should do a comprehensive review of sanitizers.

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.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of acidified sodium chlorite (ASC).

Subcommittee vote:

Motion to remove acidified sodium chlorite (ASC) from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Ashley Swaffar

Seconded by: Lisa de Lima

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

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 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:

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

All public comment received during the spring 2017 NOSB meeting was in favor of retaining carbon dioxide on the National List.

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.

Subcommittee vote:

Motion to remove carbon dioxide from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 6 Abstain: 0 Absent: 2 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](#); [10/2015 sunset review](#)

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:

Background:

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: The NOSB has received several comments both supporting and opposing relisting. Several commenters opposed to the relisting stated: There needs to be a comprehensive review by NOSB of all sanitizers used. 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. 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.¹"

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 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.

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of chlorine materials.

Subcommittee vote:

Motion to remove chlorine materials from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Ashley Swaffar

Seconded by: Joelle Mosso

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

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](#)

¹ <http://www.gpo.gov/fdsys/pkg/CFR-2012-title9-vol2/pdf/CFR-2012-title9-vol2-sec590-516.pdf>

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/22

Subcommittee Review:

Background:

Use: Magnesium chloride is used in organic food processing as a processing aid, as a coagulant/firming agent in tofu production, and used in certified organic dietary supplements. 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 USDA organic 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". Similar comments were submitted during the 2017 spring NOSB meeting in response to the material's 2019 sunset review.

During its previous sunset 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 organization 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. However, public comment received during the spring 2017 NOSB meeting pointed out that magnesium chloride is also used in certified organic dietary supplements.

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 for this 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 at the time supported 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 2016 TR 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)

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

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? If not, why?
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. If only non-synthetic magnesium chloride was allowed in organic processing and handling, would the supply be sufficient for all users?
4. Is there any difference in functionality or application between synthetic and non-synthetic magnesium chloride?
5. Besides a coagulant in making tofu, are there any other uses of magnesium chloride in organic processing/handling?

This material satisfies the OFPA Evaluation criteria and the Handling Subcommittee supports the relisting of magnesium chloride.

Subcommittee vote:

Motion to remove magnesium chloride from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

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

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 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:**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 commenters opposed continued listing of this material during the sunset review in 2015, nor during the Spring 2017 review (advanced sunset review).

Potassium acid tartrate is currently allowed under the National Organic Program (NOP) 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 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 technical report (TR), it recommended continued listing of potassium acid tartrate. A new TR, dated January 11, 2017, was received and is utilized for this 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).

FDA 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 (C₄H₅KO₆, 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 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. Comments from the Spring 2017 NOSB review agreed that this material could be reclassified. The Handling Subcommittee supports continued listing of this material.

Additional information requested by NOSB: none

Subcommittee vote:

Motion to remove potassium acid tartrate from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Steve Ela

Seconded by: Ashley Swaffar

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

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 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:

Background:

The listing for sodium phosphates was recommended for addition to the National List in 1996 with the “dairy use only” annotation. The material is derived from phosphoric acid.

Uses: pH control agents and buffer, acidulant, sequestrant, texturizer, and nutrient. The NOP regulations restrict the use of sodium phosphates to organic dairy products only. In milk and cheese, they act as stabilizer, and as an emulsifier in cheese. Disodium phosphate can be used as a processing agent in heavy whipping cream, where it binds to milk minerals to prevent the milk from coating the equipment during processing. Sodium phosphates are used in some organic milk products, such as half and half and heavy whipping cream, to stabilize the milk protein and to ensure the products do not separate or lose protein prior to consumer use (Technical Report 2016).

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 (mono- 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). They also noted low calcium reported in susceptible individuals (p 6).

On the topic of the effect of phosphates on bone health, the 2016 technical report (TR) identified studies showing a range of conclusions. For example, one study found that phosphate additives were more harmful to bone health than other phosphorus sources (Kemi et al. 2009) (TR lines 615-622).

While another study showed that higher dietary phosphorus does not always lead to the associated negative health effects (Rue and Kestenbaum 2009) (TR lines 624-628) This is just one example of the contradictory studies presented in the TR.

The 2001 TAP suggests calcium citrate, potassium citrate, and sodium citrate as possible substitutes in certain applications such as dairy cheese processing, as well as calcium citrate as an alternative to trisodium phosphate in milk processing. The TAP also listed a number of alternatives such as lecithin, agar, alginic acid, pectins and gums, but these were only identified as appropriate for soy processing. (TAP lines 404-425)

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 (Japan).

Discussion: In 2015 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 an 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. Other public comment noted that while phosphorus is not listed on the nutritional panel, it would be listed on the ingredient panel when used as an ingredient. When used as an indirect food additive or processing aid, sodium phosphates may not appear on the ingredient panel as additives in these classes are not always required to be labeled. 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.

Public comment from the Spring 2017 NOSB meeting was varied, similar to the public comment received during the 2015 meetings. The spectrum included some commenters requesting sodium phosphate be removed from the National List due to human health concerns and lack of essentiality, with others suggesting an annotation limiting the material to those uses considered essential. One organization noted that research on sodium phosphates found negative impacts on bone, kidney, and heart health and that phosphate foods additives are more readily absorbed during digestion resulting in a higher phosphorus load compared to naturally occurring phosphate. Alternatively, trade groups commented that health issues were linked to only a small segment of the population (individuals with chronic kidney disease) and that research into overconsumption and wider population impacts was currently insufficient to draw conclusions.

Public comment from handlers and processors stated that sodium phosphate is essential in organic cheese products, including liquid and powdered forms. Specifically, the material acts as an emulsifier and stabilizer for shelf stable cheese products. Handlers also reiterated sodium phosphates were essential for high protein dairy beverages for protein stability. An interest group questioned if additives for novel products like high protein dairy beverages should be considered essential.

The subcommittee requested information from public about alternatives used in Europe. A trade association noted that due to differences in cultures and consumer preference products found in America did not have the same demand in Europe therefore the need for sodium phosphates is different by region.

In Conclusion: There are 4 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

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

The Subcommittee would like to hear from manufacturers about whether they have tried alternatives such as calcium citrate, potassium citrate, and sodium citrate, and what the results were.

Subcommittee vote:

Motion to remove sodium phosphates from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Tom Chapman

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

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 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:

Background:

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 nonorganic animals. Slaughterhouses do not separate certified organic and non-organic offal. Certified organic intestines from certified animals are not available commercially.

International Standards:

A review of international standards showed casings are allowed in the EU. Casings are not listed in the Japanese Agricultural Standard for Organic Processed Foods (JAS) standard, nor do they appear on the indicative list of additives in the Codex guidelines. IFOAM does not allow it, unless by regional variation. Canada only allows it for collagen casings.

Discussion:

Since 2007, all casing sunset reviews have considered limitations on the availability of casings produced from organically raised livestock and agreed that 205.606 listing is appropriate. Echoing comments in 2015 and earlier, comments on casings submitted to the Spring 2017 meeting also raised concerns about the imitated availability of organically produced casing material. No new information as to the manufacture process or possible availability of certified organic intestines was presented. All comments were in favor of retaining use of non-organically produced casings as an option for production of organic sausage meat.

Concerns were raised about the need to incentivize production of organic casings but that was viewed as a long-term effort. Future NOSB meetings should consider whether a technical report reviewing barriers to the availability of organic casings is needed.

This material satisfies all OFPA criteria, and public comment confirmed its current use and need. The Handling Subcommittee supports continued listing of casings on the National List.

Subcommittee vote:

Motion to remove casings from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima
Seconded by: Tom Chapman
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Konjac flour

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

Technical Report: None

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

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

Recent Regulatory Background: 2007 Interim Rule ([72 FR 35137](#)); Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:

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.

Prior to the Spring 2017 NOSB meeting, the Subcommittee put forth the questions below to determine if availability of organic konjac flour warrants its removal from 7 CFR 205.606. Very few public comments were received and none answered the questions posed. One food additives trade organization and one other public commenter supported relisting. No organic processors commented

in favor of relisting this material. Three certifiers and one trade organization reported they did not receive a response from their clients or members, either in support of relisting or removal.

One commenter in favor of relisting acknowledged the availability of organic konjac flour as noted during the 2015 sunset review, however expressed “concerns about these suppliers and whether the konjac flour they offer is truly in compliance with organic standards.” The commenter continues, noting they have “...not been able to evaluate the specific suppliers noted” in the 2015 review. No data or evidence has been provided to show the validity of such statements.

Two commenters supported the removal of konjac flour, citing pesticide use in its conventional production. They further cited concern regarding the potential availability of a genetically modified variety of konjac flour and that measures should be taken to avoid its use in organic production.

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?

The Subcommittee has not received evidence that the organic supply of konjac flour is insufficient to meet the demand of organic processors.

Subcommittee vote:

Motion to remove konjac flour from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (c)(1)(A)(ii): essentiality.

Motion by: Scott Rice

Seconded by: Ashley Swaffar

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

Pectin

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

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

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

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

Recent Regulatory Background: Sunset renewal notice 2017 ([82 FR 14420](#))

Sunset Date: 03/15/2022

Subcommittee Review:**Background:**

Use: Pectin is extracted from citrus and pome fruits but so far there is no organic supply 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: Public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed extensively pectin's use and necessity in organic production. Once comment noted organic pectin was listed in the organic integrity database but also noted these products use it as a dietary supplement not as a gelling agent. Comments from a trade association representing the pectin industry spoke to constraints in commercializing organic pectin due to commingled raw material supplies and the current unavailability of organic pectin. A comment from an interest group stated pectin should be limited to high methoxyl pectin (HMP), extracted from citrus peel and apple pomace and wanted an evaluation to take into consideration the use of pesticides in the production of the non-organic raw materials. Board discussion noted the desire for the development of an organic pectin and discussed how this production could be incentivized but also noted the lack of commercial availability.

Pectin meets the OFPA criteria and is not available in sufficient organic supply, and no new substantive information was received during this review to contradict this listing.

Subcommittee vote:

Motion to remove pectin from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

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