Sunset 2024
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), § 205.606
April 2022

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 which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, 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 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2022 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 1, 2022 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: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.605(a), §205.605(b), and/or §205.606, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments that do not support a substance on §205.605(a), §205.605(b), and/or §205.606, you should provide reasons why the use of the substance should no longer be allowed in

organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

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

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

For Comments on Nonorganic Agricultural Substances at Section §205.606:
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.

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

Written public comments will be accepted through April 1, 2022 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’:

- Attapulgite
- Bentonite
- Diatomaceous earth
- Magnesium chloride
- Nitrogen
- Sodium carbonate

§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’:

- Acidified sodium chlorite
- Carbon dioxide
- Sodium phosphates

§205.606 Sunsets: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”:

- Casings
- Pectin
- Potassium acid tartrate

Attapulgite

Reference: §205.605(a) *Nonsynthetics allowed:*
Attapulgite—as a processing aid in the handling of plant and animal oils.
Technical Report: 2010 TR.
Petition: 2009.
Past NOSB Actions: 4/2011 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Attapulgite is used as a natural bleaching clay for the purification of vegetable and animal oils. The function of a bleaching clay is to remove undesirable by-products (impurities) for the vegetable oil and animal fat, thus improving the appearance, flavor, taste, and stability of the final product.

Manufacture
Attapulgus is the principal mineral of attapulgus clay, which is surface mined by open-pit method with stripping by scrapers, draglines, or bulldozers and extraction by shovels, backhoes, small draglines, or front-end loaders. The clay is then loaded onto trucks and transported to the processing plant. The clay is then dried, milled, and sieved to obtain a desired range of particle sizes.

International Acceptance
Note: In the United States, the term —attapulgite is used in place of palygorskite; however, the International Nomenclature Committee determined that palygorskite is the preferred name.

Canadian General Standards Board Permitted Substances List
Canadian Food Inspection Agency, Feed Program— Schedule IV of the Feeds Regulations, 1983, lists ingredients approved for use as livestock feed. Attapulgite clay (Schedule IV Number 8.111) is listed under Class 8. Miscellaneous Product of the Feeds Regulations. It stated, —Attapulgite clay (IFN6 8-14-008) is hydrated aluminum-magnesium silica, a naturally occurring mineral mined in Attapulgus, Georgia… It shall be labeled with the following statement: This product is for use in non-medicated feeds only as an anticaking agent or pelleting aid in an amount not to exceed 0.25% of the finished feed or as an emulsifier in liquid feed supplements at a level not to exceed 2.5% of the supplement.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Regulation (EC) 1831/2003— —Attapulgite (clay) CAS No. 12174-11-7‖, under silage additives functional group, listed in Community Register of Feed Additives. The date of first entry in the Register is July 11, 2005.

ECODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Attapulgite/palygorskite is not specifically listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Attapulgite/palygorskite is not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
Attapulgite/palygorskite is not specifically listed.

Environmental Issues
Attapulgite is surface mined, and, in most countries, the mining company is required by law to reclaim the land. Common practice is to open a cut, mine the clay, and then spoil the overburden from the next cut into the mined-out area. The spoil is leveled or sloped to meet the standards prescribed by the government, and grasses and/or trees are planted. Sometimes the topsoil is put back on top of the spoil and is used for agriculture. The major environmental issue is air quality because the dust during manufacture, use, or disposal. Repeated or prolonged inhalation of dust may cause delayed lung injury.

Discussion
From the most recent sunset review: There was public support for re-listing attapulgite 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. Based on the Subcommittee review and public comment in 2017, the NOSB found attapulgite compliant with OFPA criteria, and did not recommend removal from the National List. However, the vote was not unanimous and there was concern that attapulgite is not necessary for organic production.

Questions to our Stakeholders
1. Is attapulgite used today in organic production?
2. What industries are most impacted if removed from the NL?
3. Do the health concerns from mining attapulgite outweigh the need for organic use?

Bentonite

Reference: §205.605(a) *Nonsynthetics allowed:*
Bentonite.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Bentonite is used as a processing aid, not an ingredient. Its adsorptive qualities make it useful for removing impurities in edible oils like soy, palm, and canola. It can also be used to clarify beer, fruit juice, wine, sugar, and honey and is not present in the final product.

Manufacture
It is a naturally occurring porous rock of clay materials that derives from weathered volcanic ash. It is mined and thus subject to environmental mitigation and monitoring by other agencies. It is a fine white to yellowish white or graphic aluminum silicate clay with limited shrink-swell features. It darkens and takes on a distinct clayey smell in the presence of liquid. It is insoluble in water, alcohol, dilute acids, and alkali solutions.

International Acceptance
Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The material is not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is not listed.

Japan Agricultural Standard (JAS) for Organic Production
The material is not listed as a food handling aid.

Environmental Issues
While mining activities are regulated by other agencies, bentonite does derive from mining activities, which do produce negative impacts by definition.

It is generally regarded as safe (GRAS) and does not produce human toxicity, although if consumed in large quantities, particularly during pregnancy, can produce iron deficiency.

Historically, there has been strong public support for the continued use of bentonite. Based on the Subcommittee review and public comment, the NOSB finds bentonite compliant with OFPA criteria, and does not expect to recommend removal from the National List.

Discussion
The Handling Subcommittee discussed the longstanding support for keeping bentonite on the National List in this use. At the same time, the subcommittee did note the similarity of bentonite as a food processing aid to other listed substances (for example, diatomaceous earth) and indicated a desire to understand more fully how, why, and to what extent the material is being used in organic applications.

Questions to our Stakeholders
The subcommittee seeks public comment to specifically address the ongoing need for bentonite, given other similar (although perhaps not identical) substances.

Diatomaceous earth

Reference: §205.605(a) *Nonsynthetics allowed:*
Diatomaceous earth—food filtering aid only.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Used as a filtering aid in food production of syrups, juices, beer, beverages, and other products.

Manufacture
Diatomaceous earth is made from the fossilized remains of diatoms; their skeletons are made of a natural substance called silica. Diatoms accumulate in the sediment of rivers, streams, lakes, and oceans, and is mined in quarries or open-pit.

International Acceptance
The use of diatomaceous earth is permitted in organic processing by IFOAM, EU, and Codex.

Unsure if it is allowed by Canadian General Standards Board Permitted Substances List or Japan Agricultural Standard (JAS) for Organic Production

Environmental Issues
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.

Discussion
The NOSB reviewed diatomaceous earth (DE) in November 2005, April 2010, and 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). Other filtering aids includes bentonite (also on the NL). DE is also used in swimming pool filters, which is not a food grade form. At the Spring 2017 NOSB meeting, numerous stakeholders expressed strong support for the relisting of DE. A couple comments were made suggesting a need to review the impact of mining activities; no new information was provided regarding the mining concern.

Diatomaceous earth was found to satisfy the OFPA evaluation criteria in previous reviews.

Questions to our Stakeholders
1. Are stakeholders continuing to use DE today in organic production?
2. Have there been any changes to the environmental issues of DE production?
3. Are there alternative filtration aids allowing the removal of DE from the NL?

Magnesium chloride

Reference: §205.605(a) *Non-synthetics allowed:*
Magnesium chloride.
Technical Report: 1995 TAP; 2016 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 10/1999 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577); Classification change from synthetic to nonsynthetic effective 11/22/2019 (85 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

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).

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 Acceptance

Canadian General Standards Board Permitted Substances List

Magnesium chloride is a permitted processing substance listed in CAN/CGSB-32.311-2015, Table 6.3, "ingredients classified as food additives," with the annotation, "derived from seawater."

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

The European Community regulation permits the use of the magnesium chloride (or "nigari") in processing organic foods of plant origin as a coagulation agent (EC No. 889/2008 Annex VIII, Section B – Processing Aids).

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

The Codex organic guidelines permit the use of magnesium chloride (INS 511) in food category 06.8, soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10); food category 12.9.1, soybean protein products; and food category 12.10, fermented soybean products

International Federation of Organic Agriculture Movements (IFOAM) Norms

The IFOAM Norms, Appendix 4, Table 1, permit the use of magnesium chloride (INS 511) as an additive and also as a processing and post-harvest handling aid for soybean products only.

Japan Agricultural Standard (JAS) for Organic Production

Article 4, Table 1, Food Additives permits the use of food additive INS 511, magnesium chloride, and also "crude seawater magnesium chloride," for processed foods of plant origin as a coagulating agent or for processed bean products.

Environmental Issues

The historical process of solar evaporation of sea water to obtain salt and additional minerals such as magnesium chloride creates saline ponds and infertile soil. Solar salt ponds have been reused for several millennia in the Eastern Mediterranean so that the environmental damage is localized. With respect to terminal lakes such as the Great Salt Lake, the major environmental threat here is not related to mineral extraction operations; it is the reduction of water flow into this terminal lake caused by agricultural and other diversions (Wurtsbaugh et al. 2016). Winds blowing over dry lake beds cause dust storms and urban pollution. An environmental risk with solution mining is surface subsidence, as the underlying mineral is dissolved and removed, effectively creating a cavern. (TR 414-423).

Discussion
Magnesium chloride is currently allowed under the USDA organic regulations at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." Magnesium chloride was previously listed at §205.605(b) with the annotation "derived from sea water." However, during the Spring 2018, the Board put forth a proposal to reclassify magnesium chloride as non-synthetic and to remove the annotation "derived from sea water" since there are multiple sources from which non-synthetic magnesium chloride can be derived. This proposal passed unanimously, went through the rulemaking process, and became effective on November 22, 2019.

During the 2015 and 2017 sunset reviews, public comment from tofu producers, trade associations and certifiers indicated 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".

During the 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 recommended an annotation "as a coagulant in making tofu". Public comment suggested 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. Additionally public comment received during the Spring 2017 NOSB meeting pointed out that magnesium chloride is also used in certified organic dietary supplements.

Questions to our Stakeholders
1. Is the use of magnesium chloride as a color enhancement consistent with organic principles?
2. There appear to be other materials on the National List (e.g., Glucono delta-lactone and calcium sulfate) that perform the same or similar functions most specifically in tofu production. The subcommittee is requesting information as to whether these alternatives offer the same or similar functionality and essentiality?

Nitrogen

Reference: §205.605(a) *Nonsynthetics allowed:*
Nitrogen—oil-free grades.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

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 Acceptance
The use of nitrogen is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The material is allowed in food handling.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is allowed in food handling.

Japan Agricultural Standard (JAS) for Organic Production
The material is allowed in food handling.

Environmental Issues
None. Nitrogen is a naturally occurring inert atmospheric gas.

Discussion
During the 2017 Sunset review, there was strong public support for continued use of nitrogen. The Board voted unanimously to retain nitrogen on the National List.

Questions to our Stakeholders
None

Sodium carbonate

Reference: §205.605(a) *Nonsynthetics allowed:*
Sodium carbonate.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use
Sodium carbonate is 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 processingof 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 method is considered to be the most sustainable form of producing sodium carbonate. Additionally, 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

Discussion

Public comments during prior sunset reviews have stated that 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 apH adjuster in organic laundry detergents. One certifier commented that it is also used to clean fruit and remove mold. Past public comments have been supportive of sodium carbonate remaining on the National List. Prior comments have raised concerns about possible hazards during mining and manufacturing and requested a technical report to examine possible hazards during mining and manufacturing, and also evaluate the need for this material and alternatives. Past comments have also asked for clarification that manufacturing processes are considered non-synthetic and permitted under the current listing: 205.605(a) non-synthetics allowed. This material was most recently reviewed by the NOSB in Fall of 2017 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

Questions

1. Is this material still essential for organic handling and processing?
2. Are there alternative materials that can replace sodium carbonate?
3. What are the relative environmental impacts of trona mining or brine extraction during production of sodium carbonate?
4. Is sodium carbonate produced from trona or brine extraction non-synthetic?

Acidified sodium chlorite

Reference: §205.605(b) *Synthetics allowed:*

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Technical Report: 2008 TAP; 2013 TR (livestock).
Petition: 2006.
Past NOSB Actions: 2009 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use

Acidified sodium chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation for use 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 Food Contact – Hard surface food contact sanitation.

Manufacture

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 was stated in the 2006 petition. However, there is no information in the petition regarding how the natural citric acid is manufactured.

International Acceptance

Canadian General Standards Board Permitted Substances List
Acidified sodium chlorite is not specifically listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no specific listing for acidified sodium chlorite for use in handling.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
There is no specific listing for acidified sodium chlorite for use in handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
There is no specific listing for acidified sodium chlorite for use in handling.

Japan Agricultural Standard (JAS) for Organic Production
Limited to the use for disinfecting meat and poultry at slaughter, or washing eggs.

Environmental Issues
While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004) (2013 TR, 360 - 362). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

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 is manufactured.

Discussion
In the 2017 sunset review, public comment regarding acidified sodium chlorite was mixed. Those in support stated that this is an essential tool in the fight against food borne pathogens. Those opposed to relisting stated that the NOSB should do a comprehensive review of sanitizers. The NOSB believes a review of that scope is beyond that of the sunset review process. Based on the Subcommittee review and public comment, the NOSB finds acidified sodium chlorite compliant with OFPA criteria, and does not recommend removal from the National List.

Questions to our Stakeholders
- Is the substance essential for organic food production?
- Since the material was last reviewed, have additional commercially available alternatives emerged?

The Handling Subcommittee encourages current users of acidified sodium chlorite to provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

Carbon dioxide

Reference: §205.605(b) *Synthetics allowed:*
Carbon dioxide.
Technical Report: 1995 TAP; 2006 TAP.
Petition: 2005.
Past NOSB Actions: 10/1995 minutes and vote; 2007 recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use

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

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 food processing and handling.

International Acceptance
Canadian General Standards Board Permitted Substances List
Carbonation of wine or mead is prohibited.
Allowed for controlled atmosphere storage and for storage pest control.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Listed as an allowable processing aid for ingredients of agricultural origin from organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Allowed as a pest control method in storage facilities, and as a processing aid.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Approved as processing and post-harvest handling aid (e.g., for flavoring agents).
Approved as an additive.

Japan Agricultural Standard (JAS) for Organic Production
Approved for use a fumigant in storage facilities.

Environmental Issues
According to the 2006 TAP report, the production of carbon dioxide is a byproduct of environmentally damaging processes via air pollution, solid waste streams, and drilling underground wells.

Carbon dioxide is a greenhouse gas and its use in organic food production means there may be a delayed release to the atmosphere in some cases.

Discussion

This product is on the FDA list of generally recognized as safe products. The EPA allows carbon dioxide as a pesticide as a fumigant, insecticide, and rodenticide.

In the previous sunset review, there was no substantive discussion about this material. No public comment supported delisting. There was support for its continued use by food manufacturers and associations.

Questions to our Stakeholders
1. Is carbon dioxide essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Sodium phosphates

Reference: §205.605(b) *Synthetics allowed:*
Sodium phosphates—for use only in dairy foods.
Technical Report: 2001 TAP; 2016 TR (phosphates).
Petition: 2001.
Past NOSB Actions: 10/1995 minutes and vote; 10/2001 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use
Sodium phosphates are salts used as pH control agents and buffers, acidulants, sequestrants, texturizers, and nutrients in organic dairy products. They act as stabilizers in milk and as emulsifiers 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.

Sodium phosphates are generally recognized as safe (GRAS) across multiple regulatory entities.

Manufacture
Finely ground, mined phosphate rock is mixed with sulfuric acid to form phosphoric acid. It is then reacted with sodium hydroxide to form sodium phosphate. There is a purification step in each reaction to remove substances like arsenic and fluorine.

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for dairy use only.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not listed.

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
Phosphates, including sodium phosphates, can pollute water bodies and lead to eutrophication and there have been global efforts to remove phosphates from detergents. That said, there is no widespread concern about adverse impacts of these substances in food uses (specifically dairy) on the environment.

Also, since sodium phosphates derive from the mining of phosphate rock, there are environmental impacts associated with the manufacture.

Discussion
Public comment regarding sodium phosphates has historically been mixed. During the previous sunset review, stakeholders in support of the material's use in organics stated that sodium phosphate is essential in organic cheese products, including liquid and powdered forms, specifically as an emulsifier and stabilizer for shelf stable cheese products. Opposing stakeholders have expressed concern about potential human health impacts (the 2016 technical report was inconclusive) and material essentiality. Prior subcommittee review concluded that since there are four phosphates on the National List at § 205.605(b), no single phosphate food additive or ingredient can be implicated for inordinate and isolated risk. Some studies have indicated that high levels of phosphate consumption can accelerate aging and vascular damage, although sodium phosphate itself also has use among athletes for performance enhancement.

Questions to our Stakeholders
1. How essential are sodium phosphates to your operations or the operations of your stakeholders? Are there other natural substances or synthetic substances on the National List that could perform the same essential functions as sodium phosphates?
2. Do you have any new and compelling evidence that health impacts from sodium phosphates are significant?

Casings

Reference: §205.606(b) Casings, from processed intestines.
Technical Report: N/A
Petition: 2006
Past NOSB Actions: 4/2007 recommendation; 10/2010 sunset recommendation; 10/2015 sunset review.
Recent Regulatory Background: Added to National List on 06/21/2007 (72 FR 35137); Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
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.

Casings have not received GRAS status, according to the 2019 TR.

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. The animal intestines used may be from organic or nonorganic animals. Slaughterhouses do not separate certified organic and non-organic offal.

International Standards
Canadian General Standards Board Permitted Substances List
Collagen casings are allowed for poultry sausages

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

Environmental Issues
There are no published reports of heavy metals and other contaminants present in formulations of collagen gel and casings. According to the TR, there are no published studies on environmental impacts of casings, but "the manufacture of collagen may result in reductions to livestock and fish wastes".

Discussion
Since 2007, all casings sunset reviews have considered limitations on the availability of casings produced from organically raised livestock and agreed that a §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 limited availability of organically produced casing material. 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.

There was strong public support for the continued use of casings at the last review. Some commenters encouraged the industry to examine the barriers to the availability of organic casings and raised the concern about the need to incentivize production of organic casings.

Questions to our Stakeholders
1. How much potential is there for a certified organic casings market?
2. Is separation at the slaughterhouse still a barrier to the availability of certified organic supply?

Pectin

Reference: 205.606(p) Pectin (non-amidated forms only).
Technical Report: 1995 TAP; 2009 TR; 2010 TR (supplemental); 2015 Limited Scope TR.
Petition: 2005 (low methoxy).
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

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.

Manufacture
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 Standards

Canadian General Standards Board Permitted Substances List

Compliant with the Canadian organic standards (both high and low methoxy allowed)

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

Pectin allowed in all products but meat-based products

Japan Agricultural Standard (JAS) for Organic Production

Pectin allowed in all products but meat-based products

International Federation of Organic Agriculture Movements (IFOAM).

Unmodified forms only

Environmental Issues

According to the most recent TR, the FDA "suggest that the petitioned substance is not harmful to human health or the environment. Since the manufacture of pectin is a by-product of the fruit juice industry, its production therefore serves to reduce the waste streams generated from the making of fruit juices."

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 previous Sunset reviews, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed extensively pectin's use and necessity in organic production. One 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.

There was strong public support for the continued use of pectin. Previous 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.

Questions to Stakeholders:

1. Has an organic source of pectin become commercially available?

Potassium acid tartrate

Reference: §205.606(q) Potassium acid tartrate.
Technical Report: 1995 TAP; 2017 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Classification changed from non-agricultural to agricultural 5/30/2019 (84 FR 18133).
Sunset Date: 5/30/2024

Subcommittee Review

Use
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, for stabilizing egg whites or other food uses, pH control, and as an antimicrobial agent (2017 TR). A detailed discussion of the historical documents relevant to potassium acid tartrate is provided in the 2017 TR.

Potassium acid tartrate was previously 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))." However, during the 2017 sunset review, a number of commenters noted that it should be listed at § 205.606 as a non-organically produced agricultural substance. The NOSB agreed with this assessment and passed a recommendation for the change of listing. That recommendation underwent subsequent rulemaking and potassium acid tartrate is now listed under § 205.606.

Manufacture
During the winemaking process, sediments form that 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 the listed substance.

International Use
According to the 2017 TR, international guidance and regulations include the use of potassium acid tartrate (INS 336i) in organic processing and are 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.

Canadian General Standards Board Permitted Substances List
Potassium acid tartrate ($KC_4H_5O_6$) is a permitted processing substance listed in Table 6.3, ingredients classified as food additives, with the following annotation: "If the non-synthetic form is not commercially available, the synthetic form is permitted."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Consistent with the Codex guidelines, the European Community regulation permits the use of the potassium tartrates (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) in processing organic foods of plant origin (EC No. 889/2008 Annex VIII, Section A Food Additives).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex organic guidelines permit the use of potassium acid tartrate (INS 336i) and dipotassium tartrate (INS 336ii) in plant foods, specifically confectionary, flours and starches, and cakes, but not in animal foods.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM Norms, Appendix 4, Table 1, permit the use of INS 336 (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) as an additive and as a processing and post-harvest handling aid, without limitation.

Japan Agricultural Standard (JAS) for Organic Production
Article 4, Table 1, Food Additives permits the food additive INS 336i, potassium acid tartrate, for limited use for grain processed foods or confectionary only.

Environmental Issues
Since potassium acid tartrate is a byproduct of the winemaking process, the environmental issues are limited to those associated with the production of conventional grapes. There are increasing quantities of organically produced grapes and wines available.

Discussion
Public commenters overwhelming supported relisting of this substance during the public sunset review process in 2017. As with several of the products derived from wine making, there is a question of commercial availability, and when the quantity of organic supply could meet the needs of the marketplace and this substance could be delisted. It is difficult to develop organic supply while non-organic tartrate is in the marketplace, thus making it hard to determine when there could be, or is, sufficient supply to meet the organic market needs.

Questions to our Stakeholders
1. Is there adequate supply of organically produced potassium acid tartrate to meet commercial needs?