



Sunset 2025
Meeting 1 - Request for Public Comment
Handling Substances § 205.605 & § 205.606
April 2023

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. Substances included in this document may also be viewed in the NOP's [Petitioned Substances Index](#).

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 2023 public meeting. Written public comments will be accepted through April 5, 2023 via www.regulations.gov.

These public 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:

1. Alternative management practices that would eliminate the need for the specific substance;
2. Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
3. 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 5, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605 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)).”:

§205.605(a): Nonsynthetic substances allowed in organic handling:

- [Calcium carbonate](#)
- [Flavors](#)
- [Gellan gum \(high-acyl form only\)](#)
- [Oxygen](#)
- [Potassium chloride](#)

§205.605(b): Synthetic substances allowed in organic handling:

- [Alginates](#)
- [Calcium hydroxide](#)
- [Ethylene](#)
- [Glycerides \(mono and di\)](#)
- [Magnesium stearate](#)
- [Phosphoric acid](#)
- [Potassium carbonate](#)
- [Sulfur dioxide](#)
- [Xanthan gum](#)

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

§205.606: Nonorganic agricultural substances allowed in organic handling:

- [Fructooligosaccharides](#)
- [Gums - water extracted only \(Arabic; Guar; Locust bean; and Carob bean\)](#)
- [Lecithin - de-oiled](#)
- [Tamarind seed gum](#)
- [Tragacanth gum](#)

Calcium carbonate

Reference: 205.605(a) Nonsynthetics allowed. (6) Calcium carbonate.

Technical Report: [1995 TAP](#); [2018 TR](#)

Petition(s): N/A

Past NOSB Actions: [11/1995 NOSB minutes and vote \(pg. 12\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and nutritional fortification additive. The U.S. Food & Drug Administration (FDA) allows the use of calcium carbonate as a binding agent in meat and poultry pieces and a color additive mixture for coloring foods at 21 CFR 73.70. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List in 7 CFR 205.605(b).

Manufacture

Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. Calcium carbonate is a mined mineral of at least 98% purity that is ground and screened.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#); CAN/CGSB-32.311-2015:
Allowed, prohibited for use as a coloring agent.

European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)
Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products.

Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods \(GL 32-1999\)](#)

Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items.

Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3.

[International Federation of Organic Agriculture Movements \(IFOAM\)](#)

Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handling aids.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance.

Environmental Issues

The mining and processing of calcium carbonate can have negative environmental impacts, which may include impacts on both above and below ground water systems. Mining may have impacts on biological diversity, as the mining may draw down the water table and impact surface water features that play host to a variety of species. Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will protect against these issues. There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg. The Handling Subcommittee feels that calcium carbonate continues to be essential to organic production.

Ancillary Substances

None

Discussion

During the Fall 2018 Board meeting, public commenters widely supported the relisting of this material, noting its essentiality to organic production in the absence of viable alternatives. Commenters detailed uses including in soy cheese, yogurts, and beverages as a source of calcium; as much as 15% of the RDA. Comments also pointed to its use as a stabilizer.

Calcium carbonate is not listed in the Organic Foods Production Act of 1990.

Questions to our Stakeholders

1. What are the predominate uses for calcium carbonate?
2. Can alternative substances be used without reducing product quality? If so, what are these alternative substances?

Flavors

Reference: 205.605(a) Nonsynthetics allowed. (12) Flavors - nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Technical Report: [2005 TR](#); [2022 Limited Scope TR pending](#)

Petition(s): [2015 Petition \(to amend\)](#)

Past NOSB Actions: [11/1995 NOSB minutes and vote \(pg. 6\)](#); [04/2006 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#));

Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Annotation change published 12/27/2018 ([83 FR 66559](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Natural flavors are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product. The significant function of natural flavors must be flavor rather than nutrition.

Manufacture

Flavors can be derived via several different methods. Distillates are a clear, flavorful liquids derived from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc., are essential oils dissolved in an alcohol-water mixture. Essential oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf, or peel. They are made by steam distillation or cold pressing. Essential oil isolates are a chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass. Oleoresins are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color, and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A compounded flavor is a mixture of ingredients such as extracts, essential oils, and natural isolates. Processed flavors, also known as reaction flavors, are ones that are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins, and fat, which must then be heated for a length of time to yield the desired profile.

International Acceptance

[Canadian General Standards Board Permitted Substances List.](#)

- Permitted for use - derived from biological sources and substances. May contain permitted carriers.

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

- Flavoring substances in organic products must be natural or organic under European regulations. (EC 2018/848)
- The European Union's flavor regulations have a more limited number of processes that are acceptable for the production of natural flavors (Müller, 2007; Sabisch & Smith, 2020). Certain processes in Europe lead a substance to be classified as "artificial" that are considered "natural" in the U.S. (Müller, 2007).

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

- Permitted for use

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

- The IFOAM Standards Appendix 4, Table 1, *List of Approved Additives and Processing/Post-harvest Handling Aids* includes “Flavoring Agents” with the following annotation (IFOAM, 2014):

Operators may use:

- organic flavoring extracts (including volatile oils), and, if not available,
- natural flavoring preparations approved by the control body. Such approval shall include assessment that natural flavors shall meet the following criteria:
 - the sources are plant, animal, or mineral;
 - The process of production is in accordance with a recognized organic standard;
 - They are produced by means of solvents such as vegetal oils, water, ethanol, carbon dioxide and mechanical or physical processes.”

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

- The Japanese Agricultural Standard for Organic Processed Foods allows “Flavoring” with the annotation: “Limited only to those that are not chemically synthesized” (Japanese Agricultural Standard for Organic Processed Foods, 2020).

Environmental Issues

None

Ancillary Substances

Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: “must not be produced using synthetic solvents and carrier systems or any artificial preservative.” Flavoring constituents are considered proprietary by flavoring companies and are not normally disclosed.

Discussion

The TR was received close to the Subcommittee submission deadline and therefore the information from the TR was not fully incorporated into this review. The TR will be available as soon as the Handling Subcommittee determines it to be sufficient. Its contents will be incorporated into the Board discussion at the Spring meeting as well as the Fall 2023 proposal.

During the 2018 sunset review, the National Organic Program (NOP) had not completed rulemaking on the petitioned annotation change requiring the use of organic flavors when commercially available. This was the main focus of comments at the time urging NOP to complete rulemaking. The annotation change was finalized in 2019 and is reflected in the currently listed on the National List.

The Handling Subcommittee’s discussion focused on trying to get a better idea of sources and manufacturing processes for flavors in an effort to determine the current and future availability of organic flavors in the market.

Questions to our Stakeholders

1. Do you produce or certify organic flavors that include ingredients listed on § 205.605? If so, what ingredients?
2. How would removal of flavors from § 205.605 impact the commercial availability of organic flavors?
3. Are there flavors currently used in organic products that cannot be produced organically (including any of the examples listed in the TR such as castoreum derived from beavers, Tonquin musk oil from musk deer, wood chips from nonorganic forest products, distilled liquid smoke, fish flavors)?

Gellan gum (high-acyl form only)

Reference: 205.605(a) Nonsynthetics allowed. (13) Gellan gum (CAS # 71010-52-1) - high-acyl form only.

Technical Report: [2006 TR](#); [2018 TR \(gums\)](#)

Petition(s): [2005](#)

Past NOSB Actions: [03/2007 NOSB recommendation \(§205.605\(b\), not recommended for addition\)](#); [11/2007 NOSB recommendation \(§205.605\(a\)\)](#); [10/2014 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to the National List 12/14/2010 ([75 FR 77521](#)); Sunset renewal notice published 06/19/2015 ([80 FR 35177](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Gums are used in organic handling for different reasons, including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibiting ice and sugar crystal formation, (4) aiding formulation, and (5) controlling the release of flavors.

Despite having similar characteristics, the gums are not interchangeable. Due to their structure, some gums behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life, and product use. Often the gums are used in combination to impart specific properties of the finished goods (2018 TR).

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

The 2018 TR specifies the functional uses of gellan gum as a thickener, gelling agent, and stabilizer. Gellan gum can be used at low levels in many products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring. Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution. Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR, 2006 TR). Typical use of gellan gum is at <0.5% of a finished product formula (Petition). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Manufacture

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR, 2018 TR). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g., potassium, calcium, magnesium); these deacetylated forms are not approved on 205.605(a) (2006 TR). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR).

International Acceptance

[Canadian General Standards Board Permitted Substances List.](#)

Gellan gum is permitted, and requires the use of allowable extraction solutions and precipitation aids. Isopropyl alcohols can be used for extraction as well.

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

There is no explicit mention of gellan gum in the EC regulation.

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

Gellan gum is not explicitly mentioned.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Gellan gum is not explicitly mentioned.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Gellan gum is not explicitly mentioned.

Environmental Issues

The two available technical reports (2018 and 2006 TRs) did not list any notable human health or environmental concerns regarding the use of gellan gum. A 2018 study, in response to an NOSB request for an updated study of the safety of gellan gum as a food additive, found no adverse health impacts of gellan gum and did not recommend establishing an acceptable daily intake level.ⁱ

Ancillary Substances

According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion

During the Spring 2018 public comment period, a number of manufacturers wrote in support of the material, with multiple manufacturers stating that they are using gellan gum as a carrageenan replacement due to customer concerns. Examples of specific products that use gellan gum include plant-based creamers and beverages, dairy beverages, and yogurt.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since the last review.

Questions to our Stakeholders

1. Is an organic version of gellan gum commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the last sunset review?

¹ Younes, M., Aggett, P., Aguilar, F., Crebelli, R., Filipic, M., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U. and Kuhnle, G.G., 2018. Re-evaluation of gellan gum (E 418) as food additive. *EFSA Journal*, 16(6), p.e05296.

Oxygen

Reference: 205.605(a) Nonsynthetics allowed. (21) Oxygen - oil-free grades.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 329\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Oxygen is used in modified atmosphere packaging, the processing of olives, and by wineries, breweries, and manufacturers of carbonated beverages.

Oxygen is an odorless and tasteless gas and is commonly used to help maintain color and prevent pallor in food (although in some volumes, it can have the opposite effect). It can also aid in inhibiting the growth of bacteria. Oxygen can be helpful in a modified atmosphere packaging environment because it can help prevent spoilage in products that are high in sugar or water.

Manufacture

Oxygen is separated from air cryogenically, or the super-cold temperature liquefaction of air and fractional distillation.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Permitted for use.

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

Permitted for use.

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

Permitted for use.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Permitted for use.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Permitted for use.

Environmental Issues

There does not appear to be significant environmental issues associated with the use of oxygen in modified atmosphere packaging. In fact, it can have the effect of extending shelf life or viability and reducing food waste/shrinkage.

No negative impacts on health or the environment have been previously expressed or brought to the attention of the Handling Subcommittee.

Environmental Issues

There does not appear to be significant environmental issues associated with the use of oxygen in modified atmosphere packaging. In fact, it can have the effect of extending shelf life or viability and reducing food waste/shrinkage.

No negative impacts on health or the environment have been previously expressed or brought to the attention of the Handling Subcommittee.

Ancillary Substances

None.

Discussion

The NOSB unanimously voted to relist oxygen in 2018.

Public comment prior to the Spring 2018 NOSB meeting was mostly in favor of relisting. One organization commented that oxygen should be removed from the National List if its necessity in organic production wasn't documented. According to public comment, it is used by wineries, breweries, and manufacturers of carbonated beverages. One certifier reported that it is listed on 14 Organic System Plans (OSPs). One winery commented they use it for micro-oxygenation, a process where oxygen is added to red wine at a controlled rate and flow to stabilize color, improve astringency, and aromatic components of the final wine. Micro-oxygenation also allows wines to be released to consumers at a younger age which in turn reduces the amount of sulfur dioxide that needs to be added during the wine making process.

The Handling Subcommittee has discussed the substance during its sunset review and currently supports relisting.

Questions to our Stakeholders

None.

Potassium chloride

Reference: 205.605(a) Nonsynthetics allowed. (23) Potassium chloride.

Technical Report: [1995 TAP](#); [2015 TR \(nutrient vitamins and minerals\)](#); [2023 TR \(crops, handling\) pending](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 335\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#));

Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

According to the Food & Drug Administration (FDA), potassium chloride is generally recognized as safe (GRAS). Affirmed uses of potassium chloride in foods are as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. Like salt, potassium chloride provides a salty flavor and can also often play other functional roles (such as microbial management, protein modification, flavor enhancement) that affect the taste, texture, and shelf life of food products. Potassium chloride is generally used for two main purposes in food products: to provide potassium enrichment to foods, and as a salt replacement to reduce the sodium content in foods.

Manufacture

Potassium chloride is a mineral that occurs naturally and is a product of potash mining where water is forced into ground to dissolve potassium chloride deposits. Brine is brought back to the surface where the water is evaporated off. It can similarly be produced from seawater extraction via solar evaporation.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Permitted for use from mined sources such as sylvite, carnalite, and potash.

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

Not specified as permitted for use.

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

Permitted for use.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Permitted for use.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Permitted as “fertilizers and soil improvement substances.”

Environmental Issues

Potassium chloride derives from mining activities, and there are impacts associated with its extraction. There has not been widespread concern about significant impacts.

The substance is considered to be of limited health concerns for people with normal kidney function; however, it is thought to create issues for people with conditions that make potassium excretion difficult.

At recommended daily rates of consumption, potassium chloride is thought to reduce health impacts typically associated with sodium chloride, such as high blood pressure and kidney stones.

Ancillary Substances

None.

Discussion

The National Organic Standards Board (NOSB) unanimously voted to relist potassium chloride in 2018 for its handling purposes.

At the time, public comment was unanimously in support of re-listing potassium chloride. Several commenters focused on potassium chloride as a key ingredient in low-sodium products. Another commenter stated that potassium chloride is essential in the fortification of infant baby formula.

A draft TR was submitted on December 2, 2022 and was deemed sufficient, although the Crops Subcommittee (which is also reviewing this material for different crop-related applications) requested additional information on effective organic alternatives to potassium chloride. Support for relisting among Handling Subcommittee members appears consistent with prior reviews. The draft TR primarily addressed crops-related applications of the substance.

Questions to our Stakeholders

1. Is potassium chloride widely used by handlers of organic products?

Alginates

Reference: 205.605(b) Synthetics allowed. (3) Alginates.

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

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 331\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Alginates are used in food production and handling as an emulsifier or emulsifier salt, firming agent, flavor enhancer or flavor adjuvant, formulation aid, processing aid, stabilizer or thickener, surface-active agent, and texturizer.

The use of alginates is not limited to foods. Industrial applications use alginates to improve the performance of products such as paper coating, textiles, adhesives, air freshener gels and ceramics. Alginates are also utilized in a variety of ways in the medical field. Examples include wound dressings, surgical implants, pharmaceutical preparations, and as a source of dietary fiber (2015 TR 279 – 283).

Manufacture

Alginates are produced from algin and are usually extracted from the cell walls of brown algae. Commercial alginates are isolated mainly from the following algal species: *Laminaria hyperborea*, *L. digitata*, *L. japonica*, *Ascophyllum nodosum*, *Macrocystis pyrifera*, *Eclonia maxima*, *Lessonia nigrescens*, *Durivillea antarctica*, and *Sargassum spp* (Draget, Smidsrød and Skjåk-Bræk 2005; Hay, Rehman and Ghafoor, et al. 2010). Alginic acid in brown seaweeds is mainly present as calcium, magnesium, and sodium salts. The first step in the manufacture of alginate is to convert the insoluble calcium and magnesium alginate into soluble sodium alginate by ion exchange under alkaline conditions (World Health Organization 1997). Extraction involves ion exchange in an alkaline medium followed by precipitation, purification and conversion to the appropriate salt (Saltmarsh, Barlow and eds. 2013). “Commercial manufacturing of alginate almost always involves a purification step where an acid treatment precipitates the alginate as alginic acid” (Drageta, Skjak-Bræk and Stokke 2006). The extraction process renders alginates synthetic [2015 TR 444-454].

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

The following alginates are permitted: a) alginic acid; b) potassium alginate; and c) sodium alginate

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

Permitted: E401 Sodium Alginate and E402 potassium alginate in milk-based products

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

Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

Environmental Issues

Seaweed cultivation is largely considered to be an environmentally friendly form of aquaculture due to the lack of added inputs for fertility, minimal changes in physical landscape and potential for bioremediation of polluted or nutrient rich waters (Eklof and Kautsky 2006) [2015 TR 704-706].

We are not aware of any evidence that the harvesting practices for brown seaweed are damaging to local ecosystems. Secondary environmental impacts of seaweed farming include depletion of nutrients in the coastal waters where the seaweed grows, which can affect primary food sources such as phytoplankton (Philips 1990). The use of plastic ties to secure seaweed fronds, Styrofoam floats and plastic bottle buoys has led to increased garbage and foreign debris on beaches, reefs, and mangroves. Given the insurmountable challenges of managing non-native seaweed populations, some researchers claim that it is preferable to focus on sustainable wild harvest techniques with regard to mitigating environmental impact (Titlyanov and Titlyanova 2010) [2015 TR 725-728].

Ancillary Substances

Publicly available specification sheets and ingredient lists did not report any ancillary substances (e.g., stabilizers, preservatives, or anti-caking agents). Sodium alginate and PGA are commercially prepared as 100% freeze-dried material (FMC BioPolymer 2012) [2015 TR 351-354].

Discussion

Alginates were added to the National List in 2022 and have been renewed at each sunset review.

Public comments from the previous sunset review demonstrated a continued need for this material. One stakeholder commented that alginic acid, like seaweed and fish oil, should be reviewed within the broader context of Marine Materials. Additionally, the Board was asked to consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

The Subcommittee discussion centered on the current forms of alginate that are being used in organic production.

Questions to our Stakeholders

1. What forms of alginates are currently being used in organic production (e.g., ammonium, calcium, potassium, sodium, propylene glycol)?

Calcium hydroxide

Reference: 205.605(b) Synthetics allowed. (8) Calcium hydroxide.

Technical Report: [1995 TAP](#); [2023 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 337\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Calcium hydroxide is used in food processing as a buffer, neutralizing agent, and firming agent. It is used in making calcium acid phosphate (a component of aluminum-free baking powder) and in nutrient supplements. Calcium hydroxide is an available source of calcium, an essential nutrient. In this regard, limestone (calcium carbonate) and thus calcium hydroxide, an essential intermediate in the industrial utilization of limestone, have no alternatives.

Manufacture

Calcium hydroxide is produced through four steps: 1) mining or quarrying raw limestone; 2) preparation of the limestone for the kilns; 3) calcining the limestone to produce quick lime (calcium oxide); and 4) hydrating (mixed with water) the quick lime. To produce calcium hydroxide, the temperature for calcining far exceeds temperatures achieved in the home kitchen, which the National Organic Standards Board (NOSB) has previously considered decisive in judging if a substance is synthetic.

According to the 2023 TR, new techniques for the manufacture of calcium hydroxide continue to develop. Nanoparticles of calcium hydroxide were reported to be synthesized as early as 2001 (Salvadori & Dei, 2001). One article described calcium hydroxide as “one of the most magnificent materials in

nanotechnology by virtue of its unique physical and chemical properties” (Harish et al., 2022). Most literature cited refers to medical or dental applications of calcium hydroxide nanoparticles. However, with growing interest in food applications of nanotechnology, food-grade calcium hydroxide nanoparticles may become commercially feasible. Nanotechnology is not permitted in organic production (National Organic Program (NOP) Policy Memo 15-2: Nanotechnology).

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Listed in Organic Production Systems as Permitted Substances List as ‘Lime’ in a table 7.4 ‘Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory’.

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

There is no specific listing for calcium hydroxide in handling nor any information found.

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

There is no specific listing for calcium hydroxide in handling nor any information found.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Calcium hydroxide (hydrated lime) is listed as for the application on aerial plant parts only.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Calcium hydroxide (Slaked lime) listed as ‘those derived from natural sources, or natural sources without the use of chemical treatment.’

Environmental Issues

According to the 2023 TR, literature on the environmental impacts of limestone quarrying and its processing into quick lime and hydrated lime is extensive. Limestone deposits occur in a wide range of geological formations that are connected to a variety of ecosystems. Almost all limestone is mined in open quarries or pit mines (Oates, 2008). Site preparation for open pit or quarry mining involves the clearing of trees, vegetation, and topsoil, resulting in the immediate loss of habitat (Ganapathi & Phukan, 2020). Some ecosystems are more sensitive to the intrusions of mining than others. The karst topography associated with limestone deposits creates a wide range of potential environmental impacts, including habitat and biota loss; air, noise, and water pollution; and cascading environmental impacts to natural systems far from the mining location (Langer, 2001). Limestone mining creates dust and other air pollution (U.S. EPA, 1998). Karst forms caves that are ideal bat habitat. The dust and noise from limestone mining can result in loss of that habitat and cause remaining bats to suffer increased mortality and deafness (Langer, 2001). Discharges from limestone quarries can also result in surface water contamination with sediment, heavy metals, and asbestos. This in turn can result in adverse impacts on aquatic biota, including fish mortality (U.S. EPA, 1982).

Ancillary Substances

None

Discussion

During the previous sunset review, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed calcium hydroxide use and necessity in the

processing. The majority of public comments supported relisting of calcium hydroxide. One commenter suggested that the NOSB clarify which uses of calcium hydroxide are permitted, specifically if calcium hydroxide can be used as a firming agent. Additional commenters stated that they use calcium hydroxide in infant formula.

Questions to our Stakeholders

2. Is calcium hydroxide essential for organic food production?
3. Since the last review, have additional commercially available alternatives emerged?

Ethylene

Reference: 205.605(b) Synthetics allowed. (14) Ethylene - allowed for postharvest ripening of tropical fruit and degreening of citrus.

Technical Report: [1995 TAP](#); [1999 TAP](#); [1999 TAP \(pg. 14-54\)](#); [2022 TR \(crops, handling\) pending](#)

Petition(s): [2008 \(pears\)](#)

Past NOSB Actions: [11/1995 NOSB minutes and vote \(pg. 14\)](#); [10/1999 NOSB minutes and vote \(tropical fruit and citrus\) \(pg. 443\)](#); [10/2001 NOSB recommendation \(reaffirmed 1999 recommendation\) \(pg. 2\)](#); [11/2005 NOSB sunset recommendation](#); [11/2008 NOSB recommendation \(pears, not recommended for addition\) \(pg. 14459-14491\)](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Annotation change published 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Ethylene is used in the post-harvest ripening of tropical fruit and the de-greening of citrus. Ethylene produced naturally by fruits has not been commercialized, and the amount produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires.

Manufacture

The principal source of commercial ethylene is from thermal or catalytic cracking of hydrocarbon feedstocks such as natural gas or crude oil. During this process chemical bonds within the hydrocarbon molecules are broken, and a different chemical substance is produced.

Catalytic cracking uses a catalyst, typically a zeolite, which absorbs the long-chain hydrocarbon feedstocks by removing hydrogen atoms and causes the long chains to split into shorter chain molecules with double bonds (Lazonby, 2014). Small catalytic generators dehydrate ethanol by a similar process (Kays & Beaudry, 1987) [2022 TR 364-367].

All of these methods involve reactions that produce a chemically changed substance (ethylene) from either petroleum feedstocks, or from dehydration of ethanol mediated by catalysts. Thus, all these forms should be considered synthetic (NOP, 2016a) and from nonagricultural sources (NOP, 2016b). [2022 TR 369-371]

Ethylene is the petrochemical produced in the largest quantities worldwide (IARC, 1994). In 2014, world ethylene production was 134 million (metric) tonnes (Lazonby, 2017). As of 1994, over 95% of worldwide annual production is based on thermal “cracking” of petroleum hydrocarbons with steam (IARC, 1994). These fractions are obtained from drilling (or hydrofracturing) of oil or natural gas. Thermal cracking (sometimes referred to as pyrolysis) is a chemical process by which long chain hydrocarbons with higher molecular masses are converted to short chain hydrocarbons of lower molecular mass [2022 TR 304-309].

Various feedstocks, including ethane, propane, butanes, naphthas, and gas oils are used to produce ethylene, depending on availability, price, and products desired (Lazonby, 2017). Naphthas are the principal raw material used in western Europe and Japan, accounting for over 80% of the ethylene produced. Ethane is the primary feedstock in the U.S., followed by propane, naphthas, gas oils, and butane (Zimmerman & Waltz, 2011) [2022 TR 311-315].

In thermal cracking, the feedstock gases (ethane, propane or butane) or the liquids (naphtha or gas-oil) are preheated and vaporized, and are mixed with steam and heated to 1050-1150 K (777-877 °C) in a tubular reactor. The high temperature and pressure cause the long chain hydrocarbon to be converted to low relative molecular mass alkenes plus by-products (Lazonby, 2014). [2022 TR 317-320]

Catalytic cracking

Catalytic cracking uses a catalyst, typically a zeolite, which adsorbs the long-chain hydrocarbon feedstocks and removes hydrogen atoms.^[1] This causes the long chains to split into shorter chain molecules with double bonds, which are useful to the petrochemical industry. The feedstock is gas oil, which is vaporized, passed through a fine zeolite powder, and heated to 700-800 K (427 - 527 °C) in a reactor. The products behave like a fluid and continuously flow out of the furnace with the cracking products. The temperature, residence time, and the catalyst determine the product proportions (Lazonby, 2014) [2022 TR 332-338].

Dehydration of ethanol

Dehydration of ethanol is another commercial route to ethylene (IARC, 1994; Zimmerman & Waltz, 2011; Fan 2013). In the catalytic dehydration of ethanol to form ethylene, an acid catalyst first protonates the hydroxyl group, which leaves as a water molecule. The conjugate base of the catalyst then deprotonates the methyl group, and the hydrocarbon rearranges into ethylene (Fan, 2013). This method is not commonly used to produce large volumes of ethylene, as it is endothermic with a high optimal reaction temperature (180-500 °C), which makes the ethylene expensive to produce. Dehydration of bioethanol is occurring in Brazil and India and holds promise for producing ethylene from non-fossil fuel sources (bioethanol from sugar cane or cellulose). At present, the output is relatively limited and used for further production of polyethylene (Fan, 2013; Lazonby, 2017; Schill, 2010) [2022 TR 340-349].

Catalytic generators

Small catalytic generators are used in sealed ripening rooms to dehydrate ethanol into ethylene, and can deliver controlled levels of ethylene gas to ripen fruit, e.g., 100-150 ppm for bananas. (NWHort 2008, Catalytic Generators 2022). This process uses dehydration of ethanol by passing it over a bed of solid catalyst held at high temperatures. The catalysts are typically activated alumina and phosphoric acid or zinc oxide with alumina (Kays & Beaudry, 1987) [TR 351-356].

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

- For post-harvest ripening of tropical fruit and de-greening of citrus and to control sprouting of potatoes post-harvest in holding bins.

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

- De-greening bananas, kiwis, and kakis; De-greening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions.

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

CODEX indicates:

“For degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. As sprouting inhibitor for potatoes and onions: Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers.”

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

- De-greening and ripening of citrus

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

- Limited to those used for ripening bananas, kiwifruits, and avocados after harvest.

Environmental Issues

According to the 2022 TR, the manufacturing process through cracking is highly energy intensive. Extraction and transport contribute significantly to increasing greenhouse gas emissions, acidification and eco-toxicity (air and water). [TR 479-482] A study conducted by Zhao et al. in 2018 found that China reduced CO₂ emissions by 29.4% per ton of ethylene produced from 2000-2016 due to improvements in technology, and evaluated various methods for future increased reductions. [TR 493-495]

Petroleum refineries are a major source of hazardous and toxic air pollutants. [TR 497]

As for ethylene’s impact on the environment during postharvest handling, the 2022 TR states that since the ethylene is a gas at environmental temperatures, this is the primary route of exposure to the environment. Health Canada considered environmental modelling studies and found that ethylene released to the air will remain in the air, and that only negligible amounts will partition to soil, water and sediment. [TR 507-511]

According to the U.S. EPA Toxic Release Inventory (EPA, 2021), in 2021 the total release of ethylene as airborne emissions in the U.S. was 18.2 million pounds. Of that, 17.2 million pounds was emitted by the chemical manufacturing industry, and 0.7 million pounds was from the petroleum industry. It is not known how much ethylene is released in the atmosphere due to ripening and degreening uses. It is no doubt much smaller than the amount estimated to be applied to pineapple crops in the field. The Food and Agriculture Organization of the United Nations estimates that in 2021, there were 1,046,712 hectares of pineapples grown worldwide (FAO, 2022). If every hectare in the world was treated with 800 grams of ethylene (unlikely, as the harvest takes 12-18 months from flower induction), that would result in application of 837,369 kg (1,846,082 pounds) totally. [2022 TR 513-521]

The 2022 TR states that no data was found showing an impact on invertebrates or birds, which are most likely exposed to ethylene. Ethylene is not expected to be released in the water; therefore, no unwanted exposure is expected. The TR stated the greatest eco-toxicity impact to be on terrestrial plants as they are highly sensitive to ethylene in the air. A 2016 Health Canada study concluded that there is little risk of harm to the environment or to organisms since the substance is not present in quantities or concentrations that could cause long term harmful effects on the environment or biodiversity. [2022 TR 531-536]

As for the impact on human health, the main concern is worker safety due to the explosive nature of the gas. The use of this material is highly regulated through labeling and registration requirements. Beyond the risk of harm due to an explosive accident, overexposure causes headache, drowsiness, and muscular weakness and high concentrations can cause dizziness or light-headedness. [2022 TR 551-554]

Ancillary Substances

None

Discussion

During the last review, commenters stated that no commercially viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. Others commented that the material does not fit any OPFA criteria, and it is not essential to produce the crop but rather is employed for economic reasons.

The Handling Subcommittee discussed the effects on the environment and human health, along with the apparent essentiality for the tropical fruit industry. Obviously, there is an alternative, which is to let fruit ripen naturally. However, as stated in the TR this is most ideal for local markets where fruit is picked closer to ripeness and time to market is short. According to the TR there are also alternative practices for degreening, such as being stored at low-moderate temperatures as the fruit is maturing on the tree. However, when comparing degreening via reduced temperatures vs. ethylene, ethylene was significantly faster at fully degreening fruit. There were also additional nonsynthetic substance alternatives such as smoke utilized in the Sri Lankan pit method. However, this resulted in blackening and over softening leading to decreased marketability. Smoke was also used in the past for citrus degreening, although there were problems with fire hazards, heat, and decay.

Questions to our Stakeholders

1. What types of organic tropical fruits are currently being ripened using ethylene?

Glycerides (mono and di)

Reference: 205.605(b) Synthetics allowed. (16) Glycerides (mono and di) - for use only in drum drying of food.

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

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 334\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))
Sunset Date: 6/22/2025

Subcommittee Review

Use

Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life [TR 2015 82-83]. However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals [TR 2015 91-92]. The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration [TR 2015 105-106]; at the spring 1995 National Organic Standards Board (NOSB) meeting, it was noted that the food industry was trying to move away from use of mono- and diglycerides, but that they were still needed for potato flake products [TR 2015 168-172].

Manufacture

Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources [TR 2015 56-59]. These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut, or palm oil [TR 2015 59-60], and the main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils [TR 2015 56-62].

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Mono- and diglycerides are permitted under Canada's organic standards, with annotations: From organic sources if commercially available. For use in drum drying of products.

They do not appear in the following organic standards: CODEX, EU, IFOAM or Japan.

Environmental Issues

The 2015 TR does not identify any significant environmental impacts linked to mono- or diglycerides [TR 2015 433-459]. Glycerides are derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity.

Ancillary Substances

None

Discussion

According to the 2015 TR, alternative ways to dry foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Drum drying is said to be preferred for potato flakes. Freeze drying has been suggested as an acceptable alternative to drum drying.

Evaluation question #13 in the 2015 TR suggested a few potential agricultural alternatives. One is a commercial product, made of organic rice bran extract, which is marketed as an emulsifier and drum release agent. Trials by the manufacturer concluded that rice bran extract had the highest capacity for oil-in-water binding. However, the hydrophilic–lipophilic balance of rice bran extract is narrower than that of mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of the mix to which it is added.

Organic soy lecithin and gum Arabic (both currently on the National List) were also raised as possible alternative substances to glycerides, although the use of gum Arabic in drum dried food is not widely reported. The TR also considered the use of lecithin as an alternative but stated that as compared to mono- and diglycerides it provides much less emulsion stability, much less starch interaction, and more fat modification.

The TR concluded that in general, each emulsifier (and its form) is selected based on specification of the food and the processing application [TR 2015 522-547].

The use of mono- and diglycerides appear to be limited, but compatible with OFPA because the health and environmental risks are minimal. It would be helpful to understand current uses.

Questions to our Stakeholders

1. What products are mono- and diglycerides currently used in?
2. Have any alternatives emerged?

Magnesium stearate

Reference: 205.605(b) Synthetics allowed. (19) Magnesium stearate - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Technical Report: [1995 TAP](#); [2018 TR](#)

Petition(s): N/A

Past NOSB Actions: [11/1995 NOSB minutes and vote \(pg. 16\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Magnesium stearate (CAS # 557-04-0) is not commonly used in organic products (TR 2018 102). In conventional production, it is routinely used as an anti-caking agent in salt, spices, powdered foods and drinks, leavening agents, and candy (TR 2018 103-105). It is a flow agent, food processing machine lubricant, and may be an incidental additive. The most common use of magnesium stearate is as a binding agent in dietary supplements. Magnesium stearate is permitted for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” and is prohibited in agricultural products labeled “organic.”

Manufacture

Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils, magnesium stearate is produced by adding an aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Canada allows magnesium stearate for use as an anticaking or releasing agent in products whose contents are $\geq 70\%$ and $< 95\%$ organic ingredients.

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

The 2018 TR stated that the Codex Alimentarius Commission’s “Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods” lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999). However, it does not appear to be listed currently.

Magnesium stearate does not appear in the following organic standards: EU, IFOAM, Japan.

Environmental Issues

Magnesium stearate is derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity. In addition, while some of the substances involved in manufacturing of magnesium stearate could have water and soil health impacts at high concentrations, the amounts relevant here are not likely to pose significant environmental or biodiversity impacts.

Ancillary Substances

None

Discussion

The use of magnesium stearate appears to be limited, but compatible with OFPA because the health and environmental risks are minimal. The Handling Subcommittee is interested in answers to the following questions regarding current use:

Questions to our Stakeholders

1. How is magnesium stearate currently used by organic processors?
2. Have any viable alternatives to magnesium stearate emerged?

Phosphoric acid

Reference: 205.605(b) Synthetics allowed. (23) Phosphoric acid - cleaning of food-contact surfaces and equipment only.

Technical Report: [1999 TAP \(pg. 9-20\)](#); [2003 TAP \(pg. 1-7\)](#); [2021 TR](#)

Petition(s): [2019 \(to amend\)](#); [2020 \(addendum #1\)](#); [2020 \(addendum #2\)](#); [2022 \(addendum #3\)](#)

Past NOSB Actions: [10/1999 NOSB minutes and vote \(pg. 443\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Phosphoric acid is used in organic handling and processing as a cleaning agent for “food contact surfaces and equipment,” as described in 7 CFR 205.605(b). Phosphoric acid has been approved for pH adjustment of some soil amendments (liquid fish products and squid byproducts) and as an equipment cleaner in both organic crop and livestock production. (7 CFR 205.601 and §205.603).

In addition to its appearance in 7 CFR 205.605, phosphoric acid has been used as an ingredient in plant extractions (USDA 2002, USDA 2019, USDA 2020a, USDA 2020b). When used in this manner, phosphoric acid acts as an acidifying agent and stabilizer to facilitate more efficient extraction of target compounds (Yoon et al. 2020).

In addition to organic applications, phosphoric acid is a widely used substance in conventional agriculture, with approximately 90% of wet process phosphoric acid used in the production of fertilizers (Shriver and Atkins 2008). Phosphoric acid has uses in food and beverage processing as a pH adjuster, flavor ingredient, and processing agent in dairy products (Wolke 2002, Gilmour 2019). Phosphoric acid is also a precursor to synthetic phosphates, which have a variety of uses including as fertilizers, surfactants, and detergents (Shriver and Atkins 2008) [TR 163-179].

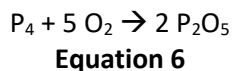
Manufacture

Phosphoric acid is produced through two methods: the wet process and the thermal process (EPA 1995, Gilmour 2019; Haghani and Daneshpazhuh 2020). Historically, the end-point use for phosphoric acid was determined by its production method. High purity, technical and food grade phosphoric acid was produced by the thermal process (EPA 1995; Gilmour 2019). Lower purity phosphoric acid, primarily used in animal feed and fertilizer applications, was produced by the wet process (EPA 1995; Shriver and Atkins 2008; Gilmour 2019). Due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as

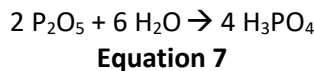
the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

Thermal process

The thermal process is broken down into three major steps: combustion, hydration, and demisting (collection) (EPA 1995; Gilmour 2019). In the combustion step, elemental yellow phosphorus (P₄) is reacted with oxygen gas, which oxidizes the phosphorous from its 0 to V oxidation state, as shown below in Equation 6 (EPA 1995; Gilmour 2019). The heat of combustion for phosphorus is highly endothermic and the reaction must be carried out at high temperatures (1650 – 2760 °C) (EPA 1995; Gilmour 2019).



Once the elemental phosphorus is oxidized to P₂O₅, it undergoes the hydration process to form orthophosphoric acid, as shown below in Equation 7 (EPA 1995; Gilmour 2019). In this process P₂O₅ is generally reacted with water, although in some cases dilute solutions of Phosphoric acid are used instead of water alone (EPA 1995). Once phosphoric acid has been produced, it is isolated in the demisting process. In this step, phosphoric acid is collected as a mist with high-pressure drop demisters. The thermal process produces phosphoric acid with P₂O₅ concentrations between 54 and 62%, which are sufficiently pure for use in technical and food grade applications (EPA 1995; Gilmour 2019).



Wet Process

The wet process produces phosphoric acid from naturally occurring phosphate mineral sources (fluorapatite [Ca₁₀(PO₄)₆F₂] and hydroxyapatite [Ca₁₀(PO₄)₆(OH)₂]) (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Once mined, these minerals are converted to phosphoric acid in four main steps, as outlined in Figure 5 below (Gilmour 2019). The phosphate rock is prepped in the initial step by being milled and ground to increase its surface area (EPA 1995; Haghani and Daneshpazhuh 2020).

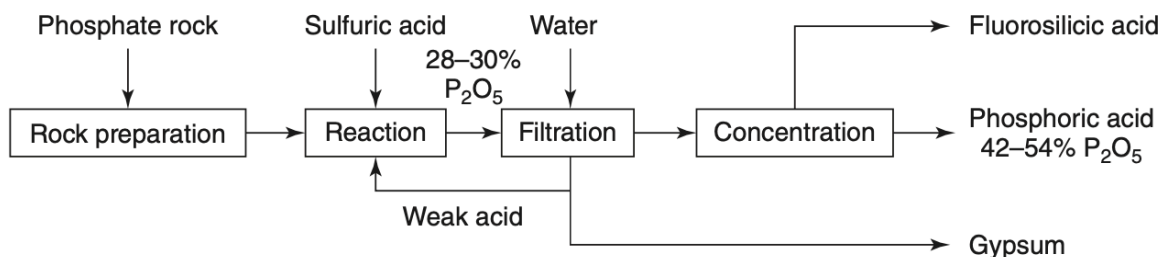
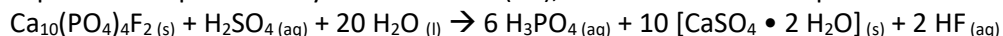


Figure 5

Once milled, the mineral phosphates are reacted with a strong mineral acid and converted to phosphoric acid, as shown in Equation 8 below (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). While sulfuric acid is shown in both Figure 5 and Equation 8, other strong mineral acids (e.g., nitric acid [HNO₃] and hydrochloric acid [HCl]) may also be used (Jin et al. 2014; Haghani and Daneshpazhuh 2020). However, most commercial processes use sulfuric acid because it provides higher phosphoric acid yields, lower costs, and a solid form of calcium (Al-Fariss et al. 1992; EPA 1995; Shriver and Atkins 2008,; Gilmour 2019). The specific reaction conditions dictate the

type of calcium sulfate hydrate ($\text{CaSO}_4 \cdot n \text{H}_2\text{O}$) formed, with lower temperatures favoring the formation of gypsum ($\text{CaSO}_4 \cdot 2 \text{H}_2\text{O}$), as shown in Equation 8 (EPA 1995). The prevalence of fluorapatite among mineral phosphates also produces hydrofluoric acid (HF), as shown below in Equation 8.



Equation 8

The gypsum formed during the reaction with the mineral acid is removed via filtration. Once removed, the gypsum solids undergo several aqueous wash cycles to remove residual phosphoric acid from the solid surface, producing phosphoric acids yields of 99.9% (EPA 1995; Gilmour 2019). As shown previously in Figure 5, the aqueous gypsum washes are sent back to the reaction vessel to aid in the conversion of mineral phosphates (EPA 1995; Gilmour 2019). The presence of mineral silicon in the initial composition reacts with hydrofluoric acid to produce less reactive forms of silicon tetrafluoride (SiF_4) and SiF_6^{2-} ions, some of which are removed as solids with the gypsum (Gilmour 2019).

The phosphoric acid isolated following the filtration process is dilute, with P_2O_5 concentrations between 26 – 30% (EPA 1995; Gilmour 2019). Vacuum evaporation is used to remove water and concentrate the Phosphoric acid to 42 – 54% P_2O_5 (Gilmour 2019). Activated silica or clay is added during the concentration process to react with residual hydrofluoric acid. Silicon tetrafluoride isolated from the concentration step is hydrolyzed to fluorosilicic acid (H_2SiF_6), as shown in Figure 5 (Gilmour 2019).

Mineral impurities, including heavy metal contaminants, remain in phosphoric acid produced via the wet process, which have historically limited its use to agricultural fertilizer applications (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Wet process phosphoric acid results in concentrations of between 42 and 54% P_2O_5 , which is largely unsuitable for technical applications (Gilmour 2019). The elemental phosphorous used in the thermal process can be purified via sublimation, resulting in no carry-over of heavy metal contaminants so that thermal phosphoric acid can be used in technical and food applications (Shriver and Atkins 2008). However, the thermal process is much more expensive and energy intensive than the wet process (~2000 °C vs ~80 °C) (EPA 1995, Gilmour 2019).

Wet process purification methods

Wet process phosphoric acid is commonly purified by crystallization or solvent extraction (Gilmour 2019). Crystallization is a common purification technique, which is based on the differing solubilities of pure and impure mixtures, with pure substances selectively crystallizing at reduced temperatures (Pavia et al. 1995). When phosphoric acid is concentrated to 61% P_2O_5 or higher, it selectively forms hemihydrate crystals ($\text{H}_3\text{PO}_4 \cdot \frac{1}{2} \text{H}_2\text{O}$) when cooled to 8 – 12 °C (Gilmour 2019). The crystals are removed from the mixture and can be melted to undergo additional recrystallization cycles to improve purity, with each cycle yielding a 10 to 100 times increase in purity (Gilmour 2019).

Solvent extraction is another traditional purification method based on solubility. In solvent extraction, the target compound migrates between immiscible phases (usually aqueous [polar] and organic [nonpolar]) based on solubility (Pavia et al. 1995). The selectivity of phosphoric acid does not differ greatly compared to its impurities, requiring additional purification steps. Prior to solvent extraction, concentrated phosphoric acid undergoes precipitation with calcium or barium salts to remove sulfate (SO_4^{2-}), sodium salts to remove fluorosilicates, and sulfides to remove arsenic (Shlewitt and Alibrahim 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Phosphoric acid extractions are performed in one or more extraction columns with many possible organic solvents, including alcohols, ethers, ketones, amines, and kerosene blends (Shlewitt and Alibrahim 2008; Jin et al. 2014; Gilmour 2019).

Following extraction with an organic solvent, phosphoric acid is recovered with water. Residual organic solvents are removed via evaporation during the concentration of the recovered phosphoric acid from the aqueous solution (Shlewitt and Alibrahim 2008, Gilmour 2019). Solvent extraction of wet process phosphoric acid improves the purity of the substance from 42-54% P₂O₅ in the raw form to up to 97% P₂O₅ (Gilmour 2019). [TR 376-482]

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Phosphoric acid is listed in the Organic Production Systems Permitted Substances List as an approved substance for pH adjustment of “fish meal, fish powder, fish wastes, hydrolysate, emulsions and solubles” that are used for “soil amendments and crop nutrition.” Phosphoric acid is also listed as a “cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment.” [TR 345-351]

[European Economic Community \(EEC\) Council Regulation, EC No. 834/2007 and 889/2008](#)
Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008. [TR 357-358]

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

Phosphoric acid is not listed in the CODEX. [TR 353-355]

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Phosphoric acid is listed in the IFOAM NORMS for organic production and processing as an “equipment cleanser and equipment disinfectant only for dairy equipment,” and as a “substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment.” [TR 364-367]

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Phosphoric acid is not listed in the JAS. [TR 360-361]

Environmental Issues

The TR indicates that phosphoric acid is relatively benign regarding its impact on the environment. However, its production does have the potential to be harmful to the environment. The thermal process for producing it is energy intensive and requires high temperatures. The high energy requirements of the thermal process may contribute to atmospheric CO₂ levels if the energy is produced from fossil fuels. The thermal process also requires the treatment of combustion gases by scrubbers, cyclonic separators, mist eliminators, and electrostatic precipitators to prevent the release of phosphoric acid to the environment (EPA 1995; Gilmour 2019). The small size (< 3 μm diameter) makes these phosphoric acid and phosphorus oxide (P₂O₅) particles difficult to capture, and contributes their release to the atmosphere at levels of “< 25 mg P₂O₅ per dry standard cubic meter of stack gas” (Gilmour 2019). Wet process phosphoric acid is produced from chemical changes to mined mineral phosphates. There may be initial harm to the environment and biodiversity in the mining process. Once the minerals are isolated, hydrofluoric acid presents the most likely source of environmental harm (Shriver and Atkins 2008). Hydrofluoric acid is removed as a solid or as fluorosilicic acid by reaction with silica sources. These include natural silicates present within the initial mineral, as well as activated silica and clay added during the manufacturing process (Shriver and Atkins 2008; Gilmour 2019). Additionally, scrubbers are used to remove gaseous fluorine compounds from concentration steps to prevent their release to the environment (EPA 1995).

In addition to the hazards from fluorine compounds, the gypsum produced may pose a hazard to the environment. Isolated gypsum may be used for other commercial applications if it is sufficiently pure (Gilmour 2019). In other cases, gypsum is left in gypsum stacks, or pumped out to sea (Gilmour 2019). However, the gypsum may also contain silicon fluorides, acids, and other impurities from the initial mineral source, which has resulted in its designation as a hazardous substance by the EPA in 40 CFR 261.4. [TR 566-594]

Ancillary Substances

None

Discussion

During the 2018 sunset review the NOSB unanimously voted to relist phosphoric acid. The discussion largely focused on the broader topic of sanitizers on the National List. It was stated at the time that while there is a general desire for a safer alternative to phosphoric acid, there didn't seem to be viable options at that time.

In 2020, the Board received a petition to expand the annotation of phosphoric acid "as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5" (USDA 2020b).

During the Fall 2022 Board meeting, the NOSB unanimously voted against the petitioned annotation expansion.

While there was a TR contracted in 2021 due to this petition, the TR focused on the petitioned use (not the current listing as an equipment sanitizer). Therefore, it did not specifically cover alternatives to phosphoric acid as an equipment sanitizer.

The Handling Subcommittee broadly discussed sanitizers and various options for how to address the broader topic. At this time the Subcommittee supports the continued listing of phosphoric acid.

Questions to our Stakeholders

1. Is phosphoric acid essential as an equipment sanitizer to be incorporated into your sanitizer rotation?
2. Is phosphoric acid used as an equipment sanitizer in a particular sector of the organic industry?

Potassium carbonate

Reference: 205.605(b) Synthetics allowed. (24) Potassium carbonate.

Technical Report: [1995 TAP](#); [2022 TR pending](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 338-339\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#));

Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Potassium carbonate is both a carbonate salt and a potassium salt with many uses. For processing and handling applications, the main uses are as follows:

Potassium carbonate is utilized in the production of yellow alkaline wheat noodles found in both Chinese and Japanese cuisines. It is used in cocoa production during the “Dutching” process to restore the desired dark pigmentation. In raisin production, potassium carbonate can be used as a drying agent to decrease drying time and reduce spoilage from open air drying. Potassium carbonate is applied as a pre-harvest spray onto fruit, or as a pre-drying dip at an optimal 0.6% concentration, along with either olive oil or ethyl oleate (Doymaz & Pala, 2002; Peacock et al., 2006). Potassium carbonate is utilized to raise the pH in the deacidification of wine. It is also an allowed substance in the production of modified hop extract, as listed at 21 CFR 172.560. Potassium carbonate is approved for use as a boiler additive in the preparation of steam that will come in direct contact with food. Meat processors are exploring the use of potassium carbonate as a replacement for phosphates in processed meat products, along with a number of other alternatives (Thangavelu et al., 2019). One study found that potassium carbonate, when applied at 0.3% or 0.5%, maintained the color of fresh pork, preserved tenderness, and reduced cooking loss when compared with an industry standard, sodium tripolyphosphate (LeMaster et al., 2019). It is also used in soap production, soft drinks, and confections.

The original technical advisory panel (TAP) notes that it be used only when sodium carbonate is not appropriate. However, it can be used to replace sodium carbonate when a lower sodium content is desired.

Manufacture

Potassium carbonate is one of several potassium-containing compounds that may be referred to as potash. Traditionally, potash was created by leaching wood ashes with water, which extracted a crude form of potassium carbonate (Schultz et al., 2000). This type of potassium carbonate, and its more refined by-product, pearl ash, have been utilized for millennia, with applications in baking and glassmaking. Following the discovery of naturally occurring potassium salts (e.g., potassium chloride or potassium sulfate) in the 1860s, wood ash-derived potassium carbonate was replaced by mineral potassium salts obtained through shaft mining, dissolution mining, and evaporation methods (Ciceri et al., 2015). Potash mining is active worldwide, and commercial production of potassium carbonate depends primarily on potassium chloride brines, which are derived from potassium chloride salts that are found in mineral potash (Schultz et al., 2000).

Modern, commercial production of potassium carbonate occurs through the reaction of potassium hydroxide with carbon dioxide, or CO₂-containing off-gases from other industrial processes (Schultz et al., 2000).

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Potassium carbonate is listed in the Canadian General Standards Board Organic Production Systems Permitted Substances List (CAN/CGSB-32.311 - 2020) in the following locations:

- In Table 6.3, as a food additive, with no origin or usage annotations.
- In Table 6.5 as an allowed processing aid, with no origin or usage annotations.
- In Table 7.4 for allowed “cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory” with the annotation that “documentation shall demonstrate that effluent discharge was neutralized to minimize negative environmental impact.”

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

Potassium carbonate is listed in (EC) No 889/2008 under “Section A — Food Additives, Including Carriers” as an allowed substance for the “preparation of foodstuffs of plant origin.” It is also listed under “Section B — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production” as allowed for the “preparation of foodstuffs of plant origin,” and specifically for drying of grapes.

EU organic standards have been updated since 2008. (EU) 2018/848 is the current regulation. Its Article 24(2)(a) authorizes certain products and substances for use in the production of processed organic food as noted in restrictive lists. These lists are currently codified in (EU) 2021/1165. Part A of Annex V lists food additives and processing aids. Potassium carbonates, E 501, appear in “Section A1 - Food Additives, Including Carriers” for addition to products of plant origin. Potassium carbonate also appears in “Section A2 — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production,” authorized only for the processing of organic grapes as a drying agent.

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

Potassium carbonate is listed in the CODEX (GL 32-1999) guidelines in Table 3.1 as a “food additive, including carriers” for specific use in “cereals/cakes & biscuits/confectionary.” It is also listed in Table 4 as “processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines” and specific use for the “drying of grape raisins.”

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Potassium carbonate is listed in the IFOAM Norms under the Standard for Organic Production and Processing in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids for use as both an additive and a processing/post-harvest handling aid, without any limitation note.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Potassium carbonate is listed in the Japanese Agricultural Standard for Organic Processed Foods under the “Appended Table 1 Additives,” where it is stated to be “limited to the use in the drying of processed fruit products or in processed grain products, sugar, products containing legumes, noodles, bread, or confections.”

Environmental Issues

Emissions associated with manufacture include heat and CO₂ into air, as well as K⁺ and OH⁻ in water (Maul et al., 2014).

As a food additive, potassium carbonate is utilized in small quantities compared to its applications as a livestock feed supplement or in other industrial processes (Chu et al., 1996; Fraley et al., 2015; Jaster & Moore, 1992). Negative effects on biodiversity or the general environment have not been reported in relation to the use of potassium carbonate as a food additive.

Ancillary Substances

None

Discussion

Potassium carbonate has a vast amount of uses in organic production. Public comments from the previous sunset review demonstrated a continued need for this material. One manufacturer noted its use as a sodium reduction agent and that removal from the list would result in a rise in sodium levels in their product by 18%. Other commenters noted use in a protein bar and as a nutritional supplement.

Questions to our Stakeholders

1. Since last reviewed, have there been any changes (either in substitute products or manufacturing process) that would warrant removal of potassium carbonate from the National List?

Sulfur dioxide

Reference: 205.605(b) Synthetics allowed. (35) Sulfur dioxide - for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.

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

Petition(s): [2010 \(to amend\)](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 333-334\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [12/2011 NOSB recommendation \(annotation change not recommended\)](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Sulfur dioxide has been used as an antimicrobial and antioxidant in food, including wine, since Greek and Roman times. Sulfur dioxide is primarily used to inhibit microbial growth and prevent spoilage and oxidation in wine. It has also been used to preserve conventionally produced meats and avoid browning in fresh and dried produce and other products. The current National List annotation limits the use of

sulfur dioxide to wine labeled “made with organic grapes” and further limits the sulfite concentration to not exceed 100 ppm.

Sulfur dioxide may play a number of roles in wine production, at multiple stages in processing. Cultivated yeasts added to enhance fermentation of wines have been selected to be more tolerant of sulfur dioxide than wild yeasts. Enough sulfur dioxide is added to deter growth of the wild yeasts or bacteria present in the grape juice, while not exceeding a level that will deter the growth of the desired added yeasts to the juice. This process helps to prevent the formation of “off” flavors. While sulfites occur naturally in wines, the level is too low to have a pragmatic effect.

Sulfites may be added to wine in various forms. Sulfur dioxide comes in pellet, liquid (sulfurous acid), or gaseous form. Potassium metabisulfite is commonly powdered; the 2022 Organic Materials Review Institute (OMRI) generic materials list states that potassium metabisulfite is prohibited.

Wine can be made successfully without added sulfites, but alternative interventions are often necessary to avoid microbial contamination, manage fermentation, and control oxidation. Sulfite reduction strategies include refrigerated fermentation in climate-controlled facilities, pasteurization via ultraviolet irradiation, and use of stable gases to fill the head space in packaging. Wines without added sulfur dioxide may also have a shortened shelf life.

Manufacture

Sulfur dioxide can be produced commercially from several sources including elemental sulfur, ores of sulfide containing minerals, gypsum and anhydrite, and waste materials or flue gasses that contain sulfur. Most commonly, sulfur dioxide is generated by simply burning sulfur in devices that control air flow and that can capture the sulfur dioxide as it is generated.

International Acceptance

Several major U.S. trade partners allow sulfur dioxide in “organic” wines and other alcoholic products produced from various fruits. Maximum sulfite levels vary depending on the product. [Demeter](#) [Biodynamic standards](#) also allow sulfur dioxide, potassium bisulfite, and potassium metabisulfite, up to 100 ppm sulfites at bottling.

[Canadian General Standards Board Permitted Substances List](#)

Sulphur dioxide, sulphurous acid, and potassium metabisulphite are allowed as preservatives in organic alcoholic beverages under Canadian organic standards, with the following limitations/specifics:

- Sulphur dioxide includes sulphites from SO₂-bottled gas; as liquid SO₂; or liberated from ignition of asbestos-free sulphur wicks
- Minimal use of SO₂ is recommended
- Maximum allowable levels of SO₂ in parts per million (ppm) are:
 - a) in alcoholic beverages containing less than 5% residual sugar, 100 ppm and 30 ppm for total and free sulphites, respectively;
 - b) in alcoholic beverages containing 5%-10% residual sugar, 150 ppm and 35 ppm for total and free sulphites, respectively; and
 - c) in alcoholic beverages containing more than 10%

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

Sulphur dioxide, potassium bisulphite, and potassium metabisulphite allowed in products of the wine sector, with maximum sulphur dioxide limits set for certain product categories (EU 203/2012):

- Sulphur dioxide content not to exceed 100 milligrams per litre for certain red wines with a residual sugar level lower than 2 grams per litre;
- Sulphur dioxide content not to exceed 150 milligrams per litre for certain white and rosé wines with a residual sugar level lower than 2 grams per litre;
- For all other wines, the standard sulphur dioxide content allowed by EU regulations shall be reduced by 30 milligrams per litre

Sulphur dioxide and potassium metabisulphite allowed (EC 889/2008):

- In fruit wines (wine made from fruits other than grapes) without added sugar (including cider and perry) or in mead: 50 mg (maximum levels available from all sources, expressed as SO₂ in mg/l)
- For cider and perry prepared with addition of sugars or juice concentrate after fermentation: 100 mg/l (maximum levels available from all sources, expressed as SO₂ in mg/l)

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

Sulphur dioxide is listed in the Codex organic guidelines for use in cider and perry, grape wines, wines (other than grapes), and mead (GL-32-1999, Annex 2, Table 3).

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

The IFOAM norms list sulfur dioxide and potassium metabisulphite for use in wine (IFOAM Norms 2014, Appendix 4 – Table 1).

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

INS #220 – Additives (Organic alcohol beverages) used in organic processed foods

Environmental Issues

There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in on the National List.

Health Issues

About 1% of the population reacts adversely to sulfites,¹ and reactions range from allergic reactions in individuals born without the enzyme needed to break down sulfur dioxide (sulfite oxidase), asthma attacks (which vary depending on individual sensitivity), hives and swelling, to anaphylaxis. Sulfite sensitivity may develop at any time, and reactions may not occur until middle age.²

U.S. law is highly protective of sensitive individuals. In the 1980s, widespread use of sulfites in restaurants, on products like salad bars and processed potatoes, led to several highly publicized deaths.³ This prompted FDA to restrict the use of sulfites on some foods and implement labeling requirements.⁴ Today, sulfur dioxide is not generally recognized as safe (GRAS) for use in meats, in food recognized as a source of vitamin B1 (because sulfites interfere with absorption), or fresh fruits and vegetables (e.g.,

¹ Paul Grothier et al., Sulfites: Separating Fact from Fiction (2011), available at <http://edis.ifas.ufl.edu/fy731>.

² Grothier et al.

³ Ruth Papazian, *Sulfites: Safe for Most, Dangerous for Some*, 30 FDA Consumer Magazine 10 (1996), available at http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/096_sulf.html; Irvin Molotsky, *House Panel Hears Plea for Food Sulfite Ban*, N.Y. Times, Mar. 28, 1985, available at <http://www.nytimes.com/1985/03/28/us/house-panel-hears-plea-for-food-sulfite-ban.html>.

⁴ Food Labeling: Declaration of Sulfiting Agents: Final Rule, 51 Fed. Reg. 25,012 (1986).

salad bars, fresh produce in supermarkets).⁵ Products with over 10 ppm sulfites must declare the presence of sulfites on the label.⁶ The Bureau of Alcohol, Tobacco, Firearms created similar labeling requirements for alcoholic beverages.⁷ Federal regulations allow up to 350 ppm sulfur dioxide in wine⁸ and require a sulfite declaration for wines with 10 ppm or more total sulfur dioxide in the finished product.⁹ Accordingly, sulfite sensitive consumers have strong access to the information they need to protect themselves from exposure.

Ancillary Substances

None

Discussion

Sulfur dioxide is considered safe at the levels allowed under the current annotation, which are more restrictive than those for nonorganic wines. Strict sulfite labeling requirements also allow sulfite-sensitive consumers to avoid products with added sulfites.

Wine can be made successfully without added sulfites, but many winemakers do not find alternative methods and materials satisfactory to prevent spoilage and oxidation in wine.

The current annotation allows the use of sulfur dioxide only in wines labeled “made with organic grapes,” which continues to contribute to confusion in the marketplace. Internationally, the U.S. is an outlier in limiting use of sulfur dioxide to wines labeled “made with organic”; our major trade partners allow it in wines labeled “organic” as well as other fermented fruit products like cider and perry.

The labeling limitations for wine produced from organic grapes using sulfur dioxide have an important relationship with the potential growth of organic grape acreage. For example, in 2020, California had 625,000 acres of wine grapes, but only about 25,000 acres of harvested organic wine grapes.¹⁰ Wine grapes are routinely treated with a wide range of pesticides, including glyphosate which has been found in wine.¹¹

The Subcommittee discussed the health risks of exposure to sulfur dioxide, as well as the protective measures that are in place for sensitive individuals and concluded that the continued listing of sulfur dioxide is compatible with the Organic Foods Production Act (OFPA). The Board may also wish to continue to discuss the current annotation and the best ways to balance the individual health risks associated with sulfites and the broader health and environmental threats of conventional wine

⁵ 21 C.F.R. § 182.3862 (1997); Grotheer et al.

⁶ 21 C.F.R. § 130.9 (1997); Grotheer et al.

⁷ Labeling of Sulfites in Alcoholic Beverages, 51 Fed. Reg. 34,706 (Sept. 30, 1986).

⁸ 27 C.F.R. § 4.22(b)(1) (2004).

⁹ 27 C.F.R. § 4.32(e) (2004).

¹⁰ California Department of Food and Agriculture (CDFA), California Grape Acreage Report, 2021 Summary, https://www.nass.usda.gov/Statistics_by_State/California/Publications/Specialty_and_Other_Releases/Grapes/Acreage/2022/grpacSUMMARY2021Crop.pdf; CDFA, California Agricultural Organics Report, 2020-2021, https://www.cdfa.ca.gov/Statistics/PDFs/2021_Organics_Publication.pdf.

¹¹ California Department of Pesticide Regulation, Summary of Pesticide Use Report Data 2018, https://www.cdpr.ca.gov/docs/pur/pur18rep/pur_data_summary_2018.pdf (sulfur, allowed on organic and nonorganic acreage, contributes to the); Moms Across America, Widespread Contamination of Glyphosate Weedkiller in California Wine, 2016, [https://d3n8a8pro7vnmx.cloudfront.net/yesmaam/pages/680/attachments/original/1458848651/3-24-16_GlyphosateContaminationinWineReport_\(1\).pdf?1458848651](https://d3n8a8pro7vnmx.cloudfront.net/yesmaam/pages/680/attachments/original/1458848651/3-24-16_GlyphosateContaminationinWineReport_(1).pdf?1458848651).

production. It would be helpful to understand the current state of the organic wine industry, label claims in use, and how sulfites are currently used in production of wine from organic grapes.

Questions to our Stakeholders

1. Do you or your members/clients produce wine from organic grapes? What label claims do you use and why?
2. What form of sulfur dioxide do you use? Is there another form you would prefer, and if so, what, and why?
3. At what stage is the sulfite content of wine measured/verified (e.g., at bottling)?

Xanthan gum

Reference: 205.605(b) Synthetics allowed. (37) Xanthan gum.

Technical Report: [1995 TAP](#); [2016 TR](#); [2018 TR \(gums\)](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote \(pg. 332\)](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [11/2016 NOSB recommendation \(none, reclassification not recommended\)](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

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Subcommittee Review

Use

Xanthan gums are one of the many gums used in organic handling for reasons including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibiting ice and sugar crystal formation, (4) aiding formulation, and (5) to control the release of flavors. Xanthan gum is an important ingredient for gluten-free products; it also is used in salad dressings, sauces, dairy products, along with other products.

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 Technical Report, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Xanthan gum was approved as a food additive by the Food and Drug Administration (FDA) in 1969 without restrictions on quantity in finished applications (2018 TR). The FDA specifies that the food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

- (a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.
- (b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.
- (c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.
- (d) The additive meets the following specifications:
 - (1) Residual isopropyl alcohol not to exceed 750 parts per million.
 - (2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 deg.F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 deg.F and 150 deg.F is in the range of 1.02 to 1.45.

Xanthan gum must pass the locust bean gum test and the pyruvic acid test. See 21CFR172.695 for more specificity.¹²

Manufacture

Xanthan gum is a high-molecular weight polysaccharide produced through natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried, and milled (2018 TR). The gum is water soluble, stable at numerous pH, salt, and temperature ranges (including frozen temperatures) (2018 TR). The side chains

¹² Code of Federal Regulations.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.695>

carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 2018). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (2018 TR). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 TR).

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

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

Allowed for use in products of plant and animal origin. Information [sourced here](#) (and not the link above).

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

Allowable in plant foods: for fats and oils, and fat emulsions; fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds; bakery wares; and salads (e.g., macaroni salad, potato salad). Not allowed in food of animal origin.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Allowed as an approved additive, processing, and handling aid, with no limitations noted.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

When used in processed products of livestock origin, limited to the use in dairy products or confections. Information found in [this document](#).

Environmental Issues

There was no mention in the TR of specific environmental issues regarding the production of xanthan gum.

Ancillary Substances

According to the 2016 TR (258-263), ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. The 2018 sunset review indicates that through a search of publicly available specification sheets, a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®. For 2023 sunset, a review of the GRINSTED® product literature reveals it is synergistic with guar and locust bean gum.

Discussion

Xanthan gum has been used for decades globally in the food system and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 2018). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR).

A review of the safety of xanthan gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources found that xanthan gum can be classified as non-toxic. Xanthan gum would not be, they found, absorbed intact and would be partially fermented as it traveled through the large intestine. In studies on different animal species (dogs, rats, neonatal piglets) no adverse effects were observed. The panel recommended collecting data on usage and levels of xanthan gum to conduct a more realistic exposure level through diet.¹³

Recent research examines the impact of xanthan gum on the gut microbiome; the rationale for examining the impact is that xanthan gum is not similar to any existing dietary fiber.¹⁴ Xanthan gum is an important ingredient for gluten-free products, and used in higher amounts for these products. Because of its 'low level but constant consumption,' a research team sought to try to understand its impact on gut microbiome health. The key finding is 'Our work demonstrates the existence of a potential xanthan gum food chain involving at least two members of different phyla of gut bacteria and provides an initial framework for understanding how widespread consumption of a recently introduced food additive influences human microbiomes.' The research team, in a different publication, indicate that in just 50 years, the introduction of xanthan gum to our diet has created a new chain (as described above).¹⁵ Thus, the NOSB should keep abreast of this evolving line of research.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since last reviewed.

Questions to our Stakeholders

1. Is xanthan gum essential?
2. Are there any ancillary substances used with this product?
3. Have any environmental or health concerns emerged since the last sunset review?

¹³ EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen, A., Aguilar, F., Crebelli, R., Di Domenico, A., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U., Lambré, C. and Leblanc, J.C., 2017. Re-evaluation of xanthan gum (E 415) as a food additive. *EFSA Journal*, 15(7), p.e04909.

¹⁴ Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2022. Mechanistic insights into consumption of the food additive xanthan gum by the human gut microbiota. *Nature Microbiology*, 7(4), pp.556-569.

¹⁵ Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2021. The food additive xanthan gum drives adaptation of the human gut microbiota. *bioRxiv*.

Fructooligosaccharides

Reference: 205.606 Nonorganic agricultural substances allowed: (g) Fructooligosaccharides (CAS # 308066-66-2).

Technical Report: [2006 TR \(FOS\)](#); [2015 TR](#)

Petition(s): [2006](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 06/21/2007 ([72 FR 35137](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Fructooligosaccharides (FOS) is on the National List at § 205.606 as a non-organically produced agricultural product allowed as an ingredient in or on products labeled as “organic”. As a non-digestible carbohydrate, this substance is used as a soluble prebiotic fiber ingredient in food products. While FOS is included in food products as a source of energy for probiotic bacteria residing in the gut of humans, it is not used as a nutrient source directly for humans. FOS is incorporated into milk products, cakes, biscuits, cookies, crackers, yogurt, ice cream, soup, and hard candy, among other foods.

Manufacture

There are two common commercial methods of producing FOS:

- 1) **Inulin derived.** Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke, agave, and other plants. Chicory inulin is extracted from the source material via water extraction; the resulting inulin undergoes partial hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger*. The hydrolysis breaks long chain inulin into shorter chain FOS
- 2) **Sucrose derived.** Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas*. The *A. japonicas* cells must be immobilized for the production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicas* culture suspended in calcium alginate, a mobilizer. The *A. japonicas* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfer molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicas* is generally inefficient. Higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzyme reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid, which is a strong acid, or sodium hydroxide, a strong base. Potassium phosphate is also used for pH control. The FOS produced can then be further purified through filtration or further fermentation.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

FOS is not officially recognized as a dietary fiber source by Health Canada. This is because the fiber policy has not been updated since 1997 (Health Canada, 2012).

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

FOS is not specifically listed.

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

FOS is not specifically listed.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

FOS is not specifically listed.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

FOS is listed in the Approved FOSHU products list and classified as “foods to modify gastrointestinal conditions”.

Environmental Issues

There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain FOS. Regarding human health concerns, there are no known harmful effects on human health after exposure to short-chain FOS.

Ancillary Substances

“There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation.” (2015 Technical Report)

Discussion

During the last Sunset review, FOS remained at § 205.606 by a vote of 14 to 1. Most stakeholder comments were in support of the continued listing of FOS. Further, there appear to be no new sources of organic FOS coming out of the last review session. Given that the strongest opposition to keeping FOS on the National List centers around the availability of organic supply, the Handling Subcommittee will focus on this aspect.

Questions to our Stakeholders

1. What is the current availability of suitable organic supply for the manufacture of FOS?

Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

Reference: 205.606 Nonorganic agricultural substances allowed: (j) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean).

Technical Report: [1995 TAP \(acacia, arabic, locust bean, guar, carob bean\)](#); [2018 TR \(gums\)](#)

Petition(s): N/A

Past NOSB Actions: [11/1995 NOSB minutes and vote \(pg. 12-13\)](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR). The gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob, and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (1995 TAP; 2018 TR). These gums are used in various food applications due to their ability to modify the viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic, and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR).

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 technical report, which distinguishes the different characteristics of common gums.

Gum Arabic is used in soft drinks, icing, fillings, chewing gum, confectionary treats, and for color stability (this is general use in food).

Guar gum is used in yogurt, ice cream, cheese, salad dressings, and sauces.

Locust bean/carob bean gum is used in ice cream, yogurt, sauces, prepared foods, and soups. In some cases, it is used with xanthan gum.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture

Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder (2018 TR).

Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR).

Guar gum is formed from the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR).

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Is permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

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

Allowed for products of plant and animal origin.

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

Allowed, although the restrictions of the General Standard for the Labeling of Prepackaged Foods apply.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Allowed as an additive.

Japan Agricultural Standard (JAS) for Organic Production

- Carob bean/locust bean: Allowed, but when used in processed products of livestock origin, limited to the use in dairy products or processed meat products.
- Guar gum: Allowed, but when used in processed products of livestock origin, limited to use in dairy products, canned meats, or egg products. Gum Arabic: Allowed, but limited to the use in dairy products, edible oils or fats, or confections.

Environmental Issues No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) Panel on Food Additives and Nutrient Sources evaluated five gums in 2017 including arabic, guar, and locust. The panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population. The panel also concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children and recommended that additional data be generated.

Ancillary Substances

According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion

Public comment received during the last review noted that while organic versions of these gums existed, the supply chain is inconsistent and therefore commenters supported continued listing at § 205.606. There was also a request that the gums be listed individually so that organic supply of each specific gum could be considered on an individual basis.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version and questions as to whether there are any environmental or human health concerns since last reviewed.

Questions to our Stakeholders

1. Are organic versions of gum arabic, locust/carob bean gum, and guar gum commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the last sunset review?

Lecithin - de-oiled

Reference: 205.606 Nonorganic agricultural substances allowed: (l) Lecithin - de-oiled.

Technical Report: [1995 TAP \(bleached, unbleached\)](#); [2009 TR \(bleached\)](#); [2022 Limited Scope TR \(pending\)](#)

Petition(s): [2004 \(to remove unbleached from §205.606\)](#); [2008 \(to remove bleached from §205.605\(b\)\)](#); [2008 \(to remove unbleached from §205.606\)](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote \(unbleached\) \(pg. 333\)](#); [05/2009 NOSB recommendation \(unbleached/de-oiled\) \(to amend §205.606\)](#); [05/2009 NOSB recommendation](#)

[\(bleached to amend § 205.605\(b\); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to National List 04/21/2001 ([65 FR 80547](#), [66 FR 15619](#)); Sunset renewal notice published 10/16/2007 ([72 FR 58469](#)); Annotation change effective 03/15/2012 ([77 FR 8089](#)); Sunset renewal notice published 06/06/2012 ([77 FR 33290](#)); Sunset renewal notice published 03/15/2017 ([82 FR 14420](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 6/22/2025

Subcommittee Review

Use

The major uses for lecithin include as an emulsifier in margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems, as with margarine products. Lecithin also helps modify chocolates for better enrobing and reduces the crystallization of cocoa fat. With baked goods and dough, lecithin improves water absorption, increasing volume and shelf life, as well as improving uniformity. In addition, lecithin is used in pharmaceuticals for a wide range of purposes, including as a dietary supplement and an emulsifying agent for intravenous injections.

Manufacture

Lecithin is extracted from soybeans and other plants. For example, soybeans are dried and flaked, and crude soybean oil is extracted almost exclusively with the use of hexane. Some expeller-pressed oil is processed further. The crude oil is filtered, hydrated, centrifuged, dried, and cooked. Standardized lecithin is the fraction that is centrifuged. Some commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color.

International Acceptance

[Canadian General Standards Board Permitted Substances List](#)

Lecithin-bleached is allowed only when the unbleached form is not available from organic sources. Lecithin is listed in the table of “Food Additives” of the “Non-organic Ingredients” section under the permitted substances list for processing and sanitation.

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

The use of lecithin as 1) a fungicide, listed in the section, “Substances of crop or animal origin”, for plant protection; and 2) a food additive, listed in the subsection “Food additives, including carriers” of the section “Ingredients of Non-Agricultural Origin”, for preparation of foodstuffs composed of essentially one or more ingredients of plant and/or animal origin.

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

Lecithin used for pest and disease control must be recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Lecithin (INS1: 322) functional uses as an antioxidant and emulsifier agent. Acceptable daily intake is not limited.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

There is no current mention of lecithin in JAS.

Environmental Issues

Hexane is used to extract crude oil in soy flakes, as it gives the highest yield. Then, hexane is then separated from the soybean oil in evaporators. The evaporated hexane is recovered and returned to the extraction process. Hydrogen peroxide or benzoyl peroxide is used in the bleaching process. Increased environmental concerns in using these chemicals have resulted in legislation which could restrict oil processing operations that use hexane. In 1979, a report contracted by the FDA concluded that there is no evidence in the available information on lecithin and lecithin bleached with hydrogen peroxide that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future.

Regarding human health, there were no acute exposure studies found for soybean-derived lecithin in humans. Lecithin, including bleached lecithin, is affirmed as generally recognized as safe (GRAS) with no limitations other than current good manufacturing practice by FDA in 21 CFR 184.1400.

Ancillary Substances

Under current uses as an emulsifier, there are no ancillary substances required for use of lecithin.

Discussion

During the last Sunset review, the NOSB voted 12 to 3 to keep lecithin-de-oiled on the National List. Stakeholder comments tended to center around the availability of suitable and sufficient supply of organic raw material (mostly soybeans or corn). Five years ago, it was felt that there was not sufficient organic supply.

The question of suitable and sufficient supply of organic raw material was addressed by the 2022 limited scope TR which was received in early February 2023. While there appears to be some products that are both organic and readily available, it was noted that these alternatives do not result in the same quality of finished product.

Question to our Stakeholders

1. Are other organic oil seed commodities (e.g., canola) used to produce de-oiled lecithin?

Tamarind seed gum

Reference: 205.606 Nonorganic agricultural substances allowed: (r) Tamarind seed gum.

Technical Report: [2018 TR](#)

Petition(s): [2017](#); [2017 \(addendum #1\)](#)

Past NOSB Actions: [10/2018 NOSB recommendation](#)

Regulatory Background: Added to National List 12/07/2020 ([85 FR 70431](#))

Sunset Date: 12/07/2025

Subcommittee Review

Tamarind seed gum is being reviewed early to sync its cycle with the other gums.

Use

Tamarind seed gum is a relatively new gum, that is used as a thickener, stabilizer, emulsifier, or gelling agent in processed foods. The peer reviewed literature lists the following uses for tamarind seed gum: emulsifier, stabilizer, gelling agent, palatability improver, antimicrobial agent, insulator, odor improver, glazing agent, stickiness preventer, and bodying agent. Converts organic waste into biofertilizers. Allows proliferation of gram-negative bacteria.¹ The product is a replacement for, or used with other gums such as carob bean gum, guar gum, tragacanth gum, and xanthan gum. There are pharmaceutical uses for this product. Tamarind seed gum is limited to non-acid hydrolyzed forms.

The primary use of tamarind seed gum is as a stabilizer and thickener. The product can be used to replace pectin when making jams and preserves.

Tamarind seed gum is agricultural and non-synthetic and might be an acceptable alternative to synthetic gums if organic tamarind kernels can be sourced in the future. The nonorganic form of the ingredient will only be permitted when organic tamarind seed gum is not commercially available.

Table 2. Comparison of properties between tamarind seed gum and other gums on §205.605-606.

Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only becomes viscous at concentrations greater than 50%)	Moderate viscosity	X					
High Viscosity at 1 % concentration			X				
High Viscosity at low concentrations (but above 1%)						X	X
Viscosity remains unchanged over time at low shear rates	X		X				
Viscosity decreases over time at low shear rates				X			
Forms thermo-reversible gels						X	
Thermally reversible						X	X
Thermally irreversible			X		X		
Insoluble in ethanol	X	X	X	X	X	X	X
Stable under acid conditions	X		X	X	X		X
Controls syneresis (weeping)	X			X	X		X

Source: Technical Report, 2018.

Manufacture

Tamarind seed gum comes from an evergreen tree, *Tamarindus indica*, a species of *Caesalpinaceae*, subfamily native to Africa and southern Asia. The tree can grow in many types of

soil, including poor soils; it fixes nitrogen; and is drought tolerant (Hemshekhar, M., K. Kemparaju, K.S Girish. 2011).

The fruit is a pod with 3-10 seeds. To manufacture the gum, the seed is roasted to remove the seed coat. Next, the tamarind kernel is pulverized to a powder. Then, a water soluble galactoxyloglucan polysaccharide is extracted from the powder. The polysaccharide is dried, pulverized, sieved, and mixed with food-grade bulking agents such as sugars (sucrose, glucose, lactose, galactose and maltose), dextrin or maltodextrin to standardize the quality of the product for desired viscosity (FAO, 2017, Chemical) The powder is light brown in color.

Galactoxyloglucan is composed of a linear chain of (1→4)-β-d-glucan that is partially substituted with side chains of (1→6)-α-d-xylopyranose and β-d-galactopyranosyl linked with (1→2)-α-d-xylopyranose linked (1→6) to glucose residues. The ratio by weight of the three sugar constituents (glucose, xylose, and galactose) in tamarind gum is roughly 3:2:1 (Health Canada, 2017)

International Acceptance

There is growing interest in tamarind seed polysaccharide. Tamarind seed polysaccharide has been used as a food additive in Japan for more than 50 years.² FAO (Food and Agriculture Organization of the United Nations) performed a technical review of tamarind seed in 2017. The Food and Drug Administration (FDA) classified tamarind seed gum as Generally Recognized As Safe (GRAS) in 2014. The GRAS notice covers the use of tamarind seed polysaccharide as a thickener, stabilizer, emulsifier, and gelling agent in 12 food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from 0.2–1.5 percent of product composition. Use levels are identified for each food category.

[Canadian General Standards Board Permitted Substances List](#)

First permitted for general use in Canada (i.e., not organic specifically) in 2017. Not mentioned in the list of approved gums.

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

Not mentioned

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

Not mentioned

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Not mentioned.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Not mentioned.

Environmental Issues

There is little to no negative environmental impact from the use of tamarind seed gum. Because it has a structure similar to cellulose, soil bacteria existing in the natural environment have enzymes that can break down tamarind seed gum. There are no documented adverse human health impacts.

Ancillary Substances

None identified

Discussion

During the last review the NOSB determined that tamarind seed gum posed no harm to the environment or human health and recommended to list it due to its compatibility with organic production and handling systems.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since it was last reviewed.

Questions to our Stakeholders

1. Is an organic version of tamarind kernels/seeds commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the product was added to the National List?

Hemshekhkar, M., K. Kemparaju, K.S Girish. 2011. Chapter 131 - Tamarind (*Tamarindus indica*) Seeds: An Overview on Remedial Qualities, Editor(s): V.R. Preedy, R.R. Watson, V. B. Patel, Nuts and Seeds in Health and Disease Prevention, Academic Press, pp. 1107-1114, <https://doi.org/10.1016/B978-0-12-375688-6.10131-8>.

FAO. 2017. Chemical and technical assessment: [Tamarind Seed Polysaccharide](#).

Health Canada, 2017. [Health Canada's Proposal to Allow the Use of Tamarind Gum as and Emulsifying, Gelling, Stabilizing and Thickening Agent in Unstandardized Foods and Certain Standardized Foods](#).

Tragacanth gum

Reference: 205.606 Nonorganic agricultural substances allowed: (s) Tragacanth gum (CAS #-9000-65-1).

Technical Report: [2018 TR \(gums\)](#)

Petition(s): [2007](#)

Past NOSB Actions: [05/2008 NOSB recommendation](#); [10/2014 NOSB sunset recommendation](#); [10/2018 NOSB sunset recommendation](#)

Regulatory Background: Added to the National List 12/14/2010 ([75 FR 77521](#)); Sunset renewal notice published 06/19/2015 ([80 FR 35177](#)); Sunset renewal notice published 05/07/2020 ([85 FR 27105](#))

Sunset Date: 06/22/2025

Use

Tragacanth gum is a polysaccharide that forms a gel that can be used as a thickener and emulsifier. Tragacanth gum forms a gelatinous mass in water and is used as suspending agent, excipient, or emulsifier in food. This material is effective at low pH and at many temperatures. Its stability at low pH is noted as one of its distinguishing characteristics, and it is commonly used in high-acid products like salad dressings (2018 TR). This gum is widely used in low-fat or non-fat products (Nejatian, M., Abbasi, S. and Azarikia, F., 2020.) The percentage of tragacanth gum in final formulations is usually low, below 1% of a total formula (2018 TR).

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 Technical Report, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species (small woody shrubs, which grow in Southwest Asia, Iran, Syria, Turkey, and Greece) during July to September. A mass of gum grows in the roots of the plant, which is collected from the taproot and mechanically ground to a fine powder (EFSA Panel on Food Additives and Nutrient Sources). It may undergo a mitigation step to reduce the microbial load of the powder (2018 TR).

International Acceptance

Tragacanth gum (TG) was decreed "generally accepted as safe" by the FDA in 1972, 21CFR184.1351.

[Canadian General Standards Board Permitted Substances List](#)

Tragacanth gum is permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

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

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

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

Permitted, although exclusions of the general standards for food additives (GSFA) apply

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#)

Allowed as an additive.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Allowed, with no listed restrictions.

Environmental Issues

No environmental or health concerns were noted in the manufacture or use of tragacanth gum.

Ancillary Substances

According to the 2018 TR, no information was found indicating that any additional materials are added to commercially available forms of the gums.

Discussion

A review of the safety of tragacanth gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources, which found that humans tolerated a high dose for 21 days, with undesirable effects. There were no known carcinogenic effects for mice. The Panel recommended that the European Commission considers lowering the current limits for the toxic elements (lead, cadmium, mercury, and arsenic) in the EU specification to ensure that the food additive will not be a significant source of exposure to those toxic elements in food. The 2018 Technical Report (TR) for gums summarized the results from the 2017 European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food, and for tragacanth gum the panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since the last review.

Questions to our Stakeholders

1. Is organic tragacanth now commercially available?
 2. Is this product essential?
 3. Are there any ancillary substances used with this product?
 4. Have any environmental or health concerns emerged since the last sunset review?
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