Sunset 2020 Meeting 2 - Review
Handling Substances §205.605, §205.606
October 2018

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable.

Request for Comments
Written public comments will be accepted through October 4, 2018 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Note: With the exception of tragacanth and gellan gum, the materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

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

Reference: 7 CFR §205.605(a) Nonsynthetics allowed:
Calcium carbonate
Flavors
Gellan Gum
Oxygen
Potassium chloride

Reference: 7 CFR §205.605(b) Synthetics allowed:
Alginates
Calcium hydroxide
Ethylene
Glycerides: mono and di
Magnesium stearate
Phosphoric acid
Potassium carbonate
Sulfur dioxide
Xanthan gum

Reference: 7 CFR §205.606
Fructooligosaccharides
Gums: Arabic, Carob bean, Guar, Locust bean
Lecithin - de-oiled
Tragacanth gum

Calcium carbonate

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

Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

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 FDA allows the use of calcium carbonate as a binding agent in meat and poultry pieces. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List. Calcium carbonate has been used as a coloring agent. However, in historic organic food processing, both within the United States and internationally, calcium carbonate is not allowed for coloration purposes.
Public comments 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.
Manufacture
Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. It is a mined mineral of at least 98% purity that is ground and screened.

International Equivalency
Canada - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Allowed, prohibited for use as a coloring agent

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

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

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

International Federation of Organic Agriculture Movements (IFOAM)

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

Environmental/Health Issues
The mining and processing of calcium carbonate can have negative environmental impacts, which may include impacts on 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 avoid 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.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee has determined that calcium carbonate continues to be essential to organic production.

Subcommittee vote
Motion to remove calcium carbonate from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Flavors

Reference: 205.605(a) Nonsynthetics allowed: Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Technical Report: 2005 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use

Natural flavors are compound substances derived from natural sources including plants, herbs, spices, botanicals and other substances. They 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.[1] The significant function of natural flavors must be flavor rather than nutrition. The FDA defines Natural Flavors in 21 CFR 101.22 as:

> The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in 172.510 of this chapter.

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 Isolate is an isolate of an 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.[2] Processed Flavors, also known as reaction flavors, are ones which 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.[3]

Flavoring components as listed here can typically make up 5-100% of the formulation of a flavor. The remaining 0-95% of flavor formulas contain carriers/solvents and/or non-flavor constituents used to stabilize or maintain the flavor. Non-synthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" or containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non-flavoring constituents from the named product but still impart the characteristic named flavor.

International

Natural/Non-synthetic flavors are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex Standards.

[1] http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf

[2] http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf

[3] http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf

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

During the Fall 2010 NOSB meeting, the NOSB completed its sunset review of flavors for re-listing and stated:

> The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors…The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was practical to individually list flavors on the National List, so chose to relist the category as a single listing…In order to avoid unnecessary disruption to industry, we are recommending relisting of flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011, the NOP issued a Policy Memorandum on Use of Natural Flavors that stated, in part:

> In 1995, the National Organic Standards Board (NOSB) reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals... The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this product market will continue to grow and develop.

On November 6, 2014, the NOP received a petition from the Organic Trade Association to change the flavor annotation to read:

> Flavors – Non-synthetic flavors may be used in products labeled as "organic" 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

At the Fall 2015 NOSB meeting, the NOSB recommended revising the annotation for flavors to read as follows:

> Flavors – Non-synthetic 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.

At the Fall 2015 NOSB meeting, substantial comment was received from industry, trade associations, and Accredited Certifying Agents (ACAs) supporting the continued listing of natural flavors as well as the adoption of the flavor petition.

On January 17, 2018, the NOP published a proposed rule (83 FR 2498) to adopt the Fall 2015 recommendation and change the annotation for flavors at § 205.605(a) to:

Flavors, non-synthetic 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.

Public comment was received from several interest groups and industry that encouraged the adoption of the 2015 NOSB proposal to change the annotation for natural flavors. There was also support from interest groups for furthering the requirements for organic flavor usage. Some commenters specified that that the flavoring constituents in the flavor, as well as the carrier system, need to be organic. Other comments objected to the fact that flavors were a categorical listing. Several businesses and trade associations commented on use and essentiality. In one of the surveys by one of the associations, manufacturers rated flavors as a 9 or 10 on a scale of 1 to 10 of essentiality; 10 being the most essential. Certifiers also reported a wide usage of flavors amongst their clients. One retailer asked about further restriction of flavors when their use is to replace the natural source of the food's advertised flavor, stating that natural flavors should not be allowed to be used as the only defining source of a food's advertised flavor. This is addressed and regulated by the FDA, particularly under 21 CFR 101.22 and 21 CFR 102.5 that define characterizing flavors based on the label, including words and pictures, advertisement or consumer expectations. If the characterizing flavors are not present without the use of a natural flavor ingredient, then the product would need to be labeled as naturally or artificially flavored on the front panel even when natural flavors were used depending on formulation.

The NOSB received no new information to support removing flavors from the National List. To the contrary, the NOSB received significant public comment in support of the relisting of natural flavors.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports the relisting of flavors.

Subcommittee vote

Motion to remove flavors from §205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Tom Chapman
Seconded by: Scott Rice
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Gellan gum

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

Technical Report: 2006 TAP; 2018 TR

Petition(s): 2004 Gellan gum

Past NOSB Actions: 2007 Formal Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 6/22/2020

Subcommittee Review

Material Use

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 (2006 TR 32-34, Petition pg. 10). 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 182-187, 2006 TR 37-41, Petition pg. 2). Typical use of gellan gum is at <0.5% of a finished product formula (Petition pg. 2). 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.

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some 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. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report 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

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 16-19, 66-70, 2018 TR 648-660). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR 662-670). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR 54-55). 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 deacylated forms are not approved on 205.605(a) (2006 TR 109-112). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR 107-117).

International Equivalency

The material is FDA approved as a direct food additive in accordance with 21 CFR 172.665; it is also approved in many countries worldwide in food and non-food items. Gellan gum is listed by the World

Health Organization Joint Expert Committee for Food Additives (Petition pg. 5).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of gellan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gellan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Gellan gum is allowed for use as compliant with Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Gellan gum is neither listed as allowed, nor as prohibited (2018 TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Gellan gum is not listed as allowed, nor prohibited (2018 TR 538-541).

East African Organic Product Standard

Gellan gum is neither listed as allowed or prohibited (2018 TR 543-541).

Ancillary Substances

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

The two available technical reports (TRs) did not list any notable human health or environmental concerns regarding the use of gellan gum.

During the 2018 spring 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.

A couple different organizations requested that the Confidential Business Information (CBI) from the original petition be disclosed and requested the material be delisted until that happens. One retailer commented that organic consumers want to avoid products with stabilizers and emulsifiers, including gellan gum, and was opposed to its re-listing.

Additional information requested by Subcommittee

None

Subcommittee vote
Motion to remove gellan gum from §205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Oxygen

Reference: 205.605(a) Nonsynthetics allowed: Oxygen—oil-free grades.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

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

Manufacture
Oxygen is separated from air cryogenically; super cold temperature liquefaction of air and fractional distillation.

International
The use of oxygen is permitted in organic standards in Canada, CODEX, EU, IFOAM, and Japan.

Ancillary Substances
None.

Additional information requested by Subcommittee
None

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 necessity 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.
No negative impacts on health or the environment were brought to the subcommittee's attention.

Subcommittee vote
Motion to remove oxygen from§205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Potassium chloride

Reference: 205.605(a) Nonsynthetics allowed: Potassium chloride.
Technical Report: 1995 TAP; 2015 TR Nutrient Vitamins and Minerals
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Specific Uses

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 (e.g. microbial management, protein modification, flavor enhancement) that impact the taste, texture, and shelf life of food products. Potassium chloride is generally used for two main purposes in food products. The first is to provide potassium enrichment to foods. The second is as a salt replacement to reduce the sodium content in foods.

Discussion

During Subcommittee review, one Board member stated that potassium chloride is primarily used in infant and baby products.

The following questions were posed to stakeholders:

1. Is the substance essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

The public comment was unanimous 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 and baby formula.

Subcommittee vote

Motion to remove potassium chloride from§205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: N/A

Motion by: A-dae Romero-Briones
Seconded by: Steve Ela
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Alginates

Reference: 205.605(b) Synthetics allowed: Alginates.
Technical Report: 1995 TAP; 2015 TR

Petition(s): 1995 Alginates

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use
Alginates are useful as gelling, thickening and stabilizing agents in a wide variety of organic products, including drinks, ice cream, puddings, cookies, meat, and pasta dishes. They are particularly useful in that they do not need heat to be activated. They can be used to gel cold products and do not melt if the product is heated. They can be used in coatings to help preserve moisture content, protect flavor and enhance shelf life. They can also be used to generate spheres with a thin membrane and liquid center that provide texture and flavor "pops" in certain foods. While not technically a preservative in themselves, they can be used as carriers for preservatives and may inhibit food deterioration due to moisture loss.

Despite their widespread use in a variety of foods, alginates have several limitations. They have limited solubility at low pH values, and high calcium content foods can interfere with their activity.

Alginates have been accepted for use in organic foods since the National Organic Program rule was published in 2000. They have been recommended for relisting in each of three sunset reviews. A 2015 technical report detailed the production of, use of, and alternatives to alginates. Information from that technical report was used for the following summation.

Manufacture
Alginates are normally extracted from the cell walls of seaweed, specifically, brown algae. While they can also be generated by bacterial fermentation, the fermentation process is not currently economically viable. To isolate alginate from seaweed, several isolation steps involving extraction, acid additions, purifications, and base additions are required. The final result is either alginic acid or the salt form, alginates. Alkali extraction renders alginates as synthetic.

International (drawn from the 2015 TR)
Canada - certain alginates are permitted under the Canada Organic Regime due to their appearance in the section titled "Non-organic Ingredients Classified as Food Additives, of the Organic Production Systems Permitted Substances List." In this section, alginates (alginic acid, sodium alginate and

potassium alginate) are included in Table 6.3 (Canadian General Standards Board 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - certain alginates are permitted. Only potassium (402) and sodium (401) alginates are listed as allowed food additives in Table 3.1 as an ingredient of nonagricultural origin in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (Codex Alimentarius Commission 2014).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 **-** alginates (E401-E405) are permitted because they are included in the list of allowed food additives for use as thickeners and stabilizers (E400-E499). Alginates are classified as nonagricultural in the EU Organic Regulations (The Council of the European Union 2008). Sodium alginate (E 401) is listed as an approved food additive for use in certain unprocessed fruit and vegetables in an amendment to Annex II of the Commission Regulation (EC) No 969/2014 (The Council of the European Union 2014).

Japan Agricultural Standard (JAS) for Organic Production **- c**ertain alginates are permitted. The JAS for Organic Processed Foods identifies sodium alginate as an allowed food additive limited to use only in processed foods of plant origin, INS number 401 (The Japanese Organic Standard 2005).

International Federation of Organic Agriculture Movements (IFOAM) **- c**ertain alginates are permitted. Sodium and potassium alginate are recognized by IFOAM as approved additives for use in organic processed products without annotation (IFOAM 2014) (Appendix 4: Table 1).

Ancillary Substances
No ancillary substances (e.g. stabilizers, 352 preservatives or anti-caking agents) were listed on publically available specification sheets (2015 TR).

Discussion
Alginates are Generally Recognized As Safe (GRAS) when used with good manufacturing practices. Alginates are not absorbed by the human body, making them useful as a low-calorie ingredient. While human health effects are generally recognized as minimal, there is evidence that alginates in foods may reduce iron absorption.

The production of alginates generally involves the harvesting of wild seaweed. Increased harvesting of seaweeds leads to questions about the sustainability. Seaweed populations are potentially impacted by overharvesting, the effects of increased ocean water temperatures, and pollution. Attempts at farming seaweed have not been economically successful, thus the sustainability of current wild harvesting is crucial to future alginate production.

While there are a number of alternative thickeners and gelling agents available to organic handlers, the property of alginates to make gels without the use of heat distinguishes them from many other products.

Additional information requested by the Handling Subcommittee
Are there any organic alternatives to alginates that have become available for use since the 2015 technical report was written?

Of the comments received during the Spring 2018 public comment period, most manufacturers and users of alginates noted that the unique properties of alginates were critical to the formulations of their products. Many commenters supported the relisting of alginates on the National List.

Other commenters noted that alginates are synthetic derivatives of brown seaweeds. Thus, issues of sustainable harvesting of seaweeds, disturbances of marine ecology through their harvesting, and bioaccumulation of contaminants such as heavy metals and radioactivity should be accounted for in the review of this material. Several of these commenters asked that the use of alginates require the seaweeds to be organically produced, either through cultivation or by following the wild harvesting rules.

Finally, several commenters noted that they believed the NOSB should review each ingredient derived from brown seaweeds separately. The National List should list each of these substances separately, together with the species name the substance is derived from, and not lump these ingredients under the more general category of "alginates".

Subcommittee vote
Motion to remove alginates from §205.605(a) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Calcium hydroxide

Reference: 205.605(b) Synthetics allowed: Calcium hydroxide.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
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Subcommittee Review

Specific Uses and approved legal uses of the Substance

Calcium hydroxide is used as a component of aluminum free baking powder, to clarify sugar for molasses, and as a conditioner for corn tortillas. It is known as "slaked lime" or "hydrated lime." Calcium hydroxide is lime that is calcined in a kiln to obtain carbon dioxide and quick lime. The quicklime is mixed with water to produce calcium hydroxide. Calcium hydroxide is used as a pH buffer and as the alkaline substance in aluminum-free baking powder. It is also used to fortify foods with calcium, clarify sugar cane or beet juice, for making hominy and masa, and as a firming agent. It is also used in the production of organic corn starch and to remove impurities from solutions.

Discussion

The subcommittee requested the following information from stakeholders:

1. Is calcium hydroxide essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment

The majority of commenters supported relisting. However, 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.

Subcommittee vote

Motion to remove calcium hydroxide from §205.605(b) from the National List based on the following criteria in the Organic Food Productions Act (OFPA) and/or 7 CFR 205.506(b) if applicable: N/A
Motion by: A-dae Romero Briones
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Ethylene

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

Technical Report: 1995 TAP; 1999 TAP - Processing

Petition(s): 1995 N/A, 2008 Ethylene (for use with pears)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote (add tropical fruit and citrus); 11/2005 sunset recommendation; 11/2008 recommendation for pears; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Ethylene is currently listed at §205.605(b) as a material allowed for postharvest ripening of tropical fruit and degreening of citrus. Ethylene (CH_2=CH_2) is a colorless gas at room temperature. It is produced naturally in small amounts by some plants and functions as a ripening agent. The commercially used form, which is synthetic, is chemically identical to the naturally occurring form. The synthetic form is produced from hydrocarbon feedstocks, such as natural gas liquids or crude oil, and may also be derived from liquid ethanol.

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

International

Canada: Allowed for post-harvest ripening of tropical fruit and degreening of citrus.
Japan: Limited to use for after-ripening banana and kiwifruits.
IFOAM: De-greening of citrus and ripening
EU: Degreening bananas, kiwis and kakis; Degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus.
CODEX: Degreening of citrus for fruit fly prevention. As sprouting inhibitor for potatoes and onions.

Ethylene is potentially flammable and also an asphyxiate if high concentrations displace oxygen, but based on previous reviews, significant impacts on human health and the environment are likely minimal.

Public comment about ethylene gas (EG) was very limited and reflects two opposing views. Some consumer groups considered EG to be an unnecessary synthetic growth regulator (ripening agent) and contrary to organic principals, while wholesale and grocer organizations considered it essential for tropical fruits and allowing organic fruit production that is important to the organic produce sector.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting of ethylene.

Subcommittee vote
Motion to remove ethylene from §205.605(b) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b): N/A
Motion by: Asa Bradman
Seconded by: Tom Chapman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Glycerides (mono and di)

Reference: 205.605(b) Synthetics allowed: 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; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

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).

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 their main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils. (TR 2015 56-62).

International

Glycerides are permitted in organic standards in Canada, with the 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.

Ancillary Substances

None.

According to the 2015 technical report (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).

Additional information requested by Subcommittee

1. The TR lists possible alternatives to drum drying, such as spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Have any of these alternatives been tried? And if so, what were the results?
2. Has rice bran extract, soy lecithin, or gum arabic been tried as an alternative to glycerides (mono and di) in drum drying? What were the results?

Subcommittee vote

Motion to remove mono- and diglycerides from §205.605(b) from the National List based on the following criteria in the Organic Food Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Magnesium stearate

Reference: 205.605(b) Synthetics allowed: 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: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewa notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Magnesium stearate (CAS # 557-04-0) is used as an anti-caking agent in salt. 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."

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.

The Canadian General Standards Board (CGSB) includes nonsynthetic sources (and synthetic sources provided that nonsynthetic sources are not commercially available) of magnesium stearate as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients. 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).

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). Magnesium stearate must meet the specifications outlined in the Food Chemicals Codex (21 CFR 184. 1440(b)) and can be used in food with no limitation other than current good manufacturing practice. There was no information provided indicating any significant human health impacts and historically there have not been comments recommending removal of this material from the National List.

In the past, the NOSB Subcommittee has requested public comment on availability of alternatives and any information on possible negative human health impacts. Public comment has been very limited. One certifier commented that two of their members use magnesium stearate to manufacture pharmaceutical and dietary products. The Council for Food Additives supported relisting. Others raised concerns about the use of pesticides/genetic engineering in the non-organic production of oils used for its manufacture and the availability of organic or sustainable alternatives. Magnesium stearate is allowed only in agricultural products labeled "made with organic." Some of those same commenters said they were not opposed to the relisting since the material is only used in "made-with products" and, hence, does not threaten organic integrity.

This proposal to remove magnesium stearate will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting magnesium stearate.

Subcommittee vote

Motion to remove magnesium stearate from §205.605(b) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: N/A
Motion by: Asa Bradman
Seconded by: Tom Chapman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Phosphoric acid

Reference: 205.605(b) Synthetics allowed: Phosphoric acid—cleaning of food-contact surfaces and equipment only
Technical Report: 2003 TAP
Petition(s):N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Specific Uses of the Substance
Phosphoric acid is used in cleaning procedures to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining on stainless steel, lime and scale from heat exchangers and in Clean-In-Place cleaning operations, especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

Discussion
The Handling Subcommittee reviewed phosphoric acid as part of a larger discussion about "sanitizers" and whether phosphoric acid has safer alternatives. The discussions were inconclusive.
The following information was requested from stakeholders:

1) Is the substance essential for organic food production?
2) Since the material was last reviewed, have additional commercially available alternatives emerged?

Public Comment
The majority of stakeholders supported the relisting of phosphoric acid; however, there were numerous comments that suggested the Board find ways to explore safer alternatives to phosphoric acid. One

commenter in particular focused attention on the environmental damage to water resources because of the continuous build of phosphoric acid when washed down drains. Many commenters focused on phosphoric acid as part of a food safety plan for organic operations since many other sanitizers cannot be used in contact with food like phosphoric acid. Other commenters mentioned that some phosphoric acid alternatives have already been removed from the list so phosphoric acid is even more important to food safety planning. The majority of commenters agreed that a safer alternative needs to be explored, but is not readily available at this time.

Subcommittee vote
Motion to remove phosphoric acid from §205.605(b) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b): N/A
Motion by: A-dae Romero-Briones
Seconded by: Scott Rice
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Potassium carbonate

Reference: 205.605(b) Synthetics allowed: Potassium carbonate.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use
Potassium carbonate has many uses. It is commonly used in the Dutch alkali process for processing cocoa and chocolate to reduce acidity. It is also used as a pH control, leavening agent, a boiler water additive, a tenderizer for tripe, in soap production, soft drinks, and confections. Also, it is used as a buffering agent in making wine and mead to reduce acidity.

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.

Public comments 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.

Manufacture:

Potassium carbonate is a strongly alkaline white salt, a major component of the mined salt potash, which is made by passing carbon dioxide through a solution of potassium hydroxide. It is a caustic material with chlorine gas, a bi-product at manufacture, collected to avoid environmental pollution and human health impacts.

International Equivalency:

Canada - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Appears on Table 6.3 - Ingredients classified as food additives

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
- 05.0 Confectionery
- 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category
- 07.007.2 Fine Bakery wares (sweet, salty, savoury) and mixes; not permitted in food of animal origin
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3
- Drying of grape raisins

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

- Appears in Annex VII, Section A - Food additives including carriers
- 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, drying of grapes

Japan Agricultural Standard (JAS) for Organic Production

- Appears in Table 1, Food additives, Limited to be used for drying processed fruit products, or used for grain processed foods, sugar, processed beans products, noodles, bread or confectionary.

International Federation of Organic Agriculture Movements (IFOAM)

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

This proposal to remove will be considered by the NOSB at its public meeting. Potassium carbonate continues to be essential to organic production, and the Handling Subcommittee supports relisting.

Subcommittee vote

Motion to remove potassium carbonate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A.

Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Sulfur dioxide

Reference: 205.605(b) Synthetics allowed: 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): 1995 N/A; 2010 Sulfur Dioxide
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 12/2011 annotation change; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Sulfur dioxide is primarily used to prevent spoilage and oxidation in wine. It may also be used to preserve meats, fruits and other products; however, there are limitations to its use. These limitations include foods used as a source for Vitamin B1, raw fruits and vegetables, foods consumed in large quantities, or meats. 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 has undergone three sunset reviews and has been relisted each time. A technical report (TR) was done in 2011 and forms the bases of the comments summarized below:

In wines, sulfur dioxide is commonly referred to as 'sulfite' or 'sulfites'. The sulfur dioxide inhibits microbial growth and prevents oxidation. Sulfur dioxide is often added to grapes to be fermented in very specific doses. 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 and helps to preserve the "freshness" flavor in white wines. While sulfur dioxide occurs naturally in wines, the level is too low to have pragmatic effect. Wines without added sulfur dioxide generally must be kept in perfect storage conditions and have a shortened shelf life of around six months. This is often very difficult to achieve, and the addition of sulfur dioxide has become accepted for meeting consumer expectations of wine quality.

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 (drawn from the 2011 TR)

Canada – Canadian standards permit the use of sulfurous acid as preservative only in alcoholic beverages labeled as organic but do allow those beverages to be made from grapes or other fruits, unlike the United States which limits its use to wine made from grapes. Furthermore, the Canadian standards allow the alcohol to be labeled as "organic" and set a range of allowable sulfite concentrations that depend on the residual sugar content of the beverage.

The European Economic Community (EEC) allows sulfur dioxide at a maximum of 50 mg/L after fermentation in fruit wines, cider, perry or mead that do not have added sugar. They allow sulfur dioxide at a maximum of 100 mg/L after fermentation for cider and perry that have sugar added. All these beverages may be labeled as organic.

The CODEX Alimentarius Commission permits the use of sulfur dioxide for making cider, perry, mead, and wines made from grapes or other fruits.

Ancillary substances

The 2011 TR makes no mention of ancillary substances associated with sulfur dioxide.

Discussion

Sulfur dioxide is considered to be Generally Recognized As Safe (GRAS) by the Food and Drug Administration when used in accordance with good manufacturing practices, except it is not to be used in meats, food recognized as a source of vitamin B1, on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented as fresh (21 CFR 182.3862). It is recognized to be used in organic products internationally, although various restrictions are placed on its use, either in limitations of concentration or on the products it may be used in.

Sulfur dioxide may cause health effects in sensitive individuals. These effects range from allergic reactions in individuals born without the enzyme sulfite oxidase, asthma attacks, which vary depending on individual sensitivity, hives and swelling, to anaphylaxis. There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in on the National List.

The current annotation allows the use of sulfur dioxide only in wine made from organic grapes. The increasing interest in ciders, wines not made from grapes, and other fermented beverages has led to inquiries about possible use in these products; however, a petition to the NOSB would be required to change the current annotation. While alternatives to sulfur dioxide for winemaking have been investigated, the TR notes that there are not organic alternatives that are satisfactory to prevent spoilage and oxidation in wine.

Public comments received during the Spring, 2018, public comment period noted the essentiality of sulfur dioxide for winemaking. Wine producers used sulfur dioxide to prevent oxidation and spoilage of wines. No alternatives have been identified, and commenters noted that they would not be able to produce quality white wines and that red wines would have a limited shelf life without the use of this material.

A number of commenters noted that in the United States, wines that use sulfur dioxide can only be labelled "made with organic grapes," whereas in many parts of the world wines may be labelled as "organic" when this material is used. Thus, the United States is more restrictive than most countries. Several commenters noted that if the material were removed, there would be a considerable loss of market share and quality for wines made with organic grapes.

Subcommittee vote

Motion to remove sulfur dioxide based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Steve Ela
Seconded by: Eric Schwartz
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Xanthan gum

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

Technical Report: 1995 TAP; 2016 TR; 2018 TR

Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Material Use

Xanthan gum is used in numerous foods products as a hydrocolloid (i.e. substances that disperse water, giving a thickening or gelling effect) including but not limited to: baked goods, beverages, dairy products, dressings, nutritional supplements, frozen foods, etc. (TR 758-759, 135-137). Xanthan gum is commercially available to consumers for use in gluten-free baking and other recipes. The gum is used in small percentages of the finished products, usually at <0.5% by weight (TR 145-146). Xanthan gum is used along with other gums to achieve the desired viscosities and product structures for firmness, water binding, flavor delivery, etc. (TR 229-236); it is particularly effective in frozen and chilled products where it can impart thickness, freeze-thaw protection, and stability during processing and shelf-life (TR 251-256). Common synergistic gums used along with xanthan gum are locust bean gums, guar gums, carrageenan gums (TR 229-236).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some 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. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report 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

Manufacture

Xanthan gum is a high-molecular weight polysaccharide produced though 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 (TR 36-38, 90-97). The gum is water soluble, stable at numerous pH, salt and temperature ranges (including frozen temperatures) (TR 120-124). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 50-55). 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 (TR 48-50). 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 Gums TR 424-432).

International Equivalency

FDA has approved the use of xanthan gum as a food additive since 1969 without restrictions on quantity in finished applications (TR 162-163, 637-638); it must be isolated by isopropyl alcohol precipitation and made into a sodium, potassium, or calcium salt (TR 164-166). It is approved by FDA at 21 CFR 172.695 but is not GRAS; although three FDA notices for GRAS allow isolation of xanthan gum by ethanol and pyruvate, and in combination with konjac glucomannan and sodium alginate (TR 651-659).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of xanthan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 Gums TR 491-496).

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

Xanthan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 Gums TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Xanthan gum is allowed for use as compliant with General Standard for Food Additives Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 Gums TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Xanthan gum is allowed in processed foods of animal origin limited to dairy or confectionary (2018 Gums TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Xanthan gum is allowed with no limitations on use (2018 Gums TR 538-541).

East African Organic Product Standard

Xanthan gums is allowed in fats, fruits and vegetable products, and cakes and biscuits.

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. Through a search of publically available specification sheets a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®.

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 637-742). 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 933, 963-976). In 2011 there was a recall of a xanthan gum product that was being fed to premature babies. The recall was due to the lack of destruction of potentially harmful bacteria that may lead to necrotizing enterocolitis; no conclusions were made regarding the safety of xanthan gum thickeners for premature baby formulas (TR 678-711).

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

During the Spring 2018 public comment period, a number of organizations, certifiers, and manufacturers expressed support for the material, with one larger certifier stating that of all the gums xanthan is the most commonly found in organic system plans. One manufacturer stated that other organic gums didn't have the same functionality in their organic baked goods. One retailer commented that organic consumers want to avoid products with stabilizers and emulsifiers, including xanthan gum, and was opposed to its re-listing.

Additional information requested by Subcommittee: None

Subcommittee vote

Motion to remove xanthan gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Fructooligosaccharides

Reference: 205.606(e) Fructooligosaccharides (CAS # 308066-66-2).
Technical Report: 2006 TAP; 2015 TR
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Use:
Fructooligosaccharides (FOS) is on the National List as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic." FOS is a non-digestible carbohydrate that is used as a soluble prebiotic fiber, sweetening agent, flavor enhancer, bulking agent and humectant. It is used in many foods including yogurts, infant foods, medical food, baked goods, candies, soups, beverages and other dairy products. FOS are mostly indigestible by human digestive enzymes.

Manufacture:
There are two common commercial methods to produce FOS:

- **Inulin derived.** Inulin, a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), Agave, and other plants. Chicory inulin is extracted from the source material via water extraction; the resulting inulin undergoes a partial enzymatic 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 the shorter chain FOS.
- **Sucrose derived.** Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas*. The *A. japonicus* cells must be immobilized for production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicus* culture suspended in calcium alginate, an immobilizer. *A. japonicus* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfer fructose molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicus* 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 enzymatic reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid (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.

Ancillary Substances:
According to the 2014 technical report (TR): "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."

International:
FOS is not specifically listed in the Codex, EU, Japanese organic standards or Canadian standards. However non-organic agricultural products are not listed in these standards.
Discussion: During the 2015 sunset review, the NOSB received limited feedback from users of this substance. However, the comments that were received supported the continued listing for usage in the baking industry and no sources of organic FOS were identified. During the current sunset review the NOSB posed questions about the development and general availability of organic FOS. No comments were received on this question. The NOSB also inquired about the difference between inulin- and sucrose-derived FOS, but no new information was presented about its manufacture that wasn't known to the NOSB in 2015 when it concurred with previous NOSB determinations that this substance was agricultural. Lastly

the NOSB asked about the functional necessity of FOS, and while detailed information was not provided, several manufacturers (some via trade associations) spoke about its essential usage as a prebiotic, particularly in baby and infant foods and in kombucha beverages.
This product is currently used in organic processed products, and no new material information was received to justify removing this substance from the national list.

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting of FOS.

Subcommittee vote
Motion to remove fructooligosaccharides (FOS) from §205.606 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Tom Chapman
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Gums: (Arabic, Guar, Locust bean , and Carob bean)

Reference: 205.606(g) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review
Material 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 78-103). These 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 (TAP pg. 8, 2018 TR 443). These gums are used in various food applications due to their ability to modify viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR 182-187). 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 189-192).
Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some 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. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 technical report 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

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 566-573)
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 594-595)
Guar gum is formed form the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR 584-586).

International Equivalency:
Gum arabic, locust/carob bean gum and guar gum are all listed by the FDA as Generally Recognized as Safe (GRAS) (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of Gum Arabic, locust/carob bean gum, and guar gum as long as they are derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Gum Arabic (414), locust/carob bean gum (410), and guar gum (412) are allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008
Gum Arabic, locust/carob bean gum, and guar gum are allowed for use in processed organic foods as a food additive in the preparation of foodstuffs of plant 508 or animal origin with no specific limitations (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Arabian gum (INS 414) is limited to dairy products, edible fat, and oil and confectionary products (2018 TR 527).
Carob bean gum/locust bean gum (INS 410) is limited to dairy and processed meats. (2018 TR 529)
Guar gum (INS 412) can be used in processed foods of animal origin limited to dairy, canned meat or egg products. (2018 TR 531)

International Federation of Organic Agriculture Movements (IFOAM)
IFOAM allows locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415). There are no restrictions on how any of these items can be used (IFOAM, 2014). (2018 TR 539-541)

East African Organic Product Standard
Locust bean gum, guar gums are allowed with no restrictions. Arabic gum is allowed for milk products, fat products, confectionary, sweets and eggs (2018 TR 544-550).

Ancillary Substances:
According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

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.
Public comment prior to the Spring 2018 NOSB meeting included manufacturers and associations in support of these gums on the National List. One manufacturer noted that they source organic guar and locust bean gum but are in favor of retaining them on the list as they don't know if the organic supply is adequate. During the public comment webinar one manufacturer said they were able to source organic gum arabic this year but that in previous years supply has been inconsistent, and that the supply chain is variable due to the geography of where the gum is coming from. One organization thought that the Board should investigate whether there is gum arabic that could be certified as wild-crafted organic and also look at the availability of organic carob/locust bean gum. A couple of organizations requested that the gums be listed individually so that organic supply could be taken into account for those that are produced organically.

Additional information requested by Subcommittee
Are organic versions of gum arabic, locust/carob bean gum, and guar gum commercially available?

Subcommittee vote
Motion to remove gum arabic, locust bean gum, carob bean gum, and guar gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Lecithin—de-oiled

Reference: 205.606(k) Lecithin—de-oiled.

Technical Report: 1995 TAP; 2009 TR
Petition(s): Lecithin, bleached (remove 2008)
Past NOSB Actions: 04/1995 NOSB minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606); 10/2015 sunset recommendation
Recent Regulatory Background: Annotation change effective 03/15/2012 (77 FR 8089); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Lecithin has a wide range of food applications, including emulsification, release properties, wetting, dispersing, and texturization. The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat. In release applications, lecithin modifies the cooking surface to allow products to be more easily removed. As an instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products. In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation. Lecithin improves water absorption in baked goods and dough, increasing volume and shelf life, and improving uniformity of the products. It is also used as a packaging aid and directly on processing equipment as a lubricant. In addition, lecithin is used in pharmaceuticals (as dietary supplements, emulsifying agent for intravenous injections, and dispersant for vitamins); in cosmetics (as emulsifier and emollient in hair and make-up preparations, creams, and oils); and in animal feeds (as a nutritional ingredient, emulsifier, and wetting aid in calf milk replacers, pet foods, and many other types of feeds required high fat and oil contents). Bleached lecithin is used in applications where a lighter color is deemed important. Unbleached fluid lecithin has a dark brown color which does not permit high use levels in white or very light colored products; however, in some formulations, brown fluid lecithin can be used effectively at low concentrations (Scocca, 1976). Dry lecithin is used in commercial applications of food systems where liquid lecithin is more difficult to handle, and the powdered or granular lecithin is more easily incorporated.

Approved Legal Uses of the Substance

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Most commercial lecithin is made from crude soy oil extracted from soy flakes. The crude soy oil is then treated with water or steam to precipitate the lecithin as gums. These wet gums are centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become a bleached lecithin.

International (acceptance/non-acceptance) by other International certification agencies

The Joint FAO/WHO Expert Committee on Food Additives— Lecithin (INS1: 322) functional uses as antioxidant and emulsifier agent. Acceptable daily intake is not limited.

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

The EU Organic Regulation No 2092/91- The use of lecithin as (1) a fungicide, listed in the section

“Substances of crop or animal origin”, for plant protections; 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 essentially of one or more ingredients of plant and/or animal origin.

The Codex Guidelines for Organically Produced Foods - Lecithin used for pest and disease control need 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 (such as dairy products and analogues, fats and oils, fat emulsions, emulsified sauces, and infant formulae and follow-on formula).

Discussion
The NOSB reviewed the points in favor of renewing the substance as well as those in favor of removal from the list. Those in favor of renewing pointed out that there is insufficient supply in an organic form, specifically from raw materials other than soy. Those in favor of removal argued the product was available in an organic form internationally and was closer to becoming available in other organic forms.

The following question was posed to stakeholders: Are there organic forms of lecithin in de-oiled form?

Public Comment:

The majority of public comment supported relisting with the exception of one commenter, who suggested de-listing based on hazards associated with the production of lecithin and current availability of organic lecithin. Another commenter said while they support re-listing, de-listing the lecithin would give more incentive to processors to create organic forms. Again, public commenters emphasized that organic lecithin is not available except from soy products.

This proposal to remove lecithin-de-oiled will be considered by the NOSB at its public meeting. The Handling Subcommittee supports relisting lecithin de-oiled.

Subcommittee vote
Motion to remove lecithin, de-oiled from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: A-dae Romero Briones
Seconded by: Eric Schwartz
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Tragacanth gum

Reference: 205.606(q) Tragacanth gum (CAS #-9000-65-1).

Technical Report: 2018 TR

Original Petition: 2007 Tragacanth Gum

Past NOSB Actions: 2008 Final Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 06/22/2020

Subcommittee Review

Material Use

Tragacanth gum is a polysaccharide that forms gels and can be used as a thickener and emulsifier. 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 is commonly used in high acid products like salad dressings (2018 TR 218-225, 337). The percentage in final formulations is usually low, below 1% of a total formula (2018 TR 338).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some 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. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report 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

Manufacture

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species during July to September (2018 TR 576-581). Once collected it is dried and ground into powder and may, or may not, undergo a mitigation step to reduce the microbial load of the powder (2018 TR 578-581).

International Equivalency

Tragacanth gum is listed as Generally Recognized as Safe (GRAS) by the FDA at 21 CFR 184.1351 (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of tragacanth gum as long as it's derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Tragacanth gum (412) is allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 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).

Japan Agricultural Standard (JAS) for Organic Production

Tragacanth gum is listed with no limitations (2018 TR 535).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows tragacanth gum (INS 413) with no restrictions on how any of this item can be used (IFOAM, 2014) (2018 TR 539-541).

East African Organic Product Standard

Tragacanth gum is allowed with no restrictions (2018 TR 547).

Ancillary Substances

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Subcommittee Review

No environmental or health concerns were noted in the manufacture or use of tragacanth gum. 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 NOSB Subcommittee noted in 2008 that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited. During the last sunset review in 2014, the Handling Subcommittee was unable to find evidence that tragacanth was available in organic form and received testimony from a certifier and a producer who used non-organic tragacanth. Public comment prior to the Spring 2018 NOSB meeting was very limited, with one organization opposed to the listing because they believed potential health effects hadn't been taken into account, as well the possible impacts of non-organic production.

Additional information requested by Subcommittee

Is organic tragacanth now commercially available?

Subcommittee vote

Motion to remove tragacanth gum based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: N/A
Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0