Sunset 2020 Review
Meeting 1 - Request for Public Comment
Handling Substances
April 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 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. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through www.regulations.gov by April 4, 2018 as explained in the meeting notice published in the Federal Register.

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

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

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

For Comments That Support Substances Under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

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

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

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

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

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

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

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

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

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Note: With the exception of tragacanth and gellan gums, 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)

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

Background from Subcommittee:
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 as a 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.

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. These may be 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.

Additional information requested by Subcommittee: None

Flavors

Reference: 205.605(a), 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

Background from Subcommittee:

Use: Natural flavors are derived from natural sources and are compound substances derived from 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 Flavorings significant function must be flavor rather than nutrition. The FDA defines Natural Flavors in 21 CFR 101.22 as:

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

> 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 liquid produced 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. It's 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. Oleoresin 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.

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:

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[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

> 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

This states in part:

> In 1995 the 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 organic market will continue to grow and develop...

On November 6th 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 approved a petition to revise the flavors listing annotation 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 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, 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.

Additional information requested by Subcommittee: None

Gellan gum

Reference: 7 CFR 205.605(a) – high acyl form only - As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

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: 6/22/20

Background from Subcommittee:

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).

Other international standards

East African Organic Product Standard uses IFOAM and thus gellan gum is not prohibited, nor allowed (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®.

Background Information:

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

Public comment in 2014 supported the ongoing essentiality of this material.

Additional information requested by Subcommittee: None

Oxygen

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

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset 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

Background from Subcommittee

Use: Oxygen is used in modified atmosphere packaging and the processing of olives.

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.

This material was reviewed by the NOSB during 2015 and the Board voted to continue its listing on the National List.

Additional information requested by Subcommittee:
None

Potassium chloride

Reference: (a) Nonsynthetics allowed:
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

Background from Subcommittee:

Manufacturing Process:
Potassium Chloride is a metal halide salt composed of potassium and chloride. Potassium Chloride is extracted from minerals sylvite, carnalite and potash. It is also extracted from salt water and can be manufactured by crystallization from solution floatation or electrostatic separation from suitable minerals. It is a by-product of the production of nitric acid from potassium nitrate and hydrochloric acid. It is odorless and has a white or colorless vitreous crystal appearance.

Specific Uses:
According to the Food & Drug Administration, 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 impacts 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.

Additional information requested by Subcommittee:

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

Alginates

Reference: 205.605(b) Synthetics allowed
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

Background from Subcommittee:

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, use 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 an 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 is 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 NOSB

Are there any organic alternatives to alginates that have become available for use since the 2015 technical report was written?

Calcium hydroxide

Reference: 205.605(b)
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)
Sunset Date: 3/15/2022

Background from Subcommittee:

Manufacturing Process:

Calcium hydroxide (also known as "slaked lime" or "hydrated lime") 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.

Specific Uses of the Substance:

It is used as a component of aluminum free baking powder, to clarify sugar for molasses, and as a conditioner for corn tortillas.

Additional information requested by Subcommittee:

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

Ethylene

Reference: 205.605(b) 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

Background from Subcommittee:

Use:

Ethylene gas (CAS # 74-85-1) is currently listed at 205.605(b) as a material allowed for postharvest ripening of tropical fruit and degreening of citrus.

Manufacture:

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 natural 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 (acceptance/nonacceptance) by other international certification agencies:

Canada: allowed for post-harvest ripening of tropical fruit and degreening of citrus.

Japan: Limited to use 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: For degreening of citrus for fruit fly prevention. As sprouting inhibitor for potatoes and onions.

Environment/Health Issues:

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

Discussion:

In previous discussions, the Handling Subcommittee considered removing ethylene gas for use in the de- greening of citrus. However, historically there has been no opposition to relisting ethylene. The 2015 NOSB approved continued use of ethylene as a post-harvest ripening tool. The Handling subcommittee found ethylene to be compatible with current organic processing standards.

Additional information requested by Subcommittee:

The NOSB requests input on the continuing need for ethylene as a fruit ripening tool.

Glycerides (mono and di)

Reference: 205.605(b) 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

Background from Subcommittee:

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 (Frank 2014). 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 (Fusaro 2012). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (O'Brien 2004).

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 (FDA 2014). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut or palm oil (Frank 2014), 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 organic standards: CODEX, EU, IFOAM or Japan.

Ancillary Substances:

None.

Alternatives:

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

Organic soy lecithin and gum arabic could be alternative substances to glycerides. Both are currently on the National List.

This material was reviewed by the NOSB during 2015 and the Board voted to continue its listing on the National List.

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. Why is drum drying preferred for the production of potato flakes? Have alternatives been tried? And if so, what were the results?
2. Have soy lecithin or gum arabic been tried as an alternative to glycerides (mono and di) in drum drying? What were the results?

Magnesium stearate

Reference: 205.605(b) - 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

Background from Subcommittee:

Use:

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))" but is prohibited in agricultural products labeled "organic."

Manufacture:

Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils. Magnesium stearate is produced by adding 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.

Alternatives:

Organic flours and starches can replace magnesium stearate as an additive in some products. Non-syntheti flow agents are available as alternatives, depending on the product and process.

International:

As reviewed in the 2018 Technical Report:

"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 was not found to be listed under any other international standard for organic handlin and processing".

Environmental/Health Issues:

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.

Discussion:

In the past, the Subcommittee has requested public comment on availability of alternatives and any information on possible negative human health impacts. Public comment has been limited.

Magnesium stearate is allowed only in agricultural products labeled "made with organic'" and is prohibite in agricultural products labeled "organic".

Additional information requested by Subcommittee:

None

Phosphoric acid

Reference: 205.605(b) - 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

Background from Subcommittee:

Manufacturing Process:

Phosphoric acid can be made in two ways: the wet process or the thermal process. In the wet process, mined phosphate ore is treated with sulfuric acid and then the resulting phosphoric acid is separated from the calcium sulfate crystals produced.

The process conserves most of the impurities found in the ore but the product can then be purified further for technical and food grade phosphoric acid. The thermally produced acid is made from the elemental phosphorus and is considerably more expensive and purer than the wet processed acid. The pure phosphorus is burned in excess air and the resulting phosphorus pentoxide is then hydrated and cooled, and the acid mist is collected.

Specific Uses of the Substance:
Phosphoric acid is used in cleaning operations 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 of 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.

Additional Information requested by Subcommittee:

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

The Handling Subcommittee encourages current users of phosphoric acid to provide detailed comments describing the situations in which it is the most effective cleaner for a given application.

Potassium carbonate

Reference: 205.605(b)
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

Background from Subcommittee:
Use:
Commonly used in the Dutch alkali process for processing cocoa and chocolate to reduce acidity. Used as a pH control; leavening agent; as a boiler water additive; as a tenderize tripe; and in soap production. Used in soft drinks and confections. Used as a buffering agent in making wine and mead to reduce acidity.

The 1995 Technical Advisory Report (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.

During the last sunset review, public comment indicated that it is not widely used.

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 as a bi-product. During manufacture the gas is 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

Additional information requested by Subcommittee:

1. Is potassium carbonate in use in organic products?
2. What type of products is it used in?

Sulfur dioxide

Reference: 205.605(b) 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

Background from Subcommittee:

Use:

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 organic 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. This annotation prevents the use of sulfur dioxide in products where the more serious health effects might be present.

Sulfur dioxide has undergone three sunset reviews and has been relisted each time. A technical report 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 have to 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 the organic rules.

The current annotation allows the use of sulfur dioxide only in wine made from 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 this annotation.

While alternatives to sulfur dioxide for winemaking have been investigated, the technical report notes that there are not organic alternatives that are satisfactory to prevent spoilage and oxidation in wine.

Additional information requested by Subcommittee:

Have any organic alternatives to sulfur dioxide for use in winemaking been identified since the issuance of the 2011 technical report?

Xanthan gum

Reference: 205.605(b)

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

Background from Subcommittee:

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). 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; though 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).

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®.

Background Information:

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 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 of specific environmental issues regarding the production of xanthan gum.

Additional information requested by Subcommittee:

None

Fructooligosaccharides

Reference: 205.606(h) 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

Background from Subcommittee:

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 a 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 hydrolyzes (breaks) the sucrose molecules into glucose and fructose and then transfers 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 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, comments were received in support of continued listing for usage in the baking industry and no sources of organic FOS were identified.

Additional information requested by NOSB

1. Have organic sources of FOS become available? What additional actions have organic industry users of FOS taken to source or develop organic FOS?
2. What functional essentiality does FOS have in current specific organic certified applications and would alternatives (i.e. other fibers, organic inulin, etc.) be functionally similar in the same application? If not, why?
3. Is the summary of both inulin derived and sucrose derived FOS correct? Do both of these processes meet the agricultural classification in line with NOP Guidance 5033 on Agricultural/Non-Agricultural classification?

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

Reference: 205.606(k) 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

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®.

Background Information:

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) re-evaluated five gums in 2017 including arabic, guar, and locust. The panel concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children, and recommend that additional data be generated.

In 2015 these gums were unanimously voted by the NOSB to remain on 205.606(k).

Additional information requested by Subcommittee:

Are organic versions of gum arabic, locust/carob bean gum, and guar gums commercially available?

Lecithin -de-oiled

Reference: 205.606(o) 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

Background from Subcommittee:

Use:

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 application, which includes 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.

Manufacture:

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 a gum. The wet gums is centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become bleached lecithin.

International:

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) (2009 TR lines 159 -163).

Environmental Health Issues:

Lecithin is found in brain, nerve, liver, kidney, heart, blood, and other tissues. Because of its strong affinity for water, it facilitates the passage of fats in and out of the cells; and it probably plays a role in fat absorption from the intestine and transport of fats from the liver (Potter, 1973). No acute exposure studies were found for soybean-derived lecithin in humans. According to MSDS, the dust is predicated to be irritating to the eyes, skin, and respiratory tract from mechanical action. Inhalation of lecithin aerosols may cause pulmonary edema; it may cause occupational asthma from pulmonary sensitization. Acute ingestion may affect the liver (fatty liver degeneration). Safety glasses, lab coat, dust respirator, and gloves are needed for personal protection.

Soy has also been recognized as one of the eight most common food allergens. During manufacture of lecithin derived from soy, most, but not all, of the soy protein is removed. Soy allergens, to the extent they are present in lecithin, would be found in the protein fraction of the ingredient. Accurately measuring lecithin’s protein content presents challenges to current analytical methodology due to the ingredient’s oily matrix and low levels of protein.

Discussion:

During the sunset review in October 2006, the NOSB recommended renewing lecithin-bleached under 7 CFR 205.605(b) Synthetics allowed. In the committee summary, the Board further recognized that there are “plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form” but that there is currently no such alternative for “bleached lecithin in dry, de-oiled form”. Because the sunset review provided no opportunities to add annotations, the board saw no alternative but to recommend renewal of bleached lecithin. In its closing summary, the Board invited a petition to restrict the use of bleached lecithin to dry forms only. Since then, the supply of organic lecithin has evolved to the point that there is now certified organic lecithin available to replace the need for non-organic bleached lecithin. But, there still remains a question of whether there is an organic lecithin that is in dry, de-oiled form.

During the May 2009 NOSB meeting, several experts and lecithin industry members provided informational presentations describing the types of lecithin available, and the methods of manufacture for each. It was explained that it is the "de-oiling" process, not the bleaching process that differentiates the types and functionality of lecithin, and dictates in which products they could be used. At this time, there are now many forms of organic lecithin available, as well as organic and conventional non-synthetic gums, which make the use of this synthetic form of lecithin no longer essential in organic handling. The board voted to remove the "bleached" form of lecithin from 205.605(b), but in a separate vote, agreed to list "lecithin – de-oiled" in
205.606, making that form available to organic manufacturers who truly needed it, but subjecting its use to commercial availability scrutiny by certifiers. Both the petitioner and lecithin-using handlers present at the NOSB meeting were satisfied with this recommendation.

In 2009, the NOSB reviewed the arguments for and against renewal of lecithin. Those in favor of renewing pointed out that there is was insufficient supply in an organic form, specifically from raw materials other than soy. Additionally other sources were not yet in production and were located in a country under political turmoil. Those in favor of removal argued the product was available in an organic form internationally. The majority of the NOSB concluded that it meets the OFPA criteria, is not available in an organic form, and should be renewed.

Additional information requested by Subcommittee:

Are there commercially available organic forms of lecithin in de-oiled form?

Tragacanth gum

Reference: 7 CFR 205.606(x) - As nonorganically produced agricultural product allowed as ingredient in or on processed products.

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: 06/22/20

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®.

Background Information:

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

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. In October 2014 organic tragacanth gum was not known to be in production. The 2014 Subcommittee was unable to find evidence that tragacanth is available in organic form, and received testimony from a certifier and a producer who currently uses non-organic tragacanth.

Additional information requested by Subcommittee:

Is organic tragacanth now commercially available?