United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Gums

Handling/Processing

Identification of Petitioned Substances

Chemical Names:
Gum arabic/acacia gum
Gellan gum
Guar gum
Locust bean gum/carob bean gum
Tragacanth gum
Xanthan gum

Other Names:
Gum arabic: acacia gum; Arabian gum; gum arabic (*Acacia Senegal*); gum arabic (*Acacia seyal*); gum hashab; gum tala.
Gellan gum: no other names identified.
Guar gum: guaran; clusterbean; calcutta lucern; guar flour; gum *Cyamopsis*.
Locust bean gum: carob gum; carobin; *Ceratonia siliqua* gum; algaroba.
Tragacanth gum: gomme adragante; astragale; coussin-de-belle-mere; goat's thorn; gomme de dragon; hog gum; cocoweed; shiraz gum.
Xanthan gum: corn sugar gum; gummi xanthanum; gum xanthan.

Trade Names:
Gum arabic: TICorganic® Gum Arabic SF.
Gellan gum: Kelcogel®; Phytagel™; Gel-Gro™.
Guar gum: MEYPRODOR®; GRINSTED® Guar.
Locust bean gum: GRINSTED® LBG; Genu® Gum.
Xanthan gum: Keltrol®; Satiaxane® GRINSTED® Xanthan; NovaXan™; Ticaxan®; Ziboxan®.

CAS Numbers:
Gum arabic: 9000-01-5
Gellan gum: 71010-52-1
Guar gum: 9000-30-0
Locust bean gum: 9000-40-2
Tragacanth gum: 9000-65-1
Xanthan gum: 11138-66-2

Other Codes:
Gum arabic: E 414; INS 414; EINECS No. 232-519-5
Gellan gum: E418; EINECS No. 275-117-5
Guar gum: E412; INS 412; EINECS No. 231-536-8
Locust bean gum: E 410; INS 410; EINECS No. 232-541-5;
Tragacanth gum: E 413; INS 413; EINECS No. 232-252-5
Xanthan gum: E415; INS 415; EINECS No. 234-394-2

Summary of Petitioned Use

There are seven gums currently allowed as nonorganic ingredients and processing aids under the National Organic Program (NOP) regulations. These gums are identified in four listings on the National List of Allowed and Prohibited Substances (National List).

- At § 205.605(a) as an allowed nonsynthetic substance, "Gellan gum" (CAS# 71010-52-1) is listed with the annotation, "high acyl form only."
- At § 205.605(b) as an allowed synthetic substances, "Xanthan gum" is listed without any additional annotation.
- At § 205.606 as allowed agricultural substances, "Gums" are listed with the annotation, "water extracted only (Arabic; Guar; Locust bean; and Carob bean)."
- Also at § 205.606 as an allowed agricultural substance, "Tragacanth gum" (CAS# 9000-65-1) is listed without any additional annotation.

These gums are polysaccharides widely used in a variety of food products to perform a number of functions, including: thickening; gelling; stabilization of foams, emulsions, and dispersions; inhibition of ice and sugar crystal formation; aiding formulation; and in the controlled release of flavors (Williams and Phillips, 2003; CP Kelco, 2017; Danisco, 2007; Cybercolloids, 2017; Prospector, 2017; TIC Gums, 2017b).

Note on How Substance Names are Referenced:
The National List refers to locust bean gum and carob bean gum as two separate substances. In practice, however, these are the same substance. Locust bean gum is derived from the carob tree (*Ceratonia siliqua* (L.) Taub). FDA regulations refer to "Locust (carob) bean gum." The CAS# 9000-4-2 references "Locust (Carob) Bean Gum." There is no separate CAS number for Carob bean gum. The listings for both locust

bean gum and carob bean gum will be referred to under the single term "Locust bean gum" throughout the remainder of this report.

The National List refers to the substance Arabic Gum. However, in the literature reviewed, this material is most commonly referred to as "gum arabic." Because gum arabic is derived from the plant genus *Acacia*, it is also often called "acacia gum" or, less commonly, "gum acacia." FDA regulations refer to "Acacia (gum arabic)." This substance will be referred to as "gum arabic" for the remainder of this report.

Note on Report Sources:
Technical reports have previously been prepared for gellan gum (USDA NOP, 2006) and xanthan gum (USDA NOP, 2016) and are incorporated by reference into this report. Information from those earlier technical reports is only repeated in this technical report as needed to compare with the other gums.

Some of the gums that are the subject of this report have been used for thousands of years, and others for many decades, and thus there has evolved a large body of information. References cited in this report represent a cross-section of sources, including peer-reviewed research articles, recent meta-analyses, and industry information. Where information is limited or not available the report will so indicate.

Characterization of Petitioned Substances

Composition of the Substances:

Gum Arabic

Gum arabic is a high-molecular-weight, complex, heterogeneous polysaccharide consisting of galactopyranose, arabinopyranose, arabinofuranose, rhamnopyranose, glucuropyranosyl uronic acid and a small amount (1 to 3 percent) of protein. The carbohydrate structure indicates a core of galactose units with compact branches consisting of galactose and arabinose terminating with rhamnose and glucuronic acid (Williams and Phillips, 2003; Renard, 2006; Anderson, 1985; JECFA, 2006b; CODEX, 2017; EFSA, April 2017).

Gellan Gum

Gellan gum is high-molecular-weight polysaccharide composed of a linear tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucose units, and is substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters (Williams and Phillips, 2003; USDA NOP, 2006; Commission Regulation (EU), 2012; JECFA, 2014).

Guar Gum

Guar gum is a high-molecular-weight polysaccharide composed of galactopyranose and mannopyranose units combined through glycosoidaic linkages, which may be described chemically as galactomannan (Commission Regulation (EU), 2012). Also described as a mannose sugar backbone with galactose sugar side groups (Williams and Phillips, 2003; Weilinga, 2009), the mannan-to-galactose ratio is about 2:1 (Slavin and Greenberg, 2003; EFSA, 2017; Williams and Phillips, 2003; McCleary et al., 1985; JECFA, 2008).

Locust Bean Gum

Locust bean gum is a high-molecular-weight polysaccharide composed of galactomannans (galactose and mannose), similar to guar gum. The structure varies, but it has on average 3.5 randomly distributed mannose residues for every galactose residue. This structure can affect the properties. The mannose-to-galactose ratio is about 4:1 (JECFA, 2008; CODEX, 2017; Cyber Colloids Ltd., 2017; EFSA, 2017; McCleary et al., 1985; Williams and Phillips, 2003; Commission Regulation (EU), 2012).

Tragacanth Gum

Tragacanth gum is a high-molecular-weight, highly branched, heterogeneous polysaccharide (galactoarabans and acidic polysaccharides). Tragacanth gum consists of a water-swellable fraction called tragacanthic acid (or bassorin) and a water soluble fraction called tragacanthin (Williams and Phillips, 2003; Verbeken, 2003; Balaghi, 2011; JECFA, 2006a; EFSA, June 2017). Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present

(CODEX, 2017; EFSA, 2017c; Williams and Phillips, 2003; Commission Regulation (EU), 2012). The composition of the gum from different *Astragalus* species shows considerable variation, especially in sugar composition, methoxyl content and relative proportion of soluble and insoluble components (Anderson, 1985; Verbeken, 2003).

Xanthan Gum

Xanthan gum is a high-molecular-weight polysaccharide consisting of a cellulose backbone with trisaccharide side chains (Belitz, 2009). Each xanthan gum repeat unit consists of five sugar residues: two glucose, two mannose, and one glucuronic acid. Each side chain comprises a glucuronic acid residue between two mannose units. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid (CP Kelco, 2007; EU, 2012; JECFA, 2016; CODEX, 2017; EFSA, 2017d; USDA NOP, 2016).

<u>Source or Origin of the Substances:</u>

Four of the gums in this report (gum arabic, tragacanth gum, guar gum, and locust bean gum) are derived from plants in the plant family *Leguminosae (*alternatively called *Fabaceae)*. Gum arabic and tragacanth gum are both exudates of leguminous plants (Anderson, 1985; Verbeken, 2003). Guar gum and locust bean gum are not exudates of leguminous plants; they are instead storage polysaccharides obtained from the endosperms of leguminous seeds. The other two gums in this report (gellan gum and xanthan gum) are microbial in origin, derived from bacteria (*Sphingomonas elodea* for gellan and *Xanthonomas campestris* for xanthan). For more details on the manufacturing of these gums, see *<u>Evaluation Question 1</u>*.

Gum Arabic

Gum arabic is the dried, gummy exudate of hardened sap from stems and branches of various species of acacia tree. The substance was originally derived from *Acacia nilotica* (L.) Delile, but present-day sources are predominantly derived from *Acacia Senegal* (L.) Willd. and *Acacia syal* Delile. Gum arabic is commercially collected from native trees in the "gum belt" of Africa, a vast area which extends over Senegal, Niger, Nigeria, Chad, Sudan, Ethiopia, Somalia, Uganda, and Kenya, with Sudan being the largest producer (Verbeken, 2003).

Tragacanth Gum

Tragacanth gum is the dried exudation obtained from the dried sap collected from the tap root and also from stems and branches of several species of legumes in the genus *Astragalus* including *Astragalus tragacantha*, (L.) *Astragalus gummifera* Labill., *Astragalus adscendens* Boiss & Hausskn., *Astragalus brachycalyx* Phil. (ILDS, 2017; CODEX, 2017; Verbeken, 2003). Most commercial gums are obtained from *Astragalus gummifer* a small shrub growing in the highlands and deserts of Turkey, Iran, Iraq, Syria, Lebanon, Afghanistan, Pakistan, and southern Russia. Iran is the biggest producer of Tragacanth gum (Verbeken, 2003).

Guar Gum

Guar gum is derived from the ground endosperm from the seeds of guar bean plant, *Cyamoposis tetragonoloba* (L.) Taub, or *Cyamopsis psoraloides* (Lam.) D.C. (21 CFR 184.1339; CODEX, 2017; ILDS, 2017). India and Pakistan are responsible for about 80 percent of the world's production of this plant, and it is also cultivated in the United States, Australia, and Africa (EFSA, 2017; 21 CFR 184.1339; Verbeken, 2003; Prem, 2005).

Locust Bean Gum

Locust bean gum is derived from the pure ground, macerated endosperm extracted from the seeds of the carob tree, *Ceratonia siliqua* (L.), in the Mediterranean region (CODEX, 2017; EFSA, 2017; ILDS, 2017).

Gellan Gum

Gellan gum is produced commercially from the naturally occurring bacteria *Sphingomonas elodea* (formerly known as *Pseudomonas elodea,* prior to 1990), by a pure culture aerobic fermentation of a carbohydrate. It is a gram-negative, rod-shaped, aerobic soil bacteria (CODEX, 2017; USDA NOP, 2006).

Xanthan Gum

Xanthan gum is derived from the naturally occurring bacteria *Xanthomonas campestis*. The gum is a naturally occurring extracellular polysaccharide (secondary metabolite) produced by most bacteria of the *Xanthonomas* genus (Born, 2005; USDA NOP, 2016). The gum is produced by pure-culture aerobic fermentation of a carbohydrate with *Xanthomonas campestris* (EFSA, 2017; CODEX, 2017). This is the same plant pathogen bacteria that causes black rot to form on broccoli, cauliflower, and related vegetables. It is a gram-negative, short, rod-shaped bacteria (Garcia-Ochoa, 2000).

<u>Properties of the Substances:</u>

Gums have a wide array of functional properties. There is a large body of research on properties of gums, and only a representative sample is provided in this report. This section includes further details on each of the petitioned gums. For a summary comparison of these gums, see Table 1.

The gums described in this report are *hydrocolloids*, which are substances that modify the *rheology*, or flow of matter, in food. Hydrocolloids are a heterogeneous group of long chain polymers (polysaccharides and proteins) characterized by their property of forming viscous dispersions and/or gels when dispersed in water. Thus, gums are substances that disperse in water and provide a thickening and/or gelling effect by increasing the viscosity of a solution. This effect is common to all hydrocolloids, serving as gums' primary function (Saha and Battacharya, 2010; Edwards, 2003).

Hydrocolloids with thickening properties include gum arabic, tragacanth gum, locust bean gum, guar gum, and xanthan gum (along with starch and gum karaya). While all hydrocolloids thicken aqueous dispersions, only a comparative few gums form gels. Gelling hydrocolloids include gellan gum, along with agar, pectin, gelatin, and carrageenan (Saha and Battacharya, 2010).

The viscosity of gum solutions/hydrocolloids depends on how the hydrocolloid behaves in various concentrations or environments, including temperature, pH, or amount of physical agitation. Viscosity at low concentrations only depends on temperature, but at higher concentrations, gum viscosity depends on shear rate thinning or thickening. *Shear rate* is a term used to describe the flow characteristics of materials that exhibit a combination of fluid, elastic, viscous, and plastic properties and behaviors (Saha and Battacharya, 2010; Chenlo, 2010). *Shear stress* is the force acting in the plane of the fluid (CP Kelco, 2007).

Gums will dissolve or swell in water, although in many cases high temperature and vigorous agitation are needed before achieving complete dissolution. The solutions formed are usually thick and viscous even at low concentrations (e.g., 1 percent). Most gums produce viscous solutions in their isolated form, with the level of viscosity depending on the length of molecule and constituent sugars (Edwards, 2003).

Gum Arabic

Commercial products are pale white to yellow-white powders, flakes, or granules that are roller-dried or spray-dried (FAO, 1997). Because of its compact branched structure and composition, gum arabic solutions are characterized by low viscosity. Gum arabic has high solubility in hot or cold water, with simple fluid flow behavior at concentrations up to 40 percent (and only becoming viscous at concentrations greater than 50 percent, which is comparably lower than other gums in this report). It has highly effective emulsifying properties. One gram of gum arabic dissolves in 2 ml of water. It is insoluble in ethanol (Williams and Phillips, 2003; CODEX, 2017; Verbeken, 2003).

Tragacanth Gum

The powdered gum is white to pale yellow or a pinkish brown, pale tan. A smooth, stiff, opalescent mucilage is obtained by placing 1 gram of powder in 50 ml of water. It is insoluble in ethanol (CODEX, 2017). Tragacanth gum produces high viscosity solutions even at low concentrations (e.g., one percent). The viscosity decreases irreversibly on heating, and the solution is stable under acid condition. It has good emulsification characteristics (Williams and Phillips, 2003). It is one of the most acid-resistant gums. If extended storage time is the desired function of a food additive, tragacanth gum may be used because it has low shear rate viscosity that remains unchanged over time (Chenlo, 2010).

Locust Bean Gum

Locust bean gum is acid-stable over a wide range pH range, only partially soluble in cold water, needs to be heated for complete solubility, exhibits high viscosity and controls syneresis[1] (CP Kelco, 2017b; Danisco, 2017b; Saha and Battacharya, 2010). Gelling occurs when the molecules are cross-linked and tangled into an interconnected molecular network immersed in water to such an extent that they trap water and hold it in place, like a tangled three-dimensional fish net (Saha and Battachayra, 2010). Upon freezing, locust bean gum will self-associate in solution and form thermally irreversible gels (Williams and Phillips, 2003). Locust bean gum has a positive impact on protein stability (Danisco, 2017b). It is insoluble in ethanol (CODEX, 2017).

Guar Gum

Guar gum is sold as a white to yellow-white, nearly odorless, free-flowing powder (CODEX, 2017). The quality of food grade guar is defined by particle size, the viscosity generated, and the rate at which that viscosity develops. Coarser gums tend to develop viscosity earlier (Voragen, 2012). Guar can form thick pastes without forming a gel, thus, guar is not self-gelling. Guar controls syneresis, binding water in its molecular structure (Danisco, 2017a). Guar is insoluble in ethanol (CODEX, 2017), but readily soluble in cold water. At low shear rates apparent viscosity decreases over time with guar gum (Chenlo, 2010; Williams and Phillips, 2003).

Gellan Gum

The unique property of gellan gum, because of its molecular composition, is its ability to form gels. It is self-gelling, and has the ability to suspend while contributing minimal viscosity via the formation of a “fluid gel” solution with a weak gel structure. Gellan gum fluid gels have a high low-shear viscosity with high pseudoplastic or shear thinning flow properties (CP Kelco, 2017; IPCS INCHEM, 2017). The gel formed is thermo-reversible. Thermo-reversibility of gels is determined, to a large extent, by the number of molecules that form a junction zone in the overall molecular structure (Saha and Battcharya, 2010). In gellan gum, thickness and hardness is determined by acetyl groups present. With acetyl groups present, the gel is soft and elastic. Firmer gels are obtained by reducing the number of acetyl groups by adding potassium, magnesium, calcium, and/or sodium salts (USDA NOP, 2006). Gellan gum is a water-soluble, off-white powder, forming a viscous solution, but insoluble in ethanol (CODEX, 2017; USDA NOP, 2006). The microbial material forms gels when positively charged ions (cations) are added, thus the thickness can be controlled by manipulating the addition of potassium, magnesium, calcium, and/or sodium salts. There are two forms of the gum: low acyl forms of hard, non-elastic brittle gels; and high acyl forms, which are soft, very elastic, and non-brittle gels (USDA NOP, 2006).

Xanthan Gum

Commercial formulations are dry, odorless, off-white to pale yellow, free-flowing powders or granules that are water soluble with a near-neutral pH. Xanthan gum is stable at a wide pH range and the viscosity is stable at a wide range of temperatures. The viscosity of xanthan is minimally influenced by pH, temperature, and salt concentration, however the actual temperature at which dissolution occurs will control the molecular conformation and appearance. Thus, depending on the dissolution temperature, xanthan gum seems to have two conformations—helix and random coil—which in turn will impact the synergistic effect of adding xanthan gum to any of the galactomannan gums (EFSA, 2017), as further discussed in <u>*Combinations of the Substances*</u>.

[1] Syneresis is the weeping, or expulsion, of liquid from a gel. “Syneresis” and “sineresis” are both widely accepted spellings of the term; in this report, all references to this word are spelled “syneresis” for consistency.

Xanthan gum is highly pseudoplastic, responsive to changes in shear forces (Sworn, 2011), and thermo-reversible (as described in *Properties of the Substances*) (Williams and Phillips, 2003). As a solid, xanthan gum molecules have a rigid helical structure, but when melted in the presence of small quantities of salt this rigid structure becomes disorganized but stable, resulting in a thickening effect (Cargill, 2017). Low shear viscosity is responsible for xanthan gum's effectiveness in stabilizing emulsions and suspensions against separation (CP Kelco, 2007). It is insoluble in ethanol (CODEX, 2017). Research indicates that junction zones in the molecular structure can be readily disrupted even at low shear rates, resulting in a dramatic drop in viscosity (Williams and Phillips, 2003). Stiff xanthan chains tend to associate in solution, giving rise to very high viscosity at low shear rates, which is sufficient to prevent particles from sedimentation or oil drops from creaming. The chain associations are easily broken when applying shear stress (CP Kelco, 2007).

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

<u>Specific Uses of the Substances:</u>

Gums are widely used in a variety of food products to perform a number of functions including, thickening, stabilizing, gelling, stabilization of foams, emulsions and dispersions, inhibition of ice and sugar crystal formation, and in the controlled release of flavors. Several gums, including some discussed in this report, have industrial non-food applications that go beyond the scope of this technical report (Williams and Phillips, 2003; Biopolymer International, 2015). The information included in this section indicates principal functional uses in food applications that are relevant to the scope of this report.

Gum Arabic

Functional uses: emulsifier, stabilizer, thickener, formulation aid (21 CFR 184.1330; CODEX, 2017). The principal function is as an emulsifier (Williams and Phillips, 2003). Gum arabic has a long history of a very wide array of uses in food applications. Gum arabic acts as an emulsifier used to stabilize flavor oil emulsion concentrates for the soft drink industry. It is also used in production of spray-dried encapsulated flavors for use in dry packaged products such as soup and cake mixes where it prevents oxidation and evaporation. The gum's high solubility facilitates rapid flavor release. Used commonly in production of high sugar confections because of the ability of gum arabic to form concentrated solutions of low viscosity (Williams and Phillips, 2003; Verbeken, 2003). Gum arabic has a long tradition of use in wine gums, a traditional British and European soft sweet candy. Gum arabic is used increasingly as a source of dietary fiber in low calorie and dietetic beverages. (Verbeken, 2003). Winemakers use gum arabic as a wine fining agent (Vivas, 2001). It is used as a flavoring aid and adjuvant in chewing gum (21 CFR 184.1330).

Table 2. Functions of Gum Arabic

Product	Functions of Gum Arabic	Reference Sources
Beverages and beverage bases	Emulsifier, flavoring agent, adjuvant, stabilizer, thickener	21 CFR 184.1330; Prospector, 2017; Williams and Phillips, 2003; Verbeken, 2003; Vivas, 2001
Confections, chewing gum, candies, puddings, fillings	Formulation aid, stabilizer, thickener, humectant, flavoring agent, adjuvant, emulsifier	21 CFR 184.1330; Williams and Phillips, 2003; Verbeken, 2003
Dairy products	Stabilizer, thickener, formulation aid	21 CFR 184.1330
Frozen confections	Stabilizer, thickener, formulation aid	21 CFR 184.1330

Gellan Gum

Functional uses: thickener, gelling agent, stabilizer (CFR 21 172.665; CODEX, 2017; USDA NOP, 2006). Gellan gum can be used at low levels in a wide variety of products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring (CP Kelco, 2017a).

Guar Gum

Functional uses: thickener, stabilizer, emulsifier, and formulation aid (21 CFR 184.1339; CODEX, 2017). The principal function is as a thickener (Williams and Phillips, 2003; Ghodke, 2009). Guar gum prevents staling in chapatti, an unleavened Indian bread (Ghodke, 2009). Guar gum is described as a water soluble dietary fiber increasing production of *bifidobacterium* in the gut (Slavin and Greenberg, 2003). Storage time for products containing guar gum and tragacanth gum can be correlated with shear thinning properties that impact the rheological behavior (flow of matter in response to shear stress) of these gums in aqueous solutions over time (Chenlo, 2010; Ghodke, 2009).

Table 3. Functions of Guar Gum

Product	Functions of Guar Gum	Reference Sources
Baked goods, baking mixes, breakfast cereals	Emulsifier, formulation aid, stabilizer, thickener	21 CFR 184.1339; Danisco, 2017a; Ghodke, 2009
Cheese, dairy products, fats, and oils	Firming agent, formulation aid, stabilizer, thickener, eliminates syneresis	21 CFR 184.1339; AEP Colloids, 2017
Gravies, sauces, jams, jellies	Stabilizer, thickener, formulation aid	21 CFR 184.1339
Processed vegetables and vegetable juices, soups and soup mixes, sweet sauces, toppings, syrups	Stabilizer, thickener, formulation aid, eliminates syneresis	21 CFR 184.1339; Danisco, 2017a; AEP Colloids, 2017
Pet food	Binder, stabilizer, emulsifier	Sharma, 2006

Locust Bean Gum

Functional uses: stabilizer, thickener, emulsifier, gelling agent (21 CFR 184.1343; CODEX, 2017). The principal function is as a thickener (Williams and Phillips, 2003). This gum provides strong synergy with other hydrocolloids and has a stabilizing effect on proteins (Danisco, 2017b). Locust bean gum is used in ready-to-consume desserts for its thickening, water-binding, and gel strengthening properties (CP Kelco, 2017b).

Table 4. Functions of Locust Bean Gum

Product	Functions of Locust Bean gum	Reference Sources
Baked goods, baking mixes, beverages, cheeses, gelatins, puddings, jams, jellies	Stabilizer, binder, and thickener	21 CFR 184.1343; 21 CFR 133.178; 21 CFR 133.179; CP Kelco, 2017b; Sharma, 2006
Pet foods	Stabilizer, binder, thickener	Sharma, 2006

Tragacanth Gum

Functional uses: emulsifier, stabilizer, thickening agent, and formulation aid (21 CFR 133.178 and 179; CODEX, 2017). The principal function is as a thickener (Williams and Phillips, 2003). Used in preparation of low-viscosity, pourable dressings and sauces because of its high acid stability. Typical usage levels in food products ranges from 0.4 to 0.8 percent, depending on oil content (Verbeken, 2003). Tragacanth gum is used to imitate creamy mouthfeel in low-calorie oil-free dressings, and is used in ice cream to provide texture.

Table 5. Functions of Tragacanth Gum

Product	Functions of Tragacanth gum	Reference Sources
Baked goods, condiments, relishes, fats, oils, gravies, sauces, meat products, salad dressings	Emulsifier, stabilizer, thickener, formulation aid; stabilizes under acid conditions; improves texture	21 CFR 184.1351; Prospector, 2017; Williams and Phillips, 2003; Verbeken, 2003; AEP Colloids, 2017

Xanthan Gum

Functional uses: thickener, stabilizer, emulsifier, suspending agent, bodying agent, foaming agent in processed foods (21 CFR 172.695; CODEX, 2017). The principal function of xanthan gum is as a thickener (Williams and Phillips, 2003). Xanthan has a unique ability to control rheological (plasticity) properties of a wide range of products (Cargill, 2016). Xanthan gum stabilizes suspensions, emulsions, and solid particles in water-based recipes (Danisco, 2017c). Further details on the functions of xanthan gum may be found in the 2016 Technical Report (USDA NOP, 2016).

Table 6. Functions of Xanthan Gum

Product	Functions of Xanthan Gum	Reference Sources
Bakery products, gluten free-breads	Mimics viscoelastic properties of gluten, binds water, improves texture and flavor	Hager and Arendt, 2013; Sharma, 2006; Danisco, 2017
Beverages and dry mixes	Stabilizes suspension of insoluble ingredients, enhanced body and rapid viscosity development to reconstituted drinks	Palaniraj and Jayaraman, 2011
Dairy products	Stabilizes emulsions, controls viscosity, inhibits syneresis, improves texture	Sharma et al, 2006; Danisco, 2017c; 21 CFR 133.178 and 179; Cargill, 2017
Frozen foods	Retards ice crystal formation, improves freeze/thaw stability	Kuppuswami, 2014
Meat products	Binds water, inhibits syneresis, provides viscosity	Palaniraj and Jayaraman, 2011
Pet foods	Stabilizes canned gravy based food, produces gelled product with locust bean gum or guar gum	Palaniraj and Jayaraman, 2011; Sharma, 2006
Sauces, soups, toppings	Prevents separation, stabilizes emulsions, replaces starches in low-calorie dressings, increases viscosity	Palaniraj and Jayaraman, 2011; Sharma, 2006

Approved Legal Uses of the Substances:
Four of the gums are listed at 21 CFR Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe, and Maximum Usage Levels Permitted are established:

- Acacia (gum arabic), 21 CFR 184.1330;
- Guar gum, 21 CFR 184.1339;
- Locust (carob) bean gum, 21 CFR 184.1343; and
- Gum tragacanth, 21 CFR 184.1351.

The other two gums discussed in this report (gellan gum and xanthan gum**)** are listed at 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Human Consumption, Subpart G, Gums, Chewing Gum Bases and Related Substances:

- Gellan Gum, 21 CFR 172.665; Gellan gum may be used in foods where the standard of identity established under Section 401 of the Federal Food, Drugs and Cosmetic Act do not preclude such use. The substances must be free of viable cells of *Pseudomonas elodea* (*sic*) (21 CFR 172.665).
- Xanthan Gum, 21 CFR 172.695.

Acacia (gum arabic) is also listed at 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Human Consumption, Subpart H, Other Specific Usage Additives, § 172.780.

All six of the gums are listed in EAFUS (Everything Added to Food in the United States) as follows: Acacia gum (*Acacia Senegal* (L.) Willd.); Locust (carob) bean gum; Gellan gum; Guar gum (*Cyamopsis tetragonolobus* (L.)); Tragacanth gum (*Astragalus* spp.); Xanthan gum (FDA, 2017a).

Maximum usage levels vary depending on the product to which the gum is added. The total quantity of one or any mixture of tragacanth gum, locust bean gum, guar gum, and xanthan gum for addition to pasteurized Neufchatel cheese spread with other foods (21 CFR 133.178), and pasteurized process cheese spread (21 CFR 133.179), must not be more that 0.8 percent by weight of the finished food (FDA, 2017c). Guar gum and xanthan gum are permitted in the preparation of cold-pack cheese food. The total quantity of such ingredient or combination is not to exceed 0.3 percent by weight of the finished food (21 CFR 133.124).

Acceptable levels of residual solvents have been established for some solvents in the manufacture of some gums. Residual isopropyl alcohol in gellan gum must not exceed 0.075 percent (21 CFR 172.665). Residual isopropyl alcohol in xanthan gum must not exceed 750 ppm (21 CFR 172.695).

Action of the Substances:
As described in the previous sections, the gums described in this report are all complex hydrocolloids, which, as food additives, act to thicken, emulsify, and gel. Hydrocolloids thicken solutions through the nonspecific entanglement of their long molecular chains. When hydrocolloids are present in a suspension in very dilute concentrations, their individual molecules can move freely and may not cause thickening. As the concentration increases, molecule movement is restricted as they begin to come into contact with one another and solution movement becomes restricted. The disordered molecule chains become entangled and thickening takes place (Saha and Bhattacharya, 2010).

Gums are effective at either inducing or preventing flocculation in particulate dispersion. The difference in osmotic pressure between the depleted region and the bulk solution results in weak inter-particle attractive forces, which induce aggregation. Some gums, such as gum arabic, show amphiphilic properties, which make them a good stabilizer of emulsions and foams, owing to their affinity to adsorb at the oil/water or air/ice interface. In systems containing sugar or ice crystals, gums can retard crystal growth (Williams and Phillips, 2003).

Combinations of the Substances:
Gums can be used alone, but are often used in combination with each other and/or other thickeners, stabilizers, emulsifiers, and gelling agents (Palaniraj and Jayaraman, 2011; Cargill, 2016b; USDA NOP, 2016; TIC Gums Inc., 2017b). Using more than one gum can have a synergistic (multiplier) effect on viscosity, which may be beneficial for many food products (Slavin and Greenberg, 2003; Williams and Phillips, 2003). Locust bean gum is compatible with xanthan gum, resulting in a synergistic increase in viscosity. Similarly, xanthan gum is used to strengthen the gelling properties of carrageenan and agar (Kawamura, 2008).

Mixtures of gums are commonly used to impart different textures to food products and reduce costs. For example, the addition of locust bean gum to kappa-carrageenan yields softer, more transparent gels, and the addition of locust bean gum to xanthan gum induces gel formation (Williams and Phillips, 2003). TIC Gums sells various blends of gums in their TICorganic® line of products for a range of specific food additive purposes, such as TICorganic® Dairyblend YG Smooth, TICorganic® Caragum® 200, TICorganic® Saladizer® 100, and TICorganic® Stabilizer ICE-200 (TIC Gums Inc., 2017b).

Xanthan gum is not a gelling agent on its own, and is thus often used in combination with other substances. Xanthan interacts synergistically with galactomannans found in locust bean gum, guar gum, cassia gum, tara gum, and konjac glucomannan to increase viscosity or gelation (Sworn, 2009). Xanthan and gellan gums can be combined to produce ready-to-eat dessert gels (Saha and Bhattacharya, 2010). Xanthan gum can be combined with starches to thicken or stabilize, such as to slow the staling of bread, or added to starch gels to improve freeze/thaw stability (Saha and Bhattacharya, 2010; Belitz, 2009). Blends of xanthan gum, guar and locust bean gums, and carrageenan are used as stabilizers for frozen and chilled dairy products (Sworn, 2009) or meat brines (Lamkey, 2009). Locust bean gum has a strong synergy with other hydrocolloids (Danisco, 2017b).

Information was not found to indicate that any additional materials are generally added to commercially available forms of gums. However, as described in the 2016 Technical Report on xanthan gum, one xanthan and guar blend has been standardized through the addition of glucose, and the product GRINSTED Xantha Ultra is pre-dispersed by adding 1 percent polysorbate 60 (USDA NOP, 2016).

Status

Historic Use:
Gum arabic is the oldest and best known of all natural gums. Its use can be traced back to more than 3000 BC, in early Egypt, when it was sold and used as an adhering agent to make flaxen wrappings for embalming mummies and a pigment binder for making hieroglyphs. It has been used as a food thickening additive for many decades (Verbeken, 2003; Williams and Phillips, 2003; FAO, 2000).

Tragacanth gum has an ancient history, dating back to the third century BCE (Verbeken, 2003; Williams and Phillips, 2003). Historically, it was used as an emulsifier, stabilizer, and thickening agent in pharmaceuticals and foodstuffs (Anderson and Bridgeman, 1985).

Guar gum is a plant native to the Indian Subcontinent where it is grown as a major cash crop and has been cultivated as a source of gum for several decades (Prem, 2005). The first factory for processing guar was built in India in 1956. While guar gum is primarily used in the textile and paper industry, it may also be used as a food additive (Hindustan Gum, 2017).

The locust bean tree has a long history of use and cultivation. The plant was well known to the ancient Egyptians and Greeks, and the seed pods were a major item in early Arab commerce. Spaniards carried it to South America, and the British took carob to South Africa, India, and Australia. Planting in California began in the late nineteenth century. Carob will grow wherever citrus grows. The tree has multiple uses, one of which is the gum, and records indicate use of the gum in embalming mummies in ancient Egypt, although gum arabic was more commonly used for this purpose (Carobana, 2017).

The gellan-producing bacterium *Sphingomonas elodea*, formerly *Pseudomonas elodea*, was discovered in a pond in Pennsylvania and isolated by the former Kelco Division of Merck and Company in 1978. Its initial commercial product, GELRITE® gellan gum, was subsequently identified as a suitable substitute for agar as a gelling agent (USDA NOP, 2006).

Xanthan gum was discovered at the Northern Regional Research Laboratory of the USDA. Industrial production started in 1964, with commercial production in 1964 (Born, 2005). FDA approval for use in food came in 1969, with Canadian approval in 1971, FAO/WHO in 1974, and Europe in 1982 (Born, 2005). Worldwide production of xanthan gum was about 100,000 metric tons in 2014, with 65 percent used in food production (Kuppuswami, 2014).

Organic Foods Production Act, USDA Final Rule:

Seven (7) gums are identified in the NOP regulations, across four (4) separate listings in 7 CFR Part 205:

- §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))."
  (a) Nonsynthetics allowed:
  Gellan gum (CAS # 71010-52-1) – high acyl form only
  (b) Synthetics allowed:
  Xanthan gum
- §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products allowed as ingredients in or on processed products labeled as "organic."
  (g) Gums – water extracted only (Arabic; Guar; Locust bean; and Carob bean)
  (q) Tragacanth gum (CAS#9000-65-1)

International Use:

Canadian General Standards Board Permitted Substances List (Updated in November 2015)

On Table 6.3 (Ingredients Classified as Food Additives) of the Permitted Substances List, gums are listed with the annotation, "The following gums are permitted: Arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum. Shall be derived using substances listed in Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums" (CGSB, 2015).

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

CODEX provides Guidelines (CODEX Alimentarius Commission, 2013) for use of food additive gums as follows: Gum arabic (Acacia gum) (414), Carob bean gum (410), Gellan gum (418), Guar gum (412), Tragacanth gum (412), and Xanthan gum (415). CODEX General Standard for Food Additives (GSFA) provides a highly detailed range of uses and specifications for each of these substances (CODEX Alimentarius Commission, 2017).

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

The European Union allows the use of arabic gum, guar gum, locust bean gum, and xanthan gum in the production of processed organic foods as a food additive in the preparation of foodstuffs of plant or animal origin with no specific limitations. Xanthan gum is classified as an ingredient of nonagricultural origin, and locust bean gum, guar gum, and acacia gum are classified of agricultural origin (Commission of the European Communities, 2008).

Guar gum, locust bean gum, acacia gum, tragacanth gum, and xanthan gum are authorized as food additives in accordance with Annex II and III to Regulation (EC) No. 1333/2008 on food additives. Specific purity criteria have been defined in Commission Regulation (EU) No. 231/2012. Per regulation (EC) No. 1333/2008 of the European Parliament and of the Council of Food Additives, substances are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use and must be re-evaluated by the EFSA. These five gums were re-evaluated with results published in 2017. The issues identified in these results are discussed in *Evaluation Question 10* regarding human health effects.

Additionally, each of the gums has an E designated code number, as noted in *Identification of Petitioned Substances*.

Japan Agricultural Standard (JAS) for Organic Production

The Japan Agricultural Standard allows the following gums as food additives with limitations:

- Arabian gum (INS 414) – Limited to be used for dairy products, edible fat, and oil or confectionary products.
- Carob bean gum (locust bean gum) (INS 410) – In the case of processed foods of animal origin limited to be used for dairy products or processed meats.
- Guar gum (INS 412) – In the case of processed foods of animal origin limited to be used for dairy products, canned meat or egg products.
- Xanthan gum (INS 415) – In the case of processed foods of animal origin limited to be used for dairy products or confectionary.
- Tragacanth gum (INS 413) is listed with no limitations.
- Gellan gum is not listed as allowed or prohibited. (Japanese MAFF, 2012).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM permits the use of locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415) as approved additives with no limitations or notes (IFOAM, 2014). Gellan gum is neither listed as allowed nor prohibited.

Other International Standards

East African Organic Product Standard, incorporating the IFOAM basic standards and using INS numbering system, allows the following gums as additives in organic food processing (East African Community, 2007):

- Locust bean gum, guar gum, and tragacanth gum without limitations;
- Arabic gum with limitations only for milk products, fat products, confectionary, sweets, eggs; and
- Xanthan gum with limitations only in fats, fruit and vegetable products, and cakes and biscuits.
- Gellan gum is neither listed as allowed nor prohibited.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Gum arabic, tragacanth gum, guar gum, and locust bean gums are derived from plants in the plant family *Leguminosae* (*Fabaceae*). Gellan gum and xanthan gum are derived from bacteria. The sourcing, manufacturing, and purification of each of the gums is described below.

Gum Arabic

Gum arabic is the exudation from dried sap collected from stems and branches from various species of the Acacia tree, both wild grown and cultivated. The trees are typically tapped by hand during the dormant dry season (October through January) and manually collected every two weeks over the dormant season. The gum is cleaned by mechanical sieves and graded, then milled to a powder and sold. To get higher grade, the gums can also be fully dissolved in water and all of the impurities removed by filtration. A plate heat exchanger may be used to minimize bacterial contamination; care must be taken to maintain the proteins during the heat exchanger phase of cleaning (Verbeken, 2003; EFSA, 2017c; Thevenet, 2010).

Tragacanth Gum

Tragacanth gum is the exudation from dried sap collected from large tap roots of various species of legumes in the genus *Astragalus*. The plants are systematically tapped, and gum is collected every few weeks during the dry season from July to September. The gum is sorted and graded manually and sold by grade. After arrival in the importing country the gum is ground to a powder with particle size varying according to the desired viscosity. It may also be heat treated to reduce microbial contamination (Verbeken, 2003; EFSA, 2017c).

Guar Gum

Guar gum is formed from seeds of the guar bean plant, which are crushed to eliminate the germ. The remaining endosperm is dehusked, milled, and screened to obtain the ground endosperm (native guar gum). The gum is clarified by dissolution in water, filtration, and precipitation with ethanol or isopropanol. (EFSA, 2017a). Bleaching of guar with peroxide, or use of sodium hypochlorite as a processing aid have been described (EFSA, 2017; Mudgill, 2014). Modified forms of gums are available commercially, including enzyme modified, cationic and hydropropyl versions (Voragen, 2012); however there is no available information that clarifies whether or not such modified versions were used in food applications as opposed to industrial applications.

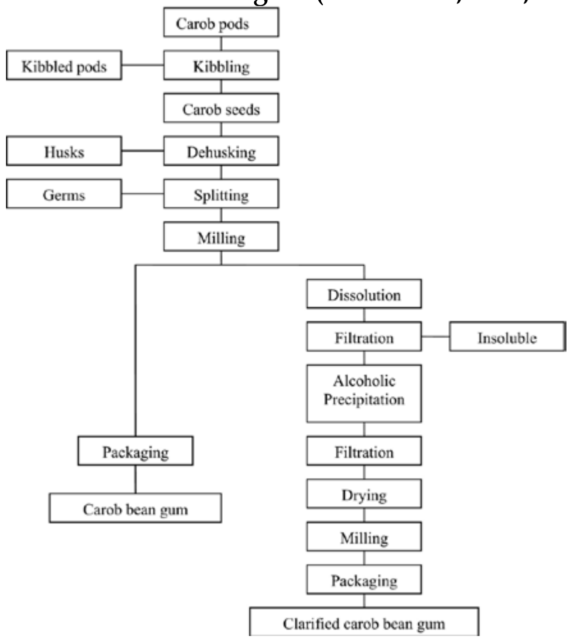
Locust Bean Gum

The seeds of carob tree are processed through a series of crushing, sifting and grinding steps (see Figure 1) to separate the endosperm from the hull (CP Kelco, 2017b). The carob seeds can be difficult to process because the seed coat is tough and hard. The process used to crack the seed pods is described as a roasting process in which the seeds are roasted in a rotating furnace where the seed coat drops off (Kawamura, 2008). This roasting process is the most prevalent process described in the majority of the literature.

Research by Kawamura (2008), which is also cited in EFSA (2017), describes an alternative acid process for breaking the seed coat. In this process the seed pods are heated with sulfuric acid to carbonize the seed coat, which is then dried and cracked. Information is not available to confirm that this acid process is used in commercial manufacturing.

After the endosperm is separated from the hull, further processing includes dissolution and clarification by dispersing in hot water filtration, and precipitation with ethanol or isopropanol, filtering, and drying and milling (CP Kelco, 2017b; Kawamura, 2008).

Figure 1. Processing flow chart for locust bean gum (Kawamura, 2008; EFSA, 2017)

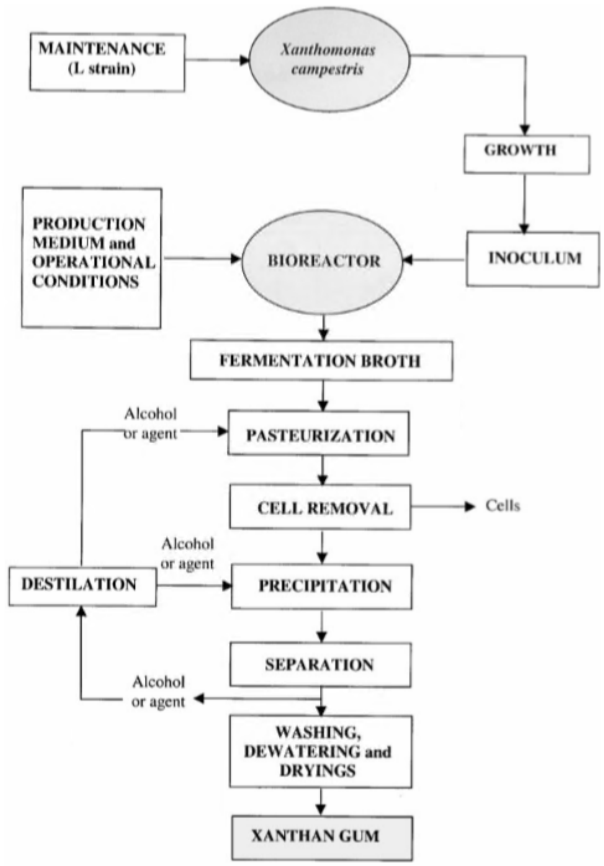


Xanthan Gum

Xanthan gum is manufactured by aerobic, pure-culture fermentation of a carbohydrate with the bacterium *Xanthomonas campestris* (see Figure 2). The fermentation substrate is composed of a carbohydrate source (primarily glucose from corn or wheat, and sucrose), nitrogen source, and several micronutrients (e.g., potassium, iron, and calcium salts). Oxygen is bubbled through the liquid during fermentation, and pH is maintained near 7.0 through addition of a base such as potassium hydroxide. After fermentation is complete, the broth is pasteurized to kill the bacteria and cells are removed by filtration or centrifuge. The gum is recovered from the fermentation broth using alcohol precipitation, which is the most common form of purification (Garcia-Ochoa, 2000). The alcohol is then removed and the resultant product is dried and milled into a fine powder for packaging and market (CP Kelco, 2007; Cargill, 2017; Palaniraj and Jayaraman, 2011; Kuppuswami, 2014; Biopolymer International, 2015; USDA NOP, 2016; Voragen, 2012; EFSA, 2017d). In some cases, the gum may be washed with a salt solution to achieve the desired purity, dewatered a second time, and dried before packaging (Palaniraj and Jayaraman, 2011). Using salt in combination with alcohol for precipitation lowers the quantity of alcohol needed for precipitation, compared to the amount used when alcohol is the sole precipitation agent (Garcia-Ochoa, 2000).

The production of xanthan gum as described in CP Kelco, 2007, states that the bacterium *Xanthomonas campestris* produces this gum at the cell wall during its normal life, and the composition of xanthan gum is identical to the naturally occurring polysaccharide formed by the same bacteria belonging to the cabbage family, where it occurs naturally (CP Kelko, 2007). This same manufacturer indicates that in order to develop optimal rheological and uniform solution properties, some type of salt should be present; usually in salts found naturally in tap water are sufficient to generate these effects (CP Kelco, 2007).

Figure 2. Processing flow chart for Xanthan Gum (Garcia-Ochoa, 2000)



The U.S. Code of Federal Regulations at 21 CFR 172.695, the European Commission Regulations (Commission Regulation (EU), 2012), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2016) indicate that the food additive xanthan gum is manufactured as the sodium, potassium, or calcium salt. However, its manufacture as a salt could not be verified by the manufacturing descriptions reviewed and cited above. Further discussion on this inconsistency is provided in Evaluation Question #2.

Gellan Gum

Gellan gum uses the same aerobic-pure-culture fermentation manufacturing process that is used for Xanthan gum, but instead utilizes the bacterium *Sphingomonas elodea* (formerly known as *Pseudomonas elodea).* The carbohydrate fermentation substrate is comprised of glucose syrup derived from maize or wheat, inorganic nitrogen, an organic nitrogen source (protein) and trace elements. Pasteurization kills the bacteria. The gum is purified by recovery with isopropyl alcohol or ethanol, dried, milled, and packaged (Cyber Colloids Ltd., 2017; Biopolymer International, 2015; USDA NOP, 2006). The gellan gum obtained from the microbial culture includes acetyl and L-glycerate groups that are removed (i.e., the gellan gum can be de-acylated) to some extent with the addition of an alkali. Gel thickness is manipulated by addition of alkali salts (i.e., by adding potassium, magnesium, calcium or sodium salts) (USDA NOP, 2006). There are three forms of commercially available gellan gum that vary based on: 1) polysaccharide content; 2) high or low acyl on the polysaccharide; and 3) the percentage of protein (IPCS INCHEM, 2017). Only the high-acyl form is allowed in organic processed products (§ 205.605(a)).

Genetically Modified Organisms used in production of Xanthan and Gellan gums

The manufacturers' association Biopolymer International (2005a and 2005b) states on its website that the microorganisms used by its members to produce gellan gum and xanthan gum are not genetically modified organisms (GMOs) as defined in the European Commission (EC, 2001). At least three certified non-GMO xanthan products are available (Cargill, 2017; TIC Gums, Inc., 2017a; Danisco, 2016). No source indicated that the bacteria used are genetically modified as defined by either the NOP or EU. Certified organic gums, which must be produced without the use of excluded methods such as GMOs, are commercially available, indicating that the use of GMO bacteria is not essential to manufacture of these gums (TIC Gums Inc., 2017b; Danisco, 2017a; Danisco, 2017b; Danisco, 2017c).

__Evaluation Question #2:__ **Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.**

Gum arabic, tragacanth gum, guar gum, and locust bean gum are derived from plants, which are agricultural sources. Mechanical processing steps (e.g., mechanical sieves, milling, grinding, dewatering, drying) are used to further process these gums. Additional processing steps, as described in *Evaluation Question 1*, may include the following:

- Locust bean undergoes a heating step (thermal cracking), which may or may not also include chemical treatment with sulfuric acid. No information was found to indicate any residues.
- Guar gum and locust bean gums undergo alcohol precipitation (with ethanol or isopropanol)[2]. Locust bean gum and guar gum may contain no more than 1 percent of isopropanol, singly or in combination (JEFCA, 2008).
- Guar gum may undergo bleaching (with peroxide or sodium hypochlorite).
- Gum arabic and tragacanth gums may involve heat treatments to reduce microbial contamination.

Gellan gum and xanthan gum are produced by fermentation of a carbohydrate with bacteria. Fermentation is a naturally occurring biological process. The bacteria strains are not an agricultural source, although agricultural materials may compose the substrate media. After fermentation, further processing is used to separate (recover) the gum from the fermentation media and purify the gum for commercial use. Additional processing steps, as described in *Evaluation Question 1*, may include the following:

- Gellan gum and xanthan gum undergo pasteurization.
- Gellan gum and xanthan gum undergo alcohol precipitation (with ethanol or isopropanol), similarly to guar gum and locust bean gum. Maximum levels of residual solvents are described in *Approved Legal Uses of the Substances*.
- Xanthan gum may be washed with a salt solution.

In order for post-fermentation extracted materials to be classified as nonsynthetic, NOP Guidance 5033 on the Classification of Materials requires that at the end of the extraction process, the material: 1) has not been transformed into a different substance via chemical change; 2) has not been altered into a form that does not occur in nature; and 3) that any synthetic materials used to extract the substance have been removed from the final substance such that they have no technical or functional effect on the final product. Reviewing the post-fermentation processing steps described above against NOP Guidance 5033, the following conclusions are made:

- Heating of biological materials is not considered a synthetic process.
- Alcohol precipitation, as described above, may be considered a nonsynthetic process provided that any residual solvents are removed such that they do not have a technical or functional effect.
- There is no evidence that the act of washing xanthan gum would result in chemical changes that would render the final xanthan gum to be synthetic.

As discussed in *Evaluation Question 1*, regulatory references suggest that xanthan gum is manufactured as the sodium, potassium, or calcium salt. However, this could not be verified by any

[2] The Material Data Safety Sheets for Isopropanol indicate that this is the chemical name for Isopropyl alcohol (CAS #67-63-0) (Science Lab, 2017c). The solvent 2-propanol is a synonym for Isopropyl alcohol. Ethanol is one of the synonyms for Ethyl alcohol, (Science Lab, 2017c; Science Lab, 2017d).

of the manufacturing descriptions for xanthan gum as a food additive. The post-fermentation purification processes described above do not indicate a transformation of xanthan gum itself into salt. If there are forms of commercially produced food-grade xanthan gum that are manufactured as a salt, the salt form may be considered synthetic based on NOP Guidance 5033 since it has been transformed into a different substance via chemical change. This matter was reviewed in 2016 by the National Organic Standards Board (NOSB) Handling Subcommittee during its review of xanthan gum. A proposed reclassification of xanthan gum from synthetic to nonsynthetic was considered. Following review, the NOSB Handling Subcommittee subsequently issued the following Statement on September 6, 2016:

> "The Handling Subcommittee requested an updated technical report on xanthan gum, focusing on the manufacturing process, to determine if it is synthetic or non-synthetic. After reviewing the information provided, it appears that there is more than one way to produce xanthan gum; some of the methods may be non-synthetic while others may lead to what the NOSB would classify as synthetic. Based on this determination, the Handling Subcommittee has concluded to take no further action on re-classification of xanthan gum at this time (NOSB, 2016)."

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b)(1)).

All of the gums discussed in this report are derived from nonsynthetic, natural sources. Further processing may impact the classification of the final substances as synthetic or nonsynthetic. Both nonsynthetic and synthetic forms of gums are currently permitted on the National List. Gellan gum (high acyl form only) is listed as a nonsynthetic substance at § 205.605(a). Xanthan gum is listed as a synthetic substance at § 205.605(b). Gum arabic, guar gum, locust bean gum, and tragacanth gum are listed as agricultural substances (water extracted only) at § 205.606.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Four of the gums are listed at 21 CFR Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe: Acacia gum, 21 CFR 184.1330; Guar gum, 21 CFR 184.1339; Locust (carob) bean gum, 21 CFR 184.1343; and Gum tragacanth, 21 CFR 184.1351.

Gellan gum and xanthan gum are not affirmed as GRAS. They are listed at 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Humans, Subpart G, Gums, Chewing gum bases and related substances: Gellan gum, 21 CFR 172.665; Xanthan gum, 21 CFR 172.695.

Three different xanthan gum preparations have been the subject of GRAS notices (Tarantino, 2003; Tarantino, 2007; Keefe, 2012). Although the FDA had no questions as to the GRAS status of xanthan gum under the intended conditions of use in foods, the agency did note that those particular xanthan gum preparations do not comply with current FDA food additive regulations, which require xanthan gum to be purified by recovery with isopropyl alcohol and to contain greater than 1.5 percent pyruvic acid by weight (21 CFR 172.695).

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary technical functions of the gums include stabilizer, thickener, suspending agent, binder, and formulation aid as detailed in previous sections in this report. None of the gums in this report are used primarily as a preservative, and the term "preservative" is not listed in 21 CFR with reference to the uses of these gums.

However, it should be noted however that many of the functions of the gums as food additives can result in extending shelf life of the products in which they are used (Williams and Phillips, 2003). The 2016 Technical Report on xanthan gum (USDA NOP, 2016) citing the International Additives Food Council (IFAC), states that xanthan gum can often be used to extend shelf life of a product. Ward (2007), in a web Global Health and Nutrition Network article, notes that xanthan gum appears to inhibit starch retrogradation (staling of bread for example), thereby extending the shelf life of baked goods. Guar gum has been noted to slow the staling process in chapatti, Indian unleavened flat bread (Ghodke, 2009).

__Evaluation Question #6:__ **Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).**

As described earlier in this report, the primary technical functions of the gums include stabilizer, thickener, suspending agent, binder, and formulation aid. None of the gums discussed in this report are listed or used primarily to recreate flavor, color or texture or nutritive values lost in processing, and no information was found to suggest otherwise.

However, the functions of stabilizing and thickening, or gelling can all contribute to improving texture. Gellan gum, locust bean gum and xanthan gum list flavor release and texturization as additional functions. For example, gellan gum is described as a multifunctional hydrocolloid and maybe be used at low levels in a wide variety of products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring (CP Kelco, 2017).

Many of today's processed foods are manufactured to exhibit specific texture, viscosity, and flavor release specifications that xanthan gum provides (Lopes, 2015; Palaniraj and Jayaraman, 2011). Xanthan gum is used to produce the desired texture in ice cream and other frozen foods (Cargill, 2016), enhance the body and texture of beverages, and improve the texture of baked goods (Palaniraj and Jayaraman, 2011). It is also used to improve flavor release in salad dressings, sauces, gravies, dairy products, and bakery fillings (Palaniraj and Jayaraman, 2011; USDA NOP, 2016).

__Evaluation Question #7:__ **Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**

The effects of isolated gums on gastric emptying, digestion, and absorption have been well-studied, but there are fewer studies on the effects of these same gums as food additives. The effect of food additive gums on the nutritional quality of foods varies depending on the type and amount of gum ingested because of their varied properties, as noted in __*Properties of the Substances*__. The gums' physiological and nutritional effects occur during transit through the stomach, small intestine, and colon, by reducing and mixing actions in the gut and by their effect on the interaction between nutrients, enzymes and mucosal cells, and finally, as a result of their fermentation, by the colonic microflora. Digestion of sugars and fats may change when foods containing gums as food additives are ingested (Edwards, 2003). Further discussion may be found under __*Evaluation Question 10*__ regarding effects on human health.

Like many of the gums used as food additives, gum arabic, locust bean gum, guar gum, tragacanth gum, and xanthan gum act as soluble dietary fibers. One reference noted that these gums can decrease mineral availability in the intestines, but that the effect of dietary fibers on mineral absorption in humans is still unclear (Baye, 2015). This potential is based on laboratory studies that have shown how various fibers have mineral binding properties *in vitro*. By contrast, animal and human *in vivo* studies of various soluble dietary fibers fail to demonstrate negative effects on mineral absorption, and some *in vivo* studies with fibers (e.g., pectin, fructooligosacccharides) have shown positive effects on mineral absorption. One possible reason for the difference observed between laboratory and *in vivo* studies is that fermentation of the fibers in the colon may free bound minerals and offset the negative mineral binding effects of the fibers (Baye, 2015).

In one laboratory study, the addition of xanthan gum to standard infant formula showed no effect on the availabilities of calcium, iron, or zinc (Bosscher, 2003); this study, however, the did not examine the availabilities of other nutrients. In another laboratory study, xanthan gum was shown to bind zinc, calcium, and iron in solutions (Debon and Tester, 2001). Edwards (2003) notes that gums may entrap minerals and delay or inhibit their absorption, and that the effect in young children is unknown and is one of the reasons why a high dietary fiber intake has not been encouraged in children under aged five. However, there is no evidence of significant mineral imbalance in children on high fiber diets (Edwards, 2003). Alternatively, several studies suggest that gums increase calcium absorption in the large intestine (Edwards, 2003).

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

No reports of residues of heavy metals or contaminants in excess of FDA's tolerances have been identified for these gums, and no substances listed on FDA's Action Levels for Poisonous or Deleterious Substances in Human Food have been reported as contaminants of concern for gum arabic, gellan gum, guar gum, locust bean gum, tragacanth gum, or xanthan gum (FDA, 2017b).

The latest edition of the Food Chemicals Codex indicates the following sets of accepted reference standards for xanthan gum: no more than 2 mg per kg of lead (U.S. Pharmacopeia, 2012). The same lead level (no more than 2 mg per kg) is also acceptable for locust bean gum, guar gum (JECFA, 2008), tragacanth gum (JECFA, 2006a), gum arabic (JECFA, 2006b), and gellan gum (JECFA, 2014).

Xanthan gum may have not more than 0.5 mg per kg for use in infant formula and formula for special medical purposes intended for infants (JECFA 2016).

The EFSA re-evaluations (EFSA, 2017) for gum arabic, locust bean gum, tragacanth gum, guar gum, and xanthan gum did not indicate any research reporting residues or heavy metal contamination in any of these gums. However, the EFSA Panel recommended lowering the European Commission specifications on lead, cadmium, mercury, arsenic, and one panelist suggested adding aluminum. These recommendations were made as a precautionary measure to avoid any exposure of infants and children to potentially toxic elements (EFSA, 2017).

Acceptable levels of residual solvents have been established for some solvents in the manufacture of some gums. 21 CFR 172.665 requires that residual isopropyl alcohol is not to exceed 0.075 percent in gellan gum when it is used as a direct food additive. Locust bean gum and guar gum can have no more than 1 percent of isopropanol, singly or in combination (JEFCA, 2008). Gellan gum may have no more than 50mg per kg of ethanol and no more than 750 mg per kg of 2-propanol (JECFA, 2014). Residual levels of isopropyl alcohol may not exceed 750 ppm for xanthan gum (21 CFR 172.695). Xanthan gum can have not more than 500mg per kg of ethanol and isopropanol either singly or in combination (JECFA 2016).

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

No sources were identified that discussed environmental contamination resulting from the commercial manufacturing of any the six gums. The solvent used to separate the gums at the dissolution phase of the process is typically isopropyl alcohol and residual solvent levels are established, as described in Evaluation Question 2 and Evaluation Question 8. The solvent used to separate xanthan gum from the fermentation broth (isopropyl alcohol) is recovered by distillation and reused (Kuppuswami, 2014; USDA NOP, 2016).

The Safety Data Sheets on gum arabic, guar gum, and tragacanth gum do not indicate issues of concern for any harm to the environment or biodiversity (Science Lab., 2017a; Science Lab, 2017b).

The Safety Data Sheets for the solvents used to precipitate xanthan gum, gellan gum, locust bean gum, and guar gum, as described in Evaluation Question 2 and Evaluation Question 8, do not indicate specific impacts on the environment or biodiversity (Science Lab, 2017c; Science Lab, 2017d).

For locust bean gum there is an alternative process in which kernels are treated with dilute sulfuric acid and thus recovery of the acid may have a potential for environmental pollution. However, this process does not appear to be used in commercial manufacturing of locust bean gum.
Xanthan gum is a naturally occurring, biodegradable polysaccharide (Muchová, 2009) that is considered by EPA to be a minimal risk inert ingredient in pesticide formulations (40 CFR 180.950(e)). No sources were identified that discussed whether the use of xanthan gum as a food additive may be harmful to the environment or biodiversity. Xanthan gum is degraded only by certain microorganisms with xanthanase enzyme activity, and the degradation products of xanthan gum are naturally occurring monosaccharides (i.e., single sugars) that make up its structure. In a laboratory study, xanthan gum was readily degraded by microorganisms from human feces or soil (USDA NOP, 2016).

Due to its low toxicity, the EPA exempted gellan gum from the requirement for a tolerance limit when used as an inactive ingredient in pesticide formulations (USDA NOP, 2006).

One source discussed the positive impact of acacia trees on biodiversity (FAO, 2000). Acacia trees have been found to be beneficial in addressing issues of desertification in the gum belt of Africa, and collaborative international efforts actively promote acacia tree planting. No information was found suggesting any negative impact of growing or harvesting gums from carob bean trees, acacia trees, or tragacanth in wild growing areas or cultivated areas. One source indicated a trend to monoculture in some locations where acacia trees were being cultivated (Verbeken, 2003).

Guar is a cultivated agricultural crop. No information was found that indicated any impact on biodiversity from guar cultivation.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

There is a considerable body of research literature, over many decades, on the nutritional and health benefits of gums, as well as potential negative health effects. Over the years, studies have differentiated between positive or negative effects on infants, especially those formulas recommended for dietary foods for infants with special medical needs, as compared with possible effects on the general adult population. The most recent EFSA re-evaluations of five gums (EFSA, 2017), discussed below, indicates the need for further data on impacts of gum additives on infants as compared with general healthy adult population. These EFSA Scientific Opinions are fully documented meta-analyses on each of the five gums they cover. Gellan gum was not included in the 2017 re-evaluation.

Gastrointestinal Effects
Guar gum has been widely studied for its therapeutic effects on cholesterol control and obesity, lowering cholesterol, and glucose levels (Butt, 2007; Zavoral, 1983). Guar gum, gum arabic and locust bean gum have been shown to help with weight reduction (Melnick, 1983). Locust bean gum, gum arabic and xanthan gum have been shown to reduce blood cholesterol levels (Edwards, 2003). Gums

resist digestive enzymes in the stomach and are fermented in the large intestine to yield short-chain fatty acids (SCFAs) and stimulate the specific growth of beneficial intestinal bacteria, notably *bifidobacteria*, and reduce the growth of harmful microorganisms such as clostridia. Gums have a beneficial health impact on increased colonic fermentation and may be used as pre-biotics (Edwards, 2003; Williams and Phillips, 2003; Giannini, 2006; Slavin and Greenberg, 2003). Gums can also change the amount of bile acid available in the gastrointestinal tract, which in turn affects fat digestion and cholesterol (Edwards, 2003). Guar gum has also been shown to have a beneficial health effect on patients with irritable bowel syndrome (Giannini, 2006).

The extent and rate of fermentation of food gums following ingestion are important. The rate of fermentation may determine the site where SCFAs are produced. Most colonic disease occurs in the distal colon, yet most fermentation takes place in the proximal colon. Therefore food gums that are slowly fermented may encourage prolonged fermentation and SCFA production at more distal sites. SCFA have many potential actions that are generally beneficial for health, including stimulation of cell proliferation, which may be important in wound healing (Edwards, 2003). Gums are considered a soluble fiber and may reduce cholesterol and promote fermentation in the large bowel. Gellan gum, specifically, has been shown to be a potent stool bulker.

Gums are widely used for fat replacement in a wide range of low-calorie products, used as single gum additives or in combination with other gums (Edwards, 2003; Williams and Phillips, 2003). Isolated gums or foods fortified with gums can have very significant effects on nutrient absorption, and microflora in the large intestine. A high intake of particular gums may help in the treatment of constipation and diabetes and in colon cancer prevention (Edward, 2003). Xanthan gum is a soluble dietary fiber (Chawla and Patil, 2010); following ingestion, xanthan gum passes through the intestinal tract largely unabsorbed, and is slowly fermented (JECFA, 1986; Edwards, 2003). The 2006 technical report on gellan gum (USDA NOP, 2006) cites one JEFCA study (1990) indicating no adverse human health impacts. This same study notes that gellan gum acts as a bulking agent and decreases serum cholesterol.

The 2016 Technical Report on xanthan gum (USDA NOP 2106) provides considerable detail and references on human health effects from use of xanthan gum. Information from this report is outlined here, but further details may be found in the 2016 Technical Report, which provides detailed information on potential negative health impacts from xanthan gum used in "SimplyThick" (an infant feed) for possible necrotizing enterocolitis that resulted in an FDA warning in 2011. In addition, the report describes and cites European review of scientific studies of xanthan gum on dietary function and as a bulking agent in bowel movements, yet does not indicate any clear relationship between xanthan gum and the health impact described.

Daly (1993) studied xanthan gum's effectiveness as a bulk laxative in healthy adult males. This study demonstrated that ingestion of 15 grams per day of xanthan gum for ten days increased stool bulk, frequency of stools, and flatulence. This study also showed that fecal bacteria from the subjects at the end of the exposure period showed an increase in the production of SFCAs, which are believed to be beneficial to colon health (Ríos-Covían, 2016).

Other Health Effects of Gums

Since its discovery in the 1960s, xanthan gum has been studied for its effects on human health. Toxicological studies conducted in the early 1960s showed no long- or short-term effects in dogs or rats, and no reproductive effects in rats (Woodward et al., 1973). Subsequent short-term animal studies were conducted on guinea pigs and rabbits in the following two decades, and no consistent toxicity or carcinogenicity was observed (JECFA, 1986). Toxicity investigations in overweight humans began as early as 1974 and continued through the mid-1980s. In these studies, no adverse effects were documented in patients administered xanthan gum over a 23 day period (JECFA, 1986; Eastwood, 1987). Research on health effects of gellan gum is presented in WHO Food Additive Series 28, cited in ICPS INCHEM (2017), concluding no adverse health effects on humans, nor adverse toxicological effects. This same report indicates that gellan gum acts as a bulking agent and decreases serum cholesterol, citing Eastwood (1987). Mudgil (2014), citing numerous studies, notes beneficial properties of guar gum in diabetes, colon cancer, bowel movements and heart disease. Anderson (1986) reported evidence of safety of gum arabic as a food additive.

Safety Data Sheets on gum arabic indicate the substance, in powder form, may produce a respiratory allergenic response and/or irritation in some individuals when inhaled (AGRIGUM, 2015; AEP Colloids, 2017). Sensitivity reactions have been reported, such as asthma from sprays used in the printing industry (ICPS/INCHEM, 2017). Safety Data Sheets on guar gum and gum tragacanth indicate slightly hazardous in case of skin contact (irritant), or inhalation or ingestion (Science Lab, 2017a; AEP Colloids, 2017), however guar gum has also been used to add viscosity to artificial tears (Simmons, 2004). Safety Data Sheets for the solvents used during manufacture (as described in answer to Question 2 above), indicate that care must be taken during manufacture to avoid inhalation of vapors (Science Lab, 2017c; Science Lab 2017d).

Gum arabic is commonly prescribed for chronic renal failure in patients in Sudan. It results in decreased uraemia and reduces the frequency of a need for dialysis, hence improving the quality of life (Eltayeb, 2004). One research study indicated that the presence of gum arabic decreases the absorption of amoxicillin (Eltayeb, 2004).

A 1985 study, consisting of healthy and diabetic subjects who were fed muffins containing xanthan gum (12 grams per day) for six weeks, showed that the diabetic patients had significantly lowered blood sugar levels as well as plasma cholesterol levels (Osilesi, 1985).

European Food Safety Authority Findings

In 2017 the European Commission (as required under EU Regulation No. 1333/2008) published the scientific opinions of the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel) for the following food additive gums: locust bean (January 2017); guar (February 2017); arabic (acacia) (April 2017); tragacanth (June 2017) and xanthan (2017) (EFSA, 2017). Their opinions of the present body of published research findings was particularly focused on differentiating between possible health impacts on infants, especially in dietary foods for infants for special medical purposes, as compared with the general adult population. Recommendations related to setting levels for possible heavy metal contamination were described in *Evaluation Question 8*. The scientific opinions of the ANS Panel, regarding health and safety, are summarized below.

Locust bean gum: The panel determined there is no need to establish a numerical acceptable daily intake (ADI) and no safety concern for the general population as a food additive. However, infants and young children consuming foods for special medical purposes[3] may show a higher susceptibility to gastrointestinal effects of locust bean gum, which may be related to the infant or child's underlying medical condition. The panel concluded there is not adequate data available to assess the bioavailability of dietary nutrients and safety of this gum for infants and young children. Thus a current maximum of 1 gram per liter remains the recommended maximum level in follow-on formulae. Further, the Panel continues to recommend that if more than one of the three substances, locust bean gum, guar gum or carrageenan, are added to a follow-on formula, the maximum level established for each of those substances is lowered with that relative part as is present of the other substances. The Panel noted that it is prudent to keep the number of food additives to the minimum necessary and that there should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in infant formulae and foods for young children (EFSA, 2017).

Guar gum: Findings of the panel indicate that there are no adverse health concerns for adults with respect to sub-chronic and carcinogenicity studies; no concern for genotoxicity, and no need to

[3] Under EFSA, "foods for special medical purposes" are a specific food category intended for people who suffer from diseases, disorders, or medical conditions and their nutritional requirements cannot be met by normal foods (EFSA, 2017e).

establish a numerical ADI No safety concerns for the general population. However, for infants, the panel considered that there are not adequate specific food studies on the effect of guar gum for consumption by infants and young children and recommended that additional data be generated. The panel considered that monitoring of abdominal discomfort should be monitored in children and infants consuming guar gum because they may have a higher level of susceptibility to the gastrointestinal effects of guar gum, especially if they have an underlying medical condition. This panel set no threshold dose for allergic reaction. (EFSA, 2017a).

Gum arabic: The Panel found that there is still no need to establish a numerical ADI. The Panel considered that adequate exposure and toxicity data are available, and no adverse effects noted. Gum arabic is unlikely to be absorbed intact and is slightly fermented by intestinal microbiota, and no safety concerns for the general adult population (EFSA, 2017b).

Tragacanth gum: The Panel found that there is still no need for a numerical ADI, and no safety concerns for the general population (EFSA, 2017c).

Xanthan gum: The Panel found that there is no need to establish a numerical ADI, and no safety concerns for general population or infants and young children at the levels used as reported by the food industry. However, the current evaluation is not considered applicable for infants under 12 weeks of age (EFSA, 2017d).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

A review of the literature did not provide any information describing alternative practices that would render the use of gum arabic, gellan gum, locust bean gum, tragacanth gum, guar gum or xanthan gum unnecessary as food additives for the purposes for which they are presently used in processed foods. These hydrocolloids, each alone or in combination, function as thickeners, stabilizers, and emulsifiers, as described elsewhere in this report. An alternative practice could be to make the product without the additive, resulting in products with different consistencies and textures. Producers of processed organic foods could, in some instances, use alternative substances, as discussed in *Evaluation Question 12* and *Evaluation Question 13.*

Evaluation Question #12: Describe all natural (nonsynthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

As discussed in *Evaluation Question 3*, all of the gums discussed in this report are derived from nonsynthetic, natural sources although some may be classified as synthetic based on their further manufacturing processes. Gellan gum is listed as nonsynthetic, and gum arabic, locust bean gum, tragacanth gums are listed as nonorganic, agricultural substances. Only xanthan gum is permitted in synthetic form. Certified organic forms of any other agricultural substance may also be eligible for use, as discussed in *Evaluation Question 13*.

The National List includes the following allowed substances which, separately or in combination, may be alternatives or substitutes to the six gums under discussion in this report:

§ 205.605(a) Nonagricultural, nonsynthetic
- Agar-agar
- Carrageenan
- Gellan gum – high acyl form only

§ 205.605(b) Nonagricultural, synthetic
- Xanthan gum

§ 205.606 Nonorganic, agricultural

- Gelatin
- Gums – water extracted only (arabic; guar; locust bean; and carob bean)
- Konjac flour
- Lecithin (de-oiled)
- Pectin (non-amidated forms only)
- Cornstarch (native)
- Sweet potato starch – for bean thread production only
- Tragacanth gum

There are many natural hydrocolloids which can be substituted for any one of the gums which are the subject of this report. These include both agricultural and non-agricultural substances. Traditional substances which are not hydrocolloids, such as starches and gelatin, can be used. The choice of gum for a particular food application is dictated by the functionalities required, but strongly influence by price and security of supply. Therefore starches, which are very economic, are the most commonly used thickening agents, and corn starch, tapioca, wheat, arrowroot, and rice starches are all available in organic forms. However, starches do not provide the same function as hydrocolloid gums. Guar gum, for example has almost eight times the water-thickening potency as cornstarch and thus only a small amount is needed to attain the desired viscosity (Williams and Phillips, 2003; Saha and Bhattacharya, 2010). Another example is xanthan gum, which despite its high price, has become the thickener of choice in many applications due to its unique rheological behavior (Williams and Phillips, 2003) as described in *Properties of the Substances*.

Gelatin is derived from partial hydrolysis of collagen fibers extracted from the bones and other body parts of domesticated animals, such as beef cattle. It is by far the most common gelling agent, but with increasing demand for non-animal products, in particular due to the bovine spongiform encephalopathy outbreak and expansion of the vegan consumer group, processors are actively seeking to replace gelatin in both organic and non-organic food processing. Gelatin could be used as an alternative to gellan, but gellan can withstand higher temperatures (Williams and Phillips, 2003).

Carrageenan is a possible agricultural alternative because it is both wild harvested and cultivated. TIC GUMS does not list Carrageenan in its list of Organic ingredients, but TIC does list an organic blend: TICorganic® Caragum® 200 (TICGums, 2017b). As noted in *Combinations of the Substances*, carrageenan is used to change properties of gum function in some products (Williams and Phillips, 2003).

Tara gum may be an alternative for use of Guar gum. Tara is derived from the endosperm of the seeds of *Caesalpinia spinosa (leguminosae*), a shrub/small tree that grows wild in Peru. Tara is also called Peruvian carob. Tara is a high molecular galactomannan, with similar cold water solubility to guar gum and similar thickening characteristics. It is odorless and tasteless compared with guar gum, improves the shelf life of products, and has a smoother, less slimy texture (Silvateam, 2017).

Konjac mannan is a soluble extract of konjac flour made from a dried tuber (*Amorphophallus konjac)* used in Japan to make noodles and konnyaku for use in traditional dishes and dessert jelly. It is a glucomannan. It can be combined with xanthan gum to increase gel strength in kappa-carrageenan gels (Williams and Phillips, 2003).

Pectin may be used as an alternative for some of the gums, under some circumstances. Pectin is produced commercially in many different forms depending on functional use required. Danisco for example lists several pectins such as GRINSTED™ Pectin RS 461, which is advertised as having properties to prevent calcium gelling and thus it can be used to restore viscosity in low sugar or low juice drinks. Pectin provides the beverages with Newtonian behavior, thus avoiding any feeling of sliminess, especially compared to gums like xanthan (Danisco, 2017d).

Tamarind seed gum has been petitioned for inclusion on the National List at § 205.606. The petition has yet to be evaluated by the NOSB (Buckley, 2017).

Security of supply is a major concern for manufacturers who use exudate gums. Manufacturers who switch to alternatives due to periods of shortage relating to climate and political instability do not necessarily switch back when production increases again. Over the years substitutes have been developed which offer a more secure and cost-effective supply, such as modified starches and synthetic polysaccharides derived from fermentation or direct enzyme action. However, many of these alternatives have proven to be poor substitutes. Exudate gums possess a unique set of properties and consumer demand for natural products continues to increase (Verbeken, 2003).

<u>Evaluation Question #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Organic Forms of Gums Discussed in This Report
Organic forms of three of the six gums appear to be available and could serves as alternatives to non-organic forms of the gums. However, little information was found as to whether the commercially available quantities would meet market demand. Organic locust bean gum, organic gum arabic, organic guar gum, and organic tara gum are available organic agricultural products (Silvateam, 2016; TIC Gums Inc., 2017b; Ciranda, 2017; Danisco, 2017a, b, c;). Organic psyllium seed husk powder is also available (BI Neutraceuticals, 2017; AEP Colloids, 2017).

Acacia senegal, the source of gum arabic, is cultivated in Sudan where wild stands are replaced by monoculture (Verbeken, 2003), and thus there is the potential for expanded organic agricultural production. The FAO has programs in the "Gum Belt" of Africa to expand planting and expansion of cultivated acacia (FAO, 2000).

No information was found indicating that organic forms of xanthan gum or gellan gum are available commercially as certified organic. As of January 16, 2018, the NOP Organic Integrity Database lists one certified producer of organic tragacanth gum.

Other Organic Agricultural Alternatives
Some of the natural hydrocolloids discussed in *<u>Evaluation Question 12</u>* are available in organic form. As of January 16, 2018, the NOP Organic Integrity Database lists seven certified handlers of organic agar products.

Organic tara gum is a potential alternative to guar gum (Silvateam, 2017). Like guar gum, tara gum is a galactomannan. Tara gum has similar cold-water solubility to guar gum and similar thickening characteristics but with additional advantages: smoother flow; ability to combine with carrageenan or xanthan to form very soft gel structure; odorless and tasteless compared with guar (which can be unpleasant to taste); better ability to release flavor compared with guar; and high gel elasticity, which improves the shelf life of products (Silvateam, 2017).

Starches, which are very economic, are the most commonly used thickening agents, and also used as stabilizers. Corn starch, tapioca starch, wheat arrowroot, potato starch, and rice starches are all available in organic forms (e.g., Aryan International, 2017; Finnamyl Ltd., 2017). They are typically used in desserts, sauces, pie fillings, and to make noodles and pasta. However, starches do not provide the same functions as the hydrocolloid gums. Natural starches form turbid gels which are prone to syneresis (Saha and Bhattacharya, 2010; TIC Gums Inc., 2017b; Williams and Phillips, 2003). Finnamyl Ltd., in Finland, produces an organic potato starch product and claims that guar gum could be replaced in many cases, totally or partially, by cold-swelling potato starch in dry blends and sometimes also in short shelf life liquid products. They further state that functional starch is much more cost-effective (Finnamyl Ltd., 2017).

Organic soy lecithin is available as an emulsifier for foods such as ice cream. Lecithin's primary function is as an emulsifier, but it also extends shelf life, acts as a viscosity modifier, and acts as a wetting/instantizing agent. It is used in baked goods and frozen doughs (Aryan International, 2017; Ciranda, 2017).

Egg yolk is frequently used as a natural emulsifier and as a food thickener in sauces, and certified organic eggs are commercially available.

Report Authorship

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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