## 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.

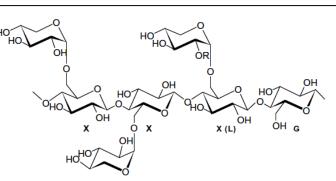
Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

## Tamarind Seed Gum

Handling/Processing

. L.	Identification of	of Peti	tioned Substance	
_		11		
	Chemical Names:	12	Trade Names:	
	Tamarind Seed Polysaccharide (TSP); Tamarind	13	GLYLOID®; GLYATE; Tamarind Gum	
	Seed Gum			
			CAS Numbers:	
	Other Names:		39386-78-2	
	Tamarind Seed Xyloglucan; Tamarind Seed			
	Galactoxyloglucan; Tamarind Gum; Tamarind		Other Codes:	
	Extract; Tamarind Xyloglucan		EC/List no. 254-442-6	
Γ	Summary	of Pe	titioned Use	
4				
	<ul> <li>Tamarind seed gum has been petitioned for addition to the National List at § 205.606 as a non-organic agricultural ingredient permitted in processed products labeled as "organic" when organic forms are not commercially available. This full technical report also addresses additional focus areas requested by the National Organic Standards Board (NOSB) Handling Subcommittee:</li> <li>The petitioner states that there are very small amounts of residuals from the processing chemicals utilized to separate the gum from the seed. Are there any health issues from these residuals, including, but not limited to methyl alcohol? <i>See Evaluation Question #10</i>.</li> <li>How do the properties of this gum vary from other gums on the National List (e.g., gellan gum, xanthar gum, Arabic gum, guar gum, locust bean gum, carob bean gum, tragacanth gum, etc.)? <i>See Evaluation Question #12</i>.</li> </ul>			
Γ	Characterization	n of Pe	titioned Substance	
	More specifically, it is a galactoxyloglucan, meani and galactose (Manchanda, 2014; Health Canada, D-xylose units attached to approximately 75 perce structure, but additional molecular side chains dif	ing it is 2017). ent of t fferent xylose	brage polysaccharide (Nishinari, Takemasa, et al. 2007). s principally comprised of three sugars: glucose, xylose The linear backbone is a $\beta$ (1 $\rightarrow$ 4)-D-glucan chain, with he glucan units. All xyloglucans share this common iate tamarind seed gum from other xyloglucan sources e units may also have a galactose unit attached by a $\beta$ 1 y be described as partial substitution at position 6 of th	



48

## 49 Figure 1. Tamarind seed gum's xyloglucan polysaccharide structure (Patel, et al. 2008). X indicates

- 50 xylosylated glucopyranose units; G indicates an unsubstituted glucopyranose unit; and L indicates a 51 galactopyranose unit attached to the xylose unit.
- 52 The petition for tamarind seed gum submitted to the National Organic Program (NOP) specifically references a
- brand name, GLYLOID. The composition information above describes GLYLOID. However, although GLYLOID is the only brand name product identified in the petition, an alternative, partially acid-hydrolyzed tamarind seed
- 55 gum is made by the same manufacturer and marketed under the brand name GLYATE (JHeimbach LLC, 2014).

56 The GRAS notification for tamarind seed polysaccharide (TSP) identifies both GLYLOID and GLYATE as

57 brand/trade names of the substance (JHeimbach LLC, 2014).

58

Acid hydrolysis is used to separate monosaccharides from polysaccharides (Gidley et al., 1991; Hoebler et al.,

60 1989) and is a processing step used in the production of GLYATE. Information regarding the specific chemical

61 composition of GLYATE was not found in the literature, however it is expected that acid hydrolysis affects its

62 chemical composition and function since it removes certain monosaccharides. The GRAS notification for TSP

63 states that in the production of GLYATE, acid hydrolysis of tamarind kernel powder (TKP) is carried out until

64 the desired viscosity is obtained (JHeimbach LLC, 2014). As will be described under <u>Action of the Substance</u>,

- 65 viscosity is largely determined by a substance's chemical composition.
- 66

## 67 Source or Origin of the Substance:

68 Tamarind seed gum comes from the kernel, or endosperm, of seeds of the tamarind tree (Tamarindus indica

69 L). Its native range includes the tropical dry savannah of Africa to India and Southeast Asia (CAMEO,

2016), with India being the predominant producer, followed by Thailand, Bangladesh, Sri Lanka, and

71 Indonesia. Thirty-six other countries including Costa Rica, Mexico, and Brazil cultivate the tamarind tree

72 (Bagul, Sonawane, and Arya, 2015). Tamarind trees are leguminous (in the Family Leguminosae, or

- Fabacae) and produce long pods that contain fruit in the form of a tart, fleshy pulp surrounding glossy, flat
- seeds. Tamarind pulp is high in tartaric acid and sugars, and is a widely-used food product. The seeds,
- 75 which are composed of 65–75 percent carbohydrates, are considered a by-product of the pulp industry.
- 76 Once dehulled and crushed, the seeds make tamarind kernel powder (TKP), a crude preparation of non-
- 57 starch polysaccharide that functions as an energy reserve for the seed. The purified, soluble polysaccharide
- 78 fraction of TKP is what is referred to as tamarind seed gum, tamarind seed polysaccharide (TSP), or
- tamarind seed xyloglucan. For more details on the manufacturing process, see *Evaluation Question* #1.
- 80

## 81 **Properties of the Substance:**

- 82 Tamarind seed gum is a free-flowing, tasteless powder that is white or light beige in color, and may be
- odorless or have a slight grease odor. It is insoluble but dispersible in cold water and insoluble in most
- organic solvents including ethanol, methanol, acetone, and ether (Manchanda, 2014) (Sidley Chemical Co.,
- Ltd. 2013) (Joseph et al., 2012). Tamarind seed gum is soluble in hot water and at least one manufacturer,
- 86 DSP Gokyo, markets a tamarind seed gum product, GLYLOID 3S, as being cold-water soluble (DSP
- GOKYO, 2017). A cold, aqueous solution of tamarind seed gum heated to 85°C results in its dissolution and
- the formation of a uniform solution (Whistler and Barkalow, 1993). The following subsections detail the
- viscosity and gelling properties of the substance, which can also be found in Table 1.

- Table 1. Properties of tamarind seed gum (Mohamed, Mohamed and Ahmed 2015) (Khounvilay and
   Sittikijyothin, 2012) (Joseph, et al., 2012) (Nishinari, Takemasa, et al., 2007) (Salazar-Montoya, Ramos-
- Sittikijyotinin, 2012) (Joseph, et al., 2012) (Nishinari, Takemasa, et al., 2007) (Salazar-Wontoya, Ka
- 93 Ramirez and Delgado-Reyes 2002).

Property	Value
Molecular weight*	Reported variously from 650,000-2,100,000
	g/mol; most commonly 880,000 g/mol
Viscosity average molecular mass	980,000 g/mol
Linear viscoelasticity	0.637–6.37 Pa of oscillary sheer stress
Viscosity	400-800 mPa s
Bulk density	0.24-0.651 g/mL
Compressibility index	15.33-16.64%
pH (1% w/v TSP)	6-6.81
Swelling index (in water)	12-17%
Surface tension	61.3-83.26 dynes/cm
Water retention	20.00 ± 1.34%
Moisture content	3.8-8.1%
Melting point	240–260°C

94 \*While molecular weight plays an important role in determining the viscosity of tamarind seed gum, there is wide variation for this

95 property reported in the literature. Several sources suggest that this is due to the self-association of the polysaccharide chains and

96 the related difficulty in isolating molecular solutions that have been fully solubilized (Picout et al., 2003) (Nishinari et al., 2007).

97 There are also differences based on the method of measurement, for example by gel permeation chromatography or light scattering. 98

## 99 Viscosity

100 Similar to other gums, tamarind seed gum is a hydrocolloid. Hydrocolloids are a heterogeneous group of

101 long chain polymers (polysaccharides and proteins) characterized by their property of forming viscous

102 dispersions and/or gels when dispersed in water. Thus, gums are substances that disperse in water and

103 provide a thickening and/or gelling effect by increasing the viscosity of a solution. This effect is common

104 to all hydrocolloids, serving as gums' primary function (Saha and Battacharya, 2010; Edwards, 2003).

105 The viscosity of gum solutions/hydrocolloids depends on how the hydrocolloid behaves in various

106 concentrations or environments, such as temperature, pH, amount of physical agitation, or addition of

107 sugars or other gums. Viscosity at low concentrations only depends on temperature, but at higher

108 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

110 properties and behaviors (Saha and Battacharya, 2010; Chenlo, 2010). *Shear stress* is the force acting in the

- 111 plane of the fluid (CP Kelco, 2007).
- 112

113 As with other gums, the viscosity of tamarind seed gum depends largely on its concentration in solution.

114 At low concentrations, the viscosity of a tamarind seed gum solution is dependent only on temperature

115 (Sidley Chemical Co. Ltd., 2013). At higher concentrations of tamarind seed gum, however, the viscosity of

a solution decreases as shear rate increases (Khounvilay and Sittikijyothin, 2012; Whistler and Barkalow,

117 1993), a phenomenon known as shear thinning. *Shear thinning* is the behavior of a fluid becoming runnier

and less viscous as it flows in response to an applied force (TACC, 2004). This phenomenon occurs due to

the structural reorganization of the polysaccharide molecules in high-concentration TSP solutions during

120 flow (Nishinari and Takahashi, 2003). A similar decrease in viscosity is not observed at lower shear rates,

121 where the solution maintains its viscosity (Khounvilay and Sittikijyothin, 2012).

122

123 Temperature also affects the viscosity of tamarind seed gum solutions, over a range of concentrations.

124 Tamarind seed polysaccharide in solution at 25°C is in a substantially disaggregated state of single chains

125 (Gidley et al., 1991). However, when boiled for 20 to 30 minutes, the viscosity peaks (Whistler and

126 Barkalow, 1993) and then decreases, but is still somewhat stable, only decreasing to half of what it was at

127 the peak after 5 hours of boiling (Sidley Chemical Co. Ltd., 2013). Tamarind seed gum has been cited as

being relatively heat resistant, though research does indicate that as temperature increases, viscosity

decreases (JHeimbach, 2014; Buckley, 2017a).

Tamarind seed gum is also salt resistant, stable at neutral pH, and only minimally affected by the presence 131

132 of organic acids in the pH range from 2 to 7. In fact, maximum gel strength for a solution with 1 percent 133 tamarind seed gum and 50 percent sugar has been reported to be at pH 2 (Wustenberg, 2015). Acidification

134 with strong inorganic acids, on the other hand, does cause dramatic decrease in tamarind seed gum's

135 viscosity (Sidley Chemical Co. Ltd., 2013). The acid-hydrolyzed tamarind seed gum product, GLYATE, has

136 a much lower viscosity, ranging from 1 to10 mPa s, compared to over 400 mPa s for non-hydrolyzed

137 tamarind seed gum.

138

139 **Gelling** Properties

140 While all hydrocolloids thicken aqueous dispersions, comparatively few gums form gels. Tamarind seed

gum does not form a gel in isolation, but does gel in the presence of alcohol and sugars, and exhibits sol to 141 gel transition at certain temperatures (Chemical Book, 2017). In the aqueous phase, tamarind seed gum 142

143 combined with 40-70 percent sugar gels over a wide range of pH levels (Nishinari and Takahashi, 2003)

144 (Wustenberg, 2015). These gels show low syneresis, meaning they do not tend to separate or weep liquid

145 (Wustenberg, 2015). Tamarind seed gum also forms a gel in the presence of alcohol (Gidley et al., 1991)

(Nitta and Nishinari, 2005) (Salazar-Montova, Ramos-Ramirez, and Delgado-Reves, 2002) or by removing 146

147 some of its galactopyranosyl side chains (Nitta, Kim, et al., 2003). One study evaluated gels made from

148tamarind seed gum and saccharose and found that gel stability and shear resistance was dependent on

149 both the saccharose and polysaccharide concentrations (Salazar-Montoya, Ramos-Ramirez, and Delgado-Reves, 2002).

150

151

152 Tamarind seed gum has also been reported to have more pronounced shear thinning than xyloglucans

153 from other plants such as apple pomace and *Nicotiana plumbaginifolia* (Sims, et al. 1998).

154

#### 155 Specific Uses of the Substance:

156 Tamarind seed gum is used in numerous applications as a food additive. Because it has rheological

157 functions that affect foods in the liquid phase, tamarind seed gum can be used as a thickening and gelling

158 agent to improve the viscosity of certain foods. It can also modify the texture of foods (Khounvilay and

159 Sittikijyothin, 2012). As an emulsifier, tamarind seed gum stabilizes foods such as ice cream, mayonnaise

160 and cheese (Bagul, Sonawane, and Arya, 2015). Tamarind seed gum forms gel at low water activity, such as

161 in solutions with sugar content greater than 60 percent, and is thus used in jams, jellies, and fruit preserves

162 in place of pectin. It can also function as a starch modifier (Nishinari, Takemasa, et al., 2007). Added to

starch, tamarind seed gum produces high viscosity paste with increased pseudo-plasticity. It can improve 163

164 the gelatinization and retrogradation of tapioca starch pastes during storage at 5°C (Pongsawatmanit et al.,

165 2006). It can also be used to replace gluten as a dough-binding agent in gluten-free food products (Bagul,

166 Sonawane and Arya, 2015). Added to foods, tamarind seed gum can enhance characteristics such as 167 maintenance of viscosity over a wide range of shear rates, water-holding, and a food's resistance to heat,

168 salt, and pH treatments used during processing (Nishinari, Takemasa, et al., 2007).

169

170 Tamarind seed gum is used in textile and jute industries as a textile thickener and for textile sizing during

171 dyeing. It is also used in industries such as printing, paper, plywood, cosmetics, and oil drilling; as a soil

172 stabilizer in mining operations, in the manufacturing of paints (Nagajothi et al., 2017), art preservation

173 (CAMEO, 2016) and other industries. A recent area of interest is its use as an excipient for pharmaceuticals

174 due to its high drug-holding capacity, high swelling index, thermal stability, and non-toxicity (Joseph et al.,

175 2012; Manchanda 2014). Other medicinal uses of tamarind seed gum include eyebaths and for the

176 treatment of ulcers (Mishra and Malhotra, 2009). It has also been suggested as an immunity booster (Bagul, Sonawane, and Arya, 2015).

177 178

#### 179 Approved Legal Uses of the Substance:

180 Tamarind seed gum, under the chemical name Tamarind Seed Polysaccharide, is Generally Recognized as

Safe (GRAS) under GRAS Notice No. 503 (JHeimbach LLC, 2014). The GRAS notice covers the use of 181

182 tamarind seed polysaccharide as a thickener, stabilizer, emulsifier and gelling agent in 12 food categories:

- 183 ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles,
- 184 tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from

Tamarind Seed Gum

0.2–1.5 percent of product composition. Use levels are identified for each food category. The stated
intended effect of the addition of tamarind seed gum to food is as a stabilizer and thickener as defined in 21
CFR § 170.3(o)(28). The FDA had no questions in its Agency Response Letter of August 12, 2014 to the

- 188
- 189

industry's determination of GRAS status for tamarind seed gum (FDA 2014).

- The GRAS Notice No. 503 for Tamarind Seed Polysaccharide covers three brand name products
   manufactured by DSP Gokyo: GLYLOID 2A (hot-water soluble), GLYLOID 3S (cold-water soluble), and
- 192 GLYATE (acid-hydrolyzed, low viscosity).
- 193
- 194 Tamarind seed gum is on the EPA's 2016 Chemical Data Reporting (CDR) Full Exempt List, which lists
- 195 chemicals that are fully exempt from reporting requirements under the Toxic Substances Control Act. 196

## 197 Action of the Substance:

- 198 The actions of thickening and stabilizing of tamarind seed gum are due to its self-association in solution.
- 199 Hydrocolloids thicken solutions through the nonspecific entanglement of their long molecular chains.
- 200 When hydrocolloids are present in a suspension in very dilute concentrations, their individual molecules
- 201 can move freely and may not cause thickening. As the concentration increases, molecule movement is
- 202 restricted as they begin to come into contact with one another. The disordered molecule chains become
- 203 entangled and thickening takes place (Saha and Battachyra, 2010). Gidley et al. (1991) also described
- 204 "hyperentaglements" which resist shear more than non-specific entanglements, and may occur when stiff 205 chains in a non-ionized environment align with nontral segments in solution
- 205 chains in a non-ionized environment align with neutral segments in solution.
- 206
- 207 The specific physiochemical properties of a xyloglucan are a function of the number and position of the
- side chains attached to its molecular backbone (Nishinari, Takemasa, et al., 2007). In tamarind seed gum,
- the molecular chain is very stiff and has restricted movement due to the extensive glycosylation (approx. 80
   percent) of its cellulose-like backbone (Gidley et al., 1991) (Nishinari and Takahashi, 2003). The polymers
- show both hydrophobic and hydrophilic properties, leading the individual macromolecules to not fully
- 212 show both hydrophobic and hydrophilic properties, leading the individual macromolecules to not runy 212 hydrate and thus to aggregate even in dilute solutions (Picout et al., 2003). Tamarind seed gum xyloglucans
- also tend to self-associates to a higher degree than do xyloglucans from other sources, even though the
- solution properties for isolated chains of all xyloglucans are very similar. This has been attributed to the
- ratio of repeating units that make up tamarind seed xyloglucan enabling more interaction with other
- 216 molecules including other xyloglucans (Nishinari, Takemasa, et al., 2007). Tamarind seed gum contains a
- 217 high ratio of heptasaccharides (XXXG; See Figure 1), which self-associate to a larger degree than do other
- 218 oligosaccharides (Nishinari, Takemasa, et al., 2007). It has also been suggested that the extensive
- substitution on the molecular backbone helps to shield the polysaccharide from hydrolyzing agents, thus
- 220 imparting tamarind seed gum's resistance to heat, mild acids, and bases (Mishra and Malhotra, 2009).
- 221

The molecular weight (or size of molecules) of a polysaccharide affects its functional properties because viscosity and flow are governed by the interaction of the molecules in solution (Patel et al., 2008; Sims et al.,

- viscosity and flow are governed by the interaction of the molecules in solution (Patel et al., 2008; Sims et al., 1998; Cidley et al., 1991). One study sought to modify tomorind cood sum's properties by breaking its
- 1998; Gidley et al., 1991). One study sought to modify tamarind seed gum's properties by breaking its
   polysaccharide units into smaller molecular weight materials via pressure and temperature treatment,
- polysaccharide units into smaller molecular weight materials via pressure and temperature treatment
   enzymatic treatment, irradiation and other methods. The result was that the intrinsic viscosity was
- decreased with increasing irradiation treatment (Patel et al., 2008). This underscores the mechanism by
- which tamarind seed gum functions to impart viscosity and thickening to solutions: through interactions
- which are determined by its physical size and chemical makeup on a molecular level.
- 230

## 231 **Combinations of the Substance:**

- 232 The petition did not suggest that any formulants are included in tamarind seed gum (Buckley, 2017a).
- 233 Tamarind seed gum is available as a pure tamarind seed polysaccharide, although some minimal solvent
- residues may remain in the final product from processing aids used in the purification process. More
- information on these processing aids is provided in *Evaluation Question* #1.
- 236
- In application, additional substances such as alcohol, sugar, or oil can be mixed with tamarind seed gum in
   order to aid in dispersion, although the petitioner states that water alone is sufficient. Tamarind seed gum

forms a gel in combination with alcohol or sugar (Chemical Book, 2017) (Nishinari, Takemasa, et al., 2007). 239 240 Tamarind seed gum is also commonly mixed with other gelling agents and food additives, including xanthan gum, guar gum, pullulan, dextran, and pectin, among others (Kumar and Bhattacharya, 2008). The 241 gelling of mixtures of various polysaccharides has been widely investigated. One study found that a 242 243 mixture of tamarind seed gum and gellan gum formed a gel under conditions that would not produce gelling with either individual polysaccharide, indicating synergistic gelation (Nitta, Kim, et al., 2003; Nitta 244 245 and Nishinari, 2005). Another study examined the relative concentrations of tamarind seed gum 246 polysaccharide and saccharose in solutions for their effects on gelation properties. Gelation increased with 247 the increase of both components and the authors suggested that the polysaccharide and saccharose likely 248 have synergistic effects on the viscoelastic properties of the resultant gel (Salazar-Montoya, Ramos-249 Ramirez, and Delgado-Reyes, 2002). Similarly, in a study on the effects of mixing tamarind seed gum with 250 tapioca starch, it was found that the gum contributed increased viscosity and heat stability to the 251 gelatinized mixtures as compared to tapioca starch alone (R. Pongsawatmanit et al., 2006). 252 253 Status 254 255 **Historic Use:** 256 Records from the eastern Mediterranean show tamarind trees under cultivation in the fourth century BCE. 257 It is apparently native to tropical Africa and Madagascar, but now found throughout the tropics and 258 introduced to tropical central and South America. It is widely cultivated and has naturalized in many 259 areas. All parts of the tree are used for medicinal purposes, from the bark and leaves to the fruit, and the 260 fruit is widely used as a food (Kew Science, 2017; Ranaivoson, 2015; JECFA, 2017; Williams, 2006; Kuru, 261 2014). 262 263 The seeds have had much more limited use and were mostly discarded until the mid to late 1900s. In 1942, 264 two Indian scientists – T.P. Ghose and S. Krishna – identified the gel-forming substance found in the seeds 265 (Morton, 1987). Its first applications were in the paper and textile industries. Difficulty of protein removal, 266 bitter taste and odor prevented its adoption in food applications (Whistler and Barkalow, 1993) until a process for its purification was patented calling the substance "jellose," "polyose," or "pectin" (Morton, 267 1987). Tamarind seed gum has been commercially available as a food additive in Japan since 1964 (DSP 268 269 Gokyo Food & Chemical, 2017). 270 271 **Organic Foods Production Act, USDA Final Rule:** Tamarind seed gum is not specifically listed in the Organic Foods Production Act of 1990 or in the USDA 272 273 organic regulations at 7 CFR Part 205. As an agricultural substance, it may only be used as an ingredient or 274 processing aid in or on foods labeled as "organic" if the substance itself is certified organic. 275 276 International: 277 Canadian General Standards Board Permitted Substances List http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html 278 Tamarind seed gum is not permitted as an ingredient on Table 6.3 of the Permitted Substances List. The 279 280 listing for Gums on this table states that "[t]he following gums are permitted: arabic gum, carob bean gum 281 (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum." 282 283 However, non-organic agricultural ingredients are permitted as a processing aid if organic forms are not 284 commercially available (see CAN/CGSB 32.310 section 9.2.1(d) and 9.2.2(d)). 285 CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of 286 287 Organically Produced Foods (GL 32-1999) http://www.codexalimentarius.org/standards/list-standards/en/?no\_cache=1 288 http://www.codexalimentarius.org/download/standards/360/cxg\_032e.pdf 289 290 Under the CODEX Alimentarius Guidelines, carob bean gum, guar gum, tragacanth gum, gum arabic, 291 xanthan gum and karaya gum are all permitted with certain restrictions at GL 32-1999 Table 3 "Ingredients

292	of non-agricultural origin referred to in section 3 of these guidelines." Tamarind seed gum, however, does
293	not appear on this table.
294	
295	Section 3.4 of the guidelines states: "Certain ingredients of agricultural origin not satisfying the
296	requirement in paragraph [3.3b, which requires agricultural ingredients to be produced organically] may
297	be used, within the limit of maximum level of 5 percent $(m/m)$ of the total ingredients excluding salt and
298	water in the final product, in the preparation of products as referred to in paragraph 1.1(b); where such
299	ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the
300	requirements of Section 4 [organic production practices] of these guidelines." As such, agricultural forms of
301	tamarind seed gum could be permitted under this section.
302	
303	European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
304	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF
305	Article 28 states that non-organic agricultural ingredients listed in Annex IX to this Regulation can be used
306	in the processing of organic food, however, tamarind seed gum is not included in on this list. Tamarind
307	seed gum is also not listed under "Food Additives, Including Carriers" in Annex VIII, Section A of EC No.
308 309	889/2008. Other gums including carob bean gum, guar gum, Arabic gum, and xanthan gum are listed in this section.
	this section.
310 311	Article 20 describes the authorization of non-organic food ingredients of agricultural origin by member
312	Article 29 describes the authorization of non-organic food ingredients of agricultural origin by member states for agricultural ingredients not appearing in Annex IX. Such non-organic agricultural ingredients
313	may be used according to the conditions laid out in Article 29, which include requirements for evidence of
314	lack of commercial organic supply and notification, among others. Tamarind seed gum could be approved
315	under this provision.
316	
317	Japan Agricultural Standard (JAS) for Organic Production
318	http://www.maff.go.jp/e/policies/standard/jas/specific/criteria_o.html
319	Tamarind seed gum is not listed in Table 1 "Additives" of the Japanese Agricultural Standard for Organic
320	Processed Foods Notification No. 1606, partially revised March 27, 2017. Other gums – including carob
321	bean gum, guar gum, tragacanth gum, Arabian gum, xanthan gum and karaya gum – do appear in Table 1.
322	
323	Article 4 describes provisions for lack of commercial organic supply: "In case of difficulty to obtain organic
324	plants, organic livestock products or organic processed foods with the same categories of those used for
325	ingredients, those prescribed in items 2 or 4 may be used." Items 2 and 4 describe plants and livestock

- 326 products that are not in the same categories as organic ingredients, and have not undergone ionizing
- radiation or recombinant DNA technology. Tamarind seed gum, if not considered in the same category as
- other listed gums, could be allowed under this provision.
- 330 IFOAM Organic International
- 331 http://www.ifoam.bio/en/ifoam-norms
- 332 Appendix 4 Table 1, "List of Approved Additives and Processing/Post-Harvest Handling Aids," lists
- locust bean gum, guar gum, tragacanth gum, Arabic gum, and xanthan gum. Tamarind seed gum is not
   included.
- 335
- 336 Section 7.2.1 states: "All ingredients used in an organic processed product shall be organically produced
- except for those additives and processing aids that appear in Appendix 4. In cases where an ingredient of
- organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic
   raw materials, provided that:
- 340 a. they are not genetically engineered or contain nanomaterials, and

341	b. the current lack of availability in that region is officially recognized <sup>1</sup> or prior permission from the
342	control body is obtained.
343	c. the requirements in section 8.1.3 [requirements for percentages of organic ingredients] shall be
344 345	met." Tamarind seed gum could be permitted under the above provision.
345 346	ramarina seed guin could be permitted under the above provision.
340 347	
348	Evaluation Questions for Substances to be used in Organic Handling
349	
350 351 352	<u>Evaluation Question #1:</u> 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,
353	animal, or mineral sources (7 U.S.C. § 6502 (21)).
354	uniniui, or initicial sources (7 0.0.C. g 0002 (21)).
355	The petition specifically references tamarind seed gum manufactured under the brand name GLYLOID by
356	DSP Gokyo, sold in the U.S. by Socius Ingredients. On the manufacturer's website, there are two forms of
357	this particular brand name product: GLYLOID 2A (hot water-soluble) and GLYLOID 3S (cold water-
358	soluble) (DSP Gokyo, 2017). Another brand name tamarind seed gum product, GLYATE, was not
359	identified in the petition but is addressed in this report in a following sub-section.
360	
361	Tamarind kernel powder (TKP) is the pre-purified starting material from which pure tamarind seed gum is
362	extracted. The petitioner (Buckley, 2017a) describes its manufacturing process, beginning with the seeds of
363	the tamarind tree. The black seeds are sieved, roasted, cooled and then put through a rotary mixer to
364 265	remove the testa, or seed coat. Whistler and Barkalow (1993) noted that the temperature and duration of
365 366	roasting must be controlled so as to minimize discoloration and decreased molecular weight, which can in turn lower the viscosity of the resulting gum. The light brown to creamy white endosperm is visually
367	sorted to remove any off-color endosperm, then polished in a rotary mixer and cut. The cut endosperm is
368	pulverized in a hammer mill and sifted with a 200-mesh filter to produce pre-purified TKP, consisting
369	primarily of polysaccharide with residual protein, lipid, minerals and no more than 10 percent moisture.
370	
371	GLYLOID
372	Extraction of the GLYLOID 2A includes use of methyl alcohol (hereafter referred to as methanol) and
373	sodium hydroxide. In order to purify and remove water from the polysaccharide, the TKP is stirred into a
374	solution of food-grade methanol (Buckley, 2017b). After stirring, food-grade sodium hydroxide is added
375	and the mixture is again stirred at a controlled temperature. Sodium hydroxide solubilizes proteins into the
376	methanol solution to facilitate their separation from the polysaccharide (Buckley, 2017b). The
377 378	polysaccharide is then separated from the protein, lipid, and minerals by centrifugation. Food-grade citric acid is added to adjust the pH by neutralizing the sodium hydroxide. In this process, hydrogen ions from
379	the citric acid combine with hydroxide ions from the sodium hydroxide to form water, leaving sodium and
380	citrate ions in the methanol solution (Buckley, 2017b).
381	entitle fond in the mentition (buckley, 2017 b).
382	Extraction of GLYLOID 3S involves heating and then rinsing in methanol to remove the colored material
383	prior to pH adjustment with citric acid. Citric acid is a weak acid and has no effect on the structure or
384 385	composition of the gum (Buckley, 2017b).
386	After extraction/purification, the polysaccharide is then dewatered, dried, pulverized, and sieved through
387	a screen (Buckley 2017a). The petitioner states that the dewatering process before drying separates the
388	methanol solution containing sodium citrate from the polysaccharides. The residual levels of methanol in
389	the tamarind seed gum product as reported by the petitioner are less than 50 ppm (Buckley, 2017b). More
390	information on safety is provided in <i>Evaluation Question #10</i> .

<sup>&</sup>lt;sup>1</sup> This may be by inclusion on a government or certification body list of permitted non-organic agricultural ingredients.

### 391 GLYATE

- Extraction of the GLYATE form of tamarind seed gum (polysaccharide) is done by treating the TKP with food-grade sulfuric acid until hydrolysis results in the desired viscosity. The solution is then neutralized using sodium hydroxide, after which it is sieved and rinsed in methanol (JHeimbach, 2014).
- 395396 Other Manufacturing Processes
- There are other manufacturing processes for tamarind seed gum described in the scientific literature that
   were not referenced in the petition. These other methods indicate a similar process to obtain the powdered
- kernel, but indicate a range of organic solvents that can be used to extract the polysaccharide.
- 400

In one process, tamarind seeds are roasted and the endosperm is pulverized, after which acetone is added to the TKP to remove oil and fat. The solution is stirred for 12 hours, after which it is filtered through filter paper and the filtrate is retained and dried. Distilled water is then added to the filtrate and the solution is boiled for 20 min at 80°C, stirred for 2 hours, and centrifuged for 60 minutes at 5000-8000 rpm to remove fiber and other residues. Finally, the supernatant is freeze dried (Nagajothi et al., 2017). A similar method was described in 2012 by Joseph et al., where the TKP is soaked in water and boiled, then filtered and

- was described in 2012 by Joseph et al., where the TKP is soaked in water and boiled, then filtered and
   added to an equal amount of acetone to precipitate the polysaccharide, followed by concentration and
   drying.
- 400 409

In another process hexane extraction is used for defatting TKP, after which the TKP is boiled in water with

411 0.2 percent citric acid or tartaric acid for 30-40 minutes and allowed to settle overnight. Following, the

412 supernatant is separated from the solution by decanting or siphoning off, and concentrated to 50 percent of

its volume by evaporation or vacuum. It may then be added to twice its volume of alcohol in order to

obtain a fibrous precipitate which is then filtered and dried (Marathe et al., 2002). The resultant product

- 415 may also be pulverized in a ball mill (Kumar and Bhattacharya, 2008).
- 416

In another method, tamarind kernel powder in cold, distilled water was poured into boiling distilled water
and boiled for 20 minutes with stirring in a water bath and then left to settle overnight. The solution was
then centrifuged and the supernatant washed with absolute ethanol, diethyl ether and petroleum ether,

420 after which it was dried under vacuum, ground and sieved (Mohamed, Mohamed, and Ahmed, 2015).

421

422 Joseph et al. (2012) described an enzymatic method in which the TKP is mixed with ethanol and treated

with the enzyme protease. Subsequently, it is centrifuged and the supernatant is again added to ethanol to

424 precipitate the gum, which is then separated and dried (Joseph et al., 2012). The authors note that the

purity of the tamarind seed gum is determined by the absence of the protein, which in the described
 process can denature, forming insoluble precipitates, thus making the separation of the gum more difficult

- 427 (Joseph et al., 2012).
- 428

A U.S. Patent granted in 1990 (Teraoka, 1990) for Shikibo Limited describes the organic solvent extraction
 process for obtaining tamarind seed polysaccharides utilizing alcohols such as methanol, ethyl alcohol,

431 propyl alcohol, especially isopropyl alcohol, and ketones such as acetone. This patent includes comparative

432 results of various extraction processes including not using any organic solvents. The patent provides

research findings on varying levels of extractant use in order to determine minimal level of extractantneeded to obtain the polysaccharide.

434 435

The JECFA report on tamarind seed polysaccharide (TSP) references the use of methanol, with additional
use of acid or alkali treatment (JECFA, 2017). Manchanda (2014) describes the use of either acetone or
absolute ethanol and absolute alcohol.

439

440 The first patents in the U.S. for extraction of polysaccharides from tamarind seeds were issued in the late

- 441 1960s. A patent from 1968 (Gordon, 1968) on behalf of Natural Dairy Product Corporation describes
- tamarind seed gum purification using a series of extractions, the first of which is with an organic solvent
- such as an alcohol, ketone, aldehyde or ether to dissolve and remove undesirable proteins and fats.
- 444 Isopropanol was identified as the preferred extractant. The resulting filtrate still contains some protein fat

and fiber of from the crude TKP, along with the polysaccharides. This filtrate is dried to prevent 445 446 degradation of the polysaccharides, after which it undergoes a water extraction with 25-35 times its weight of water, heated to 205°F. The polysaccharides are separated by filtration and recovered by roll drying or 447 alcohol precipitation. Use of roll drying requires the addition of a parting agent such as lecithin. However, 448 449 due to off flavors attributed to the added lecithin, the author recommended adding glycerol monostearate or polysorbitans as additional parting agents (Gordon, 1968). This process does not appear to be used in 450 451 current commercial manufacturing of tamarind seed gum. 452 453 Differing Perspectives on the Use of Ethanol vs. Methanol as an Extractant 454 Although Whistler and Burkalow (1993) suggest using ethanol or isopropanol to precipitate the soluble polysaccharide from TKP, the petitioner states that the use of ethanol or isopropanol in place of methanol 455 456 results in a darker color tamarind seed gum with higher levels of residual protein and fat, which impacts 457 its functionality and lowers its dispersability in water (Buckley, 2017b). One study compared extraction 458 methods using ethanol and an "Accelerated Solvent Extraction" in which methanol extraction was 459 followed by an ethanol extraction. The results showed that methanol extraction yielded pure tamarind seed gum, while the ethanol extraction contained additional components as measured by nuclear magnetic 460 461 resonance (NMR). Thus, the authors concluded that methanol should be the solvent used to extract TSP 462 (Chawananorasest, Saengtongdee, and Kaemchantuek, 2016). 463 Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a 464 465 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. 466 467 Chemicals are used in the extraction of TSP; specific chemicals and processes used in various manufacturing methods are described in *Evaluation Question 1*. Some of the chemical processes 468 described may be classified as non-synthetic or synthetic based on NOP Guidance 5033. 469 470 471 In the process described by the petitioner for the GLYLOID brand name product, the polysaccharide is not chemically modified during the purification processes described in *Evaluation Question 1*. In the 472 addendum to the petition, the petitioner explains that the purpose for the use of methanol as a solvent is to 473 remove water from the polysaccharide, which results in the polysaccharides self-associating into insoluble 474 475 clumps (Buckley, 2017b), or precipitating. This claim is supported by the literature, where alcohol is widely 476 cited for use in precipitating the polysaccharide (Marathe et al., 2002; (Joseph, et al. 2012; Gordon, 1968; Whistler and Barkalow 1993). Tamarind seed gum is insoluble in most organic solvents, including in 477 478 methanol, ethanol and acetone (Sidley Chemical Co., Ltd., 2013). Thus, processes employing these solvents, 479 where the filtrate is then filtered and/or dried, are expected to contain unmodified pure TSP with minimal 480 solvent residues. The solvents are removed such that they do not have a technical functional effect in the 481 final product. 482 483 The processes described for the GLYATE uses a strong mineral acid (sulfuric acid). Acid hydrolysis chemically modifies the polysaccharide; therefore, this form would be considered synthetic under NOP 484 485 Guidance 5033. 486 487 TSP is a naturally occurring storage polysaccharide in the endosperm of the tamarind tree seed, which is an 488 agricultural source. 489

# 490 <u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of non-synthetic or 491 natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

492

493 Non-acid-hydrolyzed tamarind seed gum may be classified as a non-synthetic agricultural material based
 494 on NOP Guidance 5033. However, acid-hydrolyzed forms (such as GLYATE) and/or forms that include
 495 synthetic additives (such as the patent process from 1968) would render the final product synthetic.

498 499 500	<u>Evaluation Question #4:</u> 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.
501 502	TSP is Generally Recognized As Safe. GRAS Notice Inventory No. 503 addresses the use of TSP as a
503	thickener, stabilizer, emulsifier and gelling agent in the following food categories: ice cream, sauces and
504	condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads
505	and fillings, flour products, soup, and all other food categories (JHeimbach LLC 2014). The FDA confirmed
506	having no questions on this Industry GRAS determination on August 12, 2014 (FDA 2014).
507	naving no questions on this industry civils determination on magast 12, 2011 (1 Dir 2011).
508	Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned
509	substance is a preservative. If so, provide a detailed description of its mechanism as a preservative
510	(7 CFR § 205.600 (b)(4)).
511	
512	The purpose of tamarind seed gum in food is to act as a stabilizer and thickener as defined in 21 CFR
513	170.3(o)(28). According to the regulations, these are "[s]ubstances used to produce viscous solutions or
514	dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and
515	bodying agents, setting agents, jellying agents, and bulking agents, etc." This definition does not include
516	the functional effects of a preservative.
517	
518	One of the notable uses of tamarind seed gum is in fruit jams, jellies, and preserves in place of pectin.
519	Processing fruit into these products is a form of fruit preservation. The degree of preservation, however, is
520	related to the water activity of the product, which is determined by the sugar content. As sugar binds to
521	water in food it is made unavailable for microbial growth (ACS, 2017). Thus, it is not the gelling – or
522	stiffness – of the gum or pectin that preserves the food, but the sugar. Jams and jellies can be made without
523	the use of pectin or any other gelling agent.
524	the use of peetin of any other genning agent.
525	Many of the functions of gums as food additives can result in extending shelf life of the products in which
526	they are used (Williams and Phillips, 2003). For example, tamarind seed gum used as a stabilizing agent of
527	ice crystals in frozen pastry products aids in shape preservation (Sidley Chemical Co., Ltd. 2013).
528	
529	Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or
530	improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)
531	and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600
532	(b)(4)).
533	
534	Tamarind seed gum is not added to food primarily to recreate flavors, colors, textures or nutritive values
535	lost in processing, although one of its functions as a food additive is to improve texture. The actions of
536	stabilizing, thickening, or gelling can all contribute to improving texture. However, none of the literature
537	reviewed for this report suggest that tamarind seed gum recreates texture quality that has been lost due to
538	processing.
539	
540	<b>Evaluation Question #7</b> : Describe any effect or potential effect on the nutritional quality of the food or
541	feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).
542	
543	The physiological and nutritional effects of ingesting tamarind seed gum occur during transit through the
544	stomach, small intestine, and colon where there is interaction among nutrients, enzymes, and mucosal
545	cells, and finally fermentation by the colonic microflora. Digestion of sugars and fats may change when
546	foods containing gums as food additives are ingested (Edwards, 2003).
547	
548	Tamarind seed gum's xyloglucan polysaccharide has the same molecular skeleton as cellulose, and like
549	cellulose, is not readily digested by enzymes found in the human digestive tract. It therefore serves as
550	dietary fiber (Picout et al., 2003). Intake of dietary fiber has numerous health benefits, including lowering
551	the risk for development of coronary heart disease, hypertension, stroke, diabetes, obesity, and certain
552	gastrointestinal diseases. It can also lower blood pressure and cholesterol levels (Koraym, Waters, and
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Williams, 2009). Literature has also suggested that xyloglucan oligosaccharides obtained via enzyme
hydrolysis may be used as a prebiotic food ingredient to foster intestinal bacteria fermentation (Mishra and
Malhotra, 2009).

556

Existing literature about gums' effect on mineral availability differs depending on whether the assessment
was done inside or outside of the organism. One reference noted that gums can decrease mineral
availability in the intestines, but that the effect of dietary fibers on mineral absorption in humans is still
unclear (Baye, Guyot, and Mouquet-River, 2015). This potential was suggested 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
- 566 mineral-binding effects of the fibers (Baye, Guyot, and Mouquet-River, 2015).
- 567

# Evaluation Question #8: 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)).

571

576

No reports of residues of heavy metals or contaminants in excess of FDA's tolerances have been identified
for tamarind seed gum, 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 tamarind seed gum (FDA,
2017).

- 577 The FDA response to the industry GRAS determination acknowledged the specifications for TSP, which 578 limit lead content to less than 2 mg/kg and arsenic to less than 1 mg/kg (FDA, 2014).
- 579 580 The GRAS notice states that the specifications set for GLYLOID 2A and 3S do not include limits for 581 mercury and cadmium. Nevertheless, the levels of these heavy metals were assessed and found to be 582 consistently below the detection level of 0.01 mg/kg. Methanol residues are also tested regularly and

consistently below the detection level of 0.01 mg/kg. Methanol residues are also tested regularly and
 consistently found to be under 50 mg/kg (ppm) (JHeimbach, 2014).

584

Information provided by petitioner, in response to questions from the NOSB, indicates non-detect levels of
 a wide array of agricultural pesticides in samples of GLYLOID 2A (Buckley, 2017 b).

587

588 Health Canada has proposed adding tamarind [seed] gum to its *List of Permitted Emulsifying, Gelling,* 

- 589 *Stabilizing or Thickening Agents.* In its rationale, the agency stated that "data was provided demonstrating 590 that tamarind gum can be manufactured, following good manufacturing practices, such that it consistently
- 591 meets the manufacturer's in-house specifications, including specifications for lead, arsenic, and microbial
- pathogens. These specifications are generally consistent with internationally-established specifications for
   many other food additives, including other plant-based gums" (Health Canada, 2017).
- 593 594
- 595 Tamarind seed gum is not presently listed in the Food Chemicals Codex (FCC).
- 596

597Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the598petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)599and 7 U.S.C. § 6517 (c) (2) (A) (i)).

600

The utilization and cultivation of tamarind trees has been cited as having beneficial environmental impacts.
 As a leguminous tree, tamarind can grow in poor soils due to its nitrogen-fixing ability and it also being

drought tolerant (Kumar and Bhattacharya, 2008). The trees are long-lived evergreens, providing a year-

- round soil cover. They store and recycle nutrients and help stabilize the soil. A mature tree may produce
- 605 330 to 500 pounds (150 to 225 kg) of fruit annually, of which seeds make up 33–40 percent. The fruit is
- 606 generally harvested during the dry season, giving farmers supplemental income in the off-season, which

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can discourage timber harvesting (Mahapatra and Tewari, 2005) or other land conversion such as slash and 607 608 burn for agriculture. The trees are widely cultivated throughout the tropics, and they readily spread and naturalize beyond their native range of Africa. They are not considered a species of concern for 609 conservation (Kew Science, 2017; Ranaivoson, 2014). In sub-Saharan Africa, tamarind trees reportedly 610 611 contribute to ecosystem stability and food security; however, planting rates are not high in that area. It has been suggested that the development of value-added tamarind products could help maximize the benefits 612 613 of tamarind trees and enhance their conservation in this area (Ebifa-Othieno et al., 2017). The economic 614 value obtained from the harvest of non-timber forest products such as tamarind has been noted for its 615 potential in sustainable forest management (Mahapatra and Tewari, 2005). In contrast, one research article attributes overexploitation of this species to causing a decline in the number and distribution of tamarind 616 617 trees within its native range of south western Madagascar (Ranaivoson, 2015). 618 619 The production of tamarind seed gum involves the use of processing aids including methanol, isopropanol, 620 sodium hydroxide and citric acid. The petitioner states that the production line is sealed, and the methanol used in the process is recovered through distillation and is then reused. The remaining solvent solution 621 containing sodium citrate is burned, producing water, CO<sub>2</sub> and ash. The petitioner maintains that 622 623 incinerator emissions are minimal and meet local standards for emissions (Buckleym 2017b). No sources 624 reviewed for this report discuss any environmental pollution resulting from the processing of tamarind 625 seeds into the purified polysaccharide. 626 627 In the environment, tamarind seed gum can be broken down via hydrolysis by enzymes of the Aspergillus 628 oryzae-niger group, as well as the cellulose decomposer Myrothecium verrucaria (Whistler and Barkalow, 629 1993). The by-products of this hydrolysis/degradation are smaller oligosaccharides, which can be further 630 metabolized by organisms present in the environment and do not pose ecological hazards. 631 Evaluation Question #10: Describe and summarize any reported effects upon human health from use of 632 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 633 634 (m) (4)). 635 636 Tamarind seed polysaccharides (TSPs), like other xyloglucans, are not digested by human digestive 637 enzymes and may be regarded as part of the dietary fiber portion of the diet (Yamatoya, 2000). Tamarind 638 seed gum is fermented by the intestinal microbiota, notably by clostridia bacteria (Hartmink, 1996). One report indicated that TSPs have a protective effect on liver functioning (Samal, 2014). 639 640 641 The possibility of allergic reaction to tamarind seed gum is negligible. The Health Canada proposal to 642 allow tamarind gum as a food additive (Health Canada, 2017) notes that research data indicate that 643 tamarind gum is not absorbed into the general circulation and there is no systemic exposure to it. The gum is broken and fermented by bacteria in the colon into individual sugars and short chain fatty acids, which 644 645 are normal constituents of the diet (Health Canada, 2017). 646 647 Tamarind seed polysaccharide (gum) was considered by the Joint FAO/WHO Expert Committee Food 648 Additives at its June 2017 meeting. The Committee noted the absence of toxicity in long-term rodent 649 studies and lack of concern regarding genotoxicity, reproductive toxicity and developmental toxicity. They therefore established the allowed daily intake as "not specified" for TSP. The Committee concluded that 650 651 the estimated dietary exposure of 75 mg/kg body weight per day based on proposed uses and use levels 652 does not present a health concern (JECFA, 2017). 653 654 The material safety data sheet for Tamarind Gum (tamarind seed Polysaccharide) published by TCI America does not indicate any carcinogenic or mutagenic concerns, but notes that information on toxicity 655 656 to humans has not been determined (TCI America, 2005). 657 658 Several toxicity studies of tamarind seed gum have been carried out on rodents. In one, rats were fed diets containing different levels of tamarind seed gum ranging from 0-120,000 ppm for 28 days. There were no 659 mortalities, no clinical or ophthalmological signs, no findings related to body weight gain, food 660 661 consumption, food efficiency, functional behavior or motor activity. There were initial decreases in body February 21, 2018

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weight gain and food consumption during the first week, but these recovered by the second week of
 tamarind seed gum administration and were considered to be likely due to reduced palatability. The No

- 664 Observed Adverse Effect Level (NOAEL) was determined to be the highest level administered: 120,000 665 ppm, which is equivalent to 10,597 mg/kg body weight for male rats and 10,691 mg/kg body weight for 666 female rats (Heimbach et al., 2013).
- 667

In a carcinogenicity study, mice were given tamarind seed gum at levels ranging from 0 to 5 percent of their diet for 78 weeks. Body weight declined in female mice given 1.25 percent or 5 percent gum after 34 weeks. However, there were no treatment-related clinical signs or adverse effects on food consumption, hematology measures, organ weights or survival rate. There were also no treatment-related increases in non-neoplastic or neoplastic lesions, leading the authors to conclude that tamarind seed gum is not carcinogenic in mice for either sex (Sano et al., 1996).

673 674

675 Potential Health Issues from Residual Chemicals Used in Processing of Tamarind Seed Gum

676 Methanol is one of several solvents that may be used in the extraction of tamarind seed gum. Methanol

677 occurs naturally in plants and animals, and is also a toxic alcohol that is, among other uses, an industrial

- solvent. Methanol poisoning occurs primarily as a result of ingesting contaminated food or beverages
- 679 (NIOSH, 2017). Inhalation and dermal or eye contact are other routes of exposure that can have adverse
- health effects. Methanol toxicity results from its being metabolized via alcohol dehydrogenase to
- formaldehyde and formic acid. Acute methanol poisoning can produce marked metabolic acidosis,
- hyperglycemia, cyanosis, respiratory failure, electrolyte imbalance, delayed onset of coma, impaired vision,
  and blindness (WHO, 2017). The prognosis in cases of methanol poisoning correlates with the amount of
  methanol ingested and resulting degree of metabolic acidosis. The minimum lethal dose of methanol in
  adults is believed to be 1 mg/kg of body weight (Korabathina, 2017). Based on the estimated dietary
  exposure of 75 mg tamarind seed gum per kg of body weight an assumed maximum residual 50 mg
  methanol per kg of the gum would result in an estimated daily exposure of 0.00375 mg methanol per kg of
  body weight from the consumption of tamarind seed gum. At this concentration methanol is considered
- 689 non-toxic (WHO, 2014).
- 690

691 The EPA Oral Reference Dose (RfD) for methanol is 0.5 milligrams per kilogram of body weight per day. 692 This number is an estimate (with uncertainty spanning perhaps an order of magnitude) of daily oral 693 exposure of a chemical to the human population (including sensitive subgroups) that is likely to be without 694 appreciable risk of deleterious effects during a lifetime. It is a reference point above which the potential risk 695 for adverse health effects increases. However, the EPA notes a lack of data on reproductive or 696 developmental toxicity, leading it to assign only medium confidence to the RfD (EPA, 2000).

697

698 21 CFR 173.250 establishes limits on methanol as an extraction residue in spice oleoresins: not to exceed 50 699 parts per million. It is also limited as an extraction residue in hops to a level not exceeding 2.2 percent by 700 weight, provided that the hops extract is added to the wort before or during cooking in the manufacture of 701 beer, and the label of the hops extract specifies the presence of methanol. Health Canada similarly limits 702 residues of methanol when used as an extraction solvent to 50 ppm in spice extracts and to 2.2 percent for 703 hops extract. In steviol glycosides, the maximum residual level permitted is 200 ppm, and for meat and egg 704 marking inks, processors are to adhere to good manufacturing practices (Health Canada 2016). In Europe, 705 methanol may be used as an extraction solvent during the processing of raw materials, of foodstuffs, of 706 food components or of food ingredients. Its residue is limited to 10 mg/kg for all uses and to 1.5 mg/kg 707 when used as an extractant of natural flavoring materials according to Directive 2009/32/EC, Annex 1, 708 Parts II and III. Methanol is a Class 2 Solvent according to USP-NF 467/ICH Q3C(R6) guidelines, meaning, 709 it is a solvent that should be limited in pharmaceutical applications due to its inherent toxicities. Its 710 permissible daily exposure in pharmaceuticals is 30 mg per day, and its concentration limit is 3000 ppm 711 (ICH, 2016).

711

Although FDA regulations do not include a legal limit on the maximum amount of methanol residue that

can remain in tamarind seed gum, the GRAS Notice for tamarind seed gum reported that methanol

715 716 717	residues are tested regularly and are consistently found to be under 50 mg/kg (ppm) (JHeimbach, 2014), which was accepted by the FDA.
718 719 720 721	Research indicates that TSPs are not soluble in organic solvents and that processing methods, as described in numerous references, indicate separation of polysaccharides from the organic solvents used during the purification process. If any residues remain they are not expected to exceed acceptable FDA levels.
722 723 724	<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).
725	A review of the literature did not provide any information describing alternative practices that would
726	render the use of gums such as tamarind seed gum unnecessary as a food additive for the purposes for
727	which it is presently approved in processed foods. Like other hydrocolloids, alone or in combination, it
728 729	functions as a thickener, stabilizer, emulsifier, and under certain conditions a gelling agent as described elsewhere in this report.
730	An alternative practice could be to make the product without the additive, resulting in products with
731	different consistencies and textures. Producers of processed organic foods could, in some instances, use
732	alternative substances, as discussed below in response to <i>Evaluation Question</i> 12 and <i>Evaluation Question</i> 13.
733 734 725	<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) 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 substance (7 U.S.C. § 6517 (c) (1) (A) (ii)).
735 736	substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).
737	As discussed previously, tamarind seed gum is derived from non-synthetic, natural sources and is also
738	classified as agricultural. It has numerous potential alternatives, some of which are non-synthetic and
739	many are also agricultural. The availability of agricultural alternatives in certified organic form will be
740 741	discussed in <i>Evaluation Question 13</i> .
742 743 744	The National List includes the following allowed substances which, separately or in combination, may be alternatives or substitutes to tamarind seed gum:
745	§205.605(a) Nonagricultural, non-synthetic
746	Agar-agar
747	Carrageenan
748	<ul> <li>Gellan gum – high acyl form only</li> </ul>
749	
750	§205.605(b) Nonagricultural, synthetic
751 752	• Xanthan gum
753	§205.606 Nonorganic, agricultural
754	• Gelatin
755	• Gums – water extracted only (Arabic; guar; locust bean; and carob bean)
756	Konjac flour
757	Lecithin (de-oiled)
758	Pectin (non-amidated forms only)
759	Cornstarch (native)
760	Sweet potato starch-for bean thread production only
761	Tragacanth gum
762	
763	Tamarind seed gum is the only xyloglucan available for commercial use (Wustenberg, 2015; Cui, 2005),
764	however there are numerous other natural hydrocolloids that could potentially be substituted for tamarind

seed gum. 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 767 768 supply. Therefore, starches, which are very economic, are the most commonly used thickening agents, and 769 corn starch, tapioca, wheat arrowroot and rice starches are all available in organic forms. However, 770 starches do not provide the same function as the hydrocolloid gums. For example, tamarind seed gum 771 imparts a viscosity similar to that of starch, however, its viscosity does not deteriorate in the presence of 772 acids, bases, salts and heat like starch does (Sidley Chemical Co. Ltd., 2013). One study evaluated the 773 influence of TSP on the rheological properties and thermal stability of tapioca starch. It found through 774 different mixing ratios of the two substances, peak and final viscosities were greater for mixes with higher 775 TSP proportions. Heat stability was improved over that of pure tapioca starch and water separation was 776 lower than for pure TSP (R. Pongsawatmanit et al., 2006). 777 778 Gelatin is derived from partial hydrolysis of collagen fibers extracted from the bones and other body parts 779 of domesticated animals, such as beef cattle. It is by far the most common gelling agent, but, with 780 increasing demand for non-animal products, in particular due to the bovine spongiform encephalopathy 781 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 tamarind seed 782 783 gum in combination with gellan gum, but the latter can withstand higher temperatures (Williams and 784 Phillips, 2003). 785 786 Other gums may serve as alternatives to tamarind seed gum. Tamarind seed gum has similar solution 787 properties to those of galactomannans (Nitta 2005) such as locust bean gum and guar gum. However, guar 788 gum is superior to tamarind seed gum in dispersion and suspension: it is readily soluble in cold water, 789 whereas tamarind seed gum takes longer to achieve full viscosity. On the other hand, tamarind seed gum 790 has better thermal stability than guar gum and also tolerates higher pH conditions (Chemtotal Pty Ltd., 791 2017). 792 793 Tamarind gum was compared with guar gum and xanthan gum and found to be at least as effective in 794 maintaining viscosity. Data for some of the tests measuring acid resistance and freeze-thaw resistance 795 showed that tamarind gum could be more effective (Health Canada, 2017). 796 797 Tara gum is another potential alternative. Tara gum is derived from the endosperm of the seeds of 798 *Caesalpinia spinosa (leguminosae),* a shrub/small tree growing wild in Peru. Tara is a high molecular 799 galactomannan, with similar cold water solubility to guar gum and similar thickening characteristics. It is 800 odorless and tasteless compared with guar gum, improves shelf life of products, and has a smoother, less 801 slimy texture (Silvateam, 2017). 802 803 Konjac mannan is a soluble extract of konjac flour made from a dried tuber (Amorphophallus konjac) used in 804 Japan to make noodles and konnyaku for use in traditional dishes and desert jelly. It is a glucomannan. It 805 can be combined with xanthan gum to increase gel strength in kappa-carrageenan gels (Williams and 806 Phillips, 2003). 807 808 Xanthan gum is of microbial origin and, as another glycosyl-branched cellulosic polysaccharide, has been 809 shown to have an extremely stiff molecular structure and is considered a weak gel. (Gidley et al., 1991). 810 Although the length of tamarind seed xyloglucans is relatively high for polysaccharides, it is much lower 811 than that of xanthan gum's polysaccharide length (Nishinari, Takemasa, et al., 2007) and thus it is relatively 812 flexible as compared to xanthan gum's chains (Picout, et al. 2003) (Nishinari, Takemasa, et al., 2007). 813 814 Pectin is another alternative to tamarind seed gum; tamarind seed gum has been widely suggested as an 815 alternative to pectin in making fruit jams, jellies and preserves. Differences between tamarind seed gum 816 and pectin have been widely described. Fruit pectins degrade with boiling, falling to one-third of their 817 original gelling value after one hour of boiling (Kumar and Bhattacharya, 2008). Tamarind polysaccharides, 818 however, do not lose their gelling ability due to boiling in neutral aqueous solutions, even for long periods 819 (Kumar and Bhattacharya, 2008). Unlike fruit pectin, tamarind seed gum can gel at a neutral pH (Marathe,

0 1	et al., 2002). Tamarind seed gum is also said to show less syneresis, or weeping, than fruit pectins (R. Whistler, 1973).
2	
3	Mohamed, Mohamed and Ahmed (2015) compared two tamarind seed gum extracts, from light brown and
-	dark brown seeds, to pectin. They found the former to have higher intrinsic viscosity and molecular weight
	than that of pectin. They reported that the TSPs form gels over a wide range of pH in the presence of
	sucrose without acid and base, while commercial pectin forms gels over a narrow (acidic) range of pH in
	the presence of sucrose. The protein levels in polysaccharide were higher than those in pectin but did not
	inhibit gel formation (Mohamed, Mohamed, and Ahmed, 2015).
	Viscosity
	The GRAS Notice (JHeimbach, 2014) compares the viscosity of TSP with xanthan gum, guar gum, locust
	bean gum, and gum arabic. The comparison indicates that TSP exhibits moderate viscosity with a linear
	dependence on concentration, and its viscosity is negatively correlated with temperature and is
	independent of the intensity of shear or stirring force (JHeimbach, 2014). Graphs showing comparisons
	with other gums for properties such as viscosity are also provided in the petition (Buckley, 2017).
	The viscosity of tamarind seed gum xyloglucan is relatively high compared to that of gums with the same
	contour length due to its self-aggregation (Nishinari, Takemasa, et al., 2007). Xyloglucans have been
	reported to have a molecular chain persistence length of 6-8 nm, which is slightly larger than that of
	cellulose and its derivatives. The stiffness of its chains is greater than that of galactomannan chains as
	found in locust bean and guar gums, but, as noted above, is relatively flexible compared xanthan gum. It's relatively higher viscosity is also due to the polysaccharide's molecular side chains, which makes it more
	rigid than that of other neutral polysaccharides. Its rigidity is comparable to that of alginates that have a
	ribbon-like structure stiffened by mutual electrostatic repulsion between adjacent residues (Gidley et al.,
	1991). Guar gum, another branched polysaccharide has a moderately stiff backbone and is described as
	having rheological properties of a simple entanglement solution (Gidley et al., 1991). Tamarind xyloglucans
	behave as linear flexible to semiflexible random coil polysaccharides (Picout et al., 2003) (Nishiniari et al.,
	2007).
	Flow
	Tamarind seed gum is similar to the galactomannans locust bean and guar gum in exhibiting consistent
	flow behavior at low concentrations and shear thinning flow behavior at higher concentrations (ca. >0.5%

w/w). Their dynamic rheological properties are similar to those of random coil polysaccharides (Cui,
2005).

854 855

856 Stabilizer

Tamarind seed gum has been found to be comparable to tragacanth, arabic, and karaya gums in stabilizing oil emulsions (R. Whistler, 1973). Comparative stability studies have been undertaken using gum acacia as a standard emulsifying agent. TSP was found to be more effective as a stable emulsifying agent in

- 860 comparison to gum acacia (Manchanda, 2014).
- 861
- 862 Other Properties

863 The sugar-induced gels of tamarind seed gum xyloglucan have high elasticity and display good water

- holding properties (Cui, 2005). These and its stability to heat, acids and shear have all been noted as unique
   to this polysaccharide (Mishra and Malhotra, 2009). Another defining characteristic of tamarind seed gum
- to this polysaccharide (Mishra and Malhotra, 2009). Another defining characteris
   as compared to other gums is its non-threading (Sidley Chemical Co. Ltd., 2013).

#### an of much only on hotelesson to 868

Table 2. Comparison of properties between tamarind seed gum and other gums on §205.605-606.						606.	
Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only	Moderate	Х					
becomes viscous at	viscosity						
concentrations							
greater than 50%)							
High Viscosity at 1 %			Х				
concentration							
High Viscosity at low						Х	Х
concentrations (but							
above 1%)							
Viscosity remains	Х		Х				
unchanged over time							
at low shear rates							
Viscosity decreases				Х			
over time at low							
shear rates							
Forms thermo-						Х	
reversible gels							
Thermally reversible						Х	Х
Thermally			Х		Х		
irreversible							
Insoluble in ethanol	Х	Х	Х	Х	Х	Х	Х
Stable under acid	Х		Х	Х	Х		Х
conditions							
Controls syneresis	Х			Х	Х		Х
(weeping)							

869

870 The relationship between polysaccharides and their rheological behavior is becoming better understood 871 (Mishra and Malhotra, 2009), opening the door to optimization of their functional properties through

872 different combinations, proportions and conditions. As Williams and Phillips (2003) noted, mixtures of

873 gums are commonly used to impart novel textural characteristics to food products. Thus, tamarind seed

874 gum either alone or in combination with other gums can impart novel characteristics to processed food.

875

#### 876 Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for 877 the petitioned substance (7 CFR § 205.600 (b) (1)).

878

879 Agricultural substances that can be used as alternatives to tamarind seed gum in food processing

880 applications include gums on the National List, and, in certain applications, pectin, starch and konjac flour,

881 which are also on the National List at § 205.606. Water-extracted gum arabic, guar gum, locust bean/carob

bean gum are permitted in non-organic form as ingredients in or on processed products labeled as 882

883 "organic" when not commercially available in organic form, per § 205.606(g). The discussion in *Evaluation* 

*Question 12,* comparing tamarind seed gum to these alternatives also applies to the same substances in 884

885 organic form. At the time of this report, the NOP Organic Integrity Database lists sources of organic locust

886 bean gum, gum arabic/acacia gum, karaya gum, guar gum, tara gum, and konjac gum (NOP, 2017).

887 However, little information was found as to whether the commercially available quantities would meet market demand. 888

889

890 No sources of organic tamarind seed gum or organic TSP are identified in the NOP Organic Integrity

891 Database. Tamarind trees are widely cultivated in the tropics worldwide and can be certified organic. At

892 the time of this report, there are nine sources of organic tamarind (fruit) and one source of tamarind

893 powder listed in the NOP Organic Integrity Database (NOP 2017). However, the processing aid methanol

894 used in the manufacture of tamarind seed gum does not appear on the National List at § 205.605, thus it

may not be possible under current regulations to process TKP from certified organic tamarind tree seeds 895 896

into certified organic tamarind seed gum. February 21, 2018

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907 908 909 910 911	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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