

# Alginates

## Handling/Processing

### Identification of Petitioned Substance

|    |  |
|----|--|
| 24 |  |
| 25 | <b>Trade Names:</b><br>Protanal<br>Protanal Ester<br>Profoam   |
|    | <b>CAS Numbers:</b><br>9005-34-9 (Ammonium alginate)<br>9005-35-0; 9019-42-5; 9019-43-6; 9060-20-2; 37228-92-5 (Calcium alginate)<br>9005-36-1 (Potassium alginate)<br>26 9005-37-2 (PGA)<br>9005-38-3 (Sodium alginate) |
|    | <b>Other Codes:</b><br>E401 (Sodium Alginate)<br>E402 (Potassium alginate)<br>E403 (Ammonium alginate)<br>E404 (Calcium alginate)<br>E405 (PGA)<br>130239 (HS Code: PGA)   |

### Summary of Petitioned Use

Classified as a synthetic substance, alginates are currently listed at 7 CFR Section 205.605(b) as nonagricultural (nonorganic) substances that are allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (USDA National Organic Program 2014). This technical report covers ammonium, calcium, potassium, and sodium alginate and propylene glycol alginate (PGA). Although the 1995 Technical Advisory Panel (TAP) Report did not include PGA (Taylor and Theuer 1995), because PGA is FDA approved as a food ingredient (21 CFR §172.858), it is included in this technical report. At the time of this report, no organic products were found that contained PGA as an ingredient.

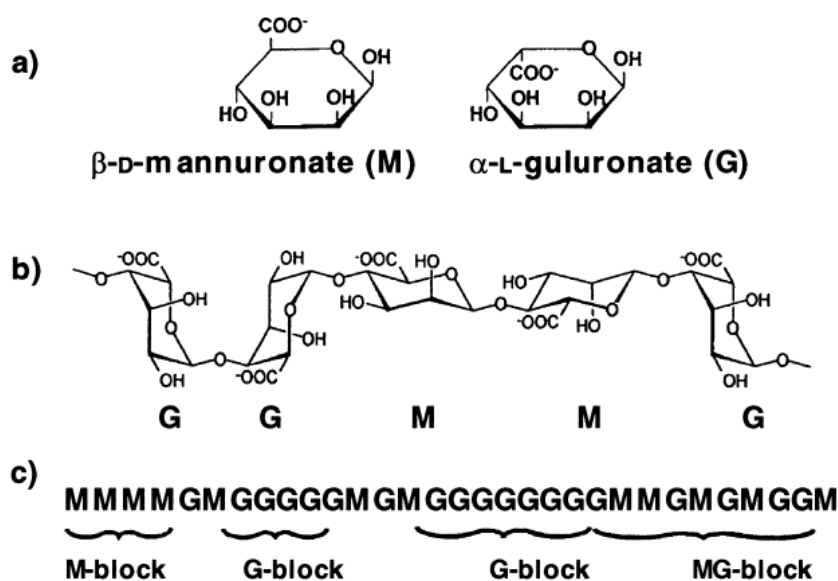
### Characterization of Petitioned Substance

#### Composition of the Substance:

Alginates are complex carbohydrates known as polysaccharides. These carbohydrate polymers are derived from brown seaweeds of the Class *Phaeophyceae* (Pawar 2012, Holdt and Kraan 2011, Mabeau and Fleurence 1993). Phycocolloid is another term for polysaccharides (e.g., agar, alginates and carrageenan) that are derived from seaweeds (Zemke-White and Ohno 1999). Similar to the structure forming components of cellulose in terrestrial plants, alginates give brown algae, including brown seaweed species, both mechanical strength and flexibility (Draget, Smidsrød and Skjåk-Bræk 2005). The main cell wall components of seaweed are anionic polysaccharides: alginates and fucoidans (Michel, et al. 2010). Algal polysaccharides differ from cellulose in their high sulfate group content, high solubility in water and high content of ionic groups (Alves, Sousa and Reis 2013). The algin found in brown algae is present as a mixed salt (sodium and/or potassium, calcium, magnesium) of alginic acid (McHugh 2003). Alginates are

53 derivatives of alginic acid. Alginate is the conjugate base of alginic acid. Through processing, the water  
 54 insoluble alginic acid is extracted and various water-soluble alginates can be produced (McHugh  
 55 2003). When extracted from the cell walls of brown algae, alginate forms a gum that is used by the food  
 56 industry to increase viscosity, as a food thickener and stabilizer, and as an emulsifier (McHugh 2003).  
 57

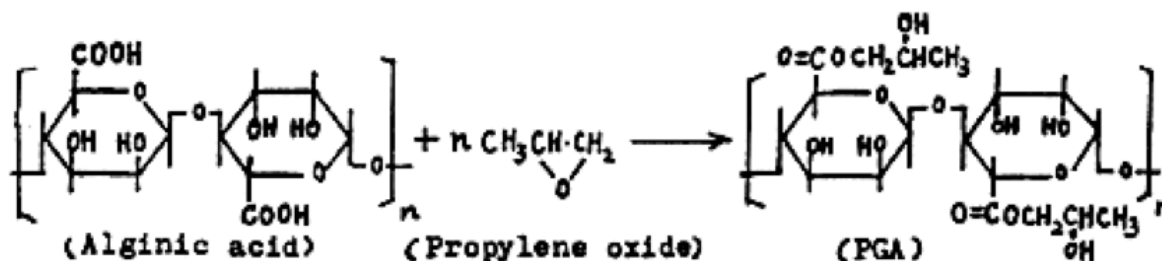
58 Polysaccharides are polymers consisting of chains of carbohydrates joined together by glycosidic bonds.  
 59 Alginates are comprised of two uronate sugars and the salts of mannuronic and guluronic acid derived  
 60 from alginic acid (Pawar 2012). During extraction of alginates from harvested seaweed, the uronic acids are  
 61 converted into the salt forms mannuronate (M) and guluronate (G) through a neutralization step (Pawar  
 62 2012). Alginate is a block copolymer composed of long chains of M or G blocks. These blocks can be  
 63 homogeneous (GG, MM) or heterogeneous (MG, GM) (Draget, Smidsrød and Skjåk-Bræk 2005). Figure 1  
 64 illustrates the chemical structure of alginate and demonstrates how G and M blocks connect in sequence  
 65 (Draget, Smidsrød and Skjåk-Bræk 2005). The proportion, distribution and length of the block types  
 66 determine the chemical and physical properties of the alginate, such as the relative stiffness or flexibility of  
 67 the gels formed in the presence of metallic ions (salts) (Yang, Ying-Jian and Wen 2011).  
 68



69  
 70  
 71 **Figure 1.** Structural characteristics of alginates: a) alginate monomers, b) chain conformation, c) block  
 72 distribution (Draget, Smidsrød and Skjåk-Bræk 2005).  
 73

74 **Propylene glycol alginate:**

75 Propylene glycol alginate (PGA) is an ester of alginic acid (World Health Organization 1997) where some of  
 76 the carboxyl groups are esterified with propylene glycol, some are neutralized with an appropriate alkali,  
 77 and some remain free. Figure 2 illustrates the reaction of propylene oxide and alginic acid to form PGA  
 78 (World Health Organization 1997). Used as an emulsifier, thickener and stabilizer in food applications,  
 79 PGA is functional in acidic conditions (Draget, Smidsrød and Skjåk-Bræk 2005).



80  
 81 **Figure 2.** Propylene glycol alginate is formed from the reaction of propylene oxide with alginic acid (World  
 82 Health Organization 1997).

83  
 84 **Source or Origin of the Substance:**  
 85  
 86 Marine algae and brown seaweeds such as kelp contain large amounts of polysaccharides that are extracted  
 87 by the hydrocolloid industry: alginate from brown seaweeds, and carrageenan and agar from red seaweeds  
 88 (Holdt and Kraan 2011, Mabeau and Fleurence 1993). Table 1 illustrates the variety of polysaccharides  
 89 present in different types of seaweed and their functional role in the plant. Seaweed species are classified  
 90 based on their photosynthetic pigments and vary by polysaccharide constituents and cell wall biology  
 91 (Alves, Sousa and Reis 2013). Comprising up to 40% of the dry matter of algae, alginate is the structural  
 92 component in the cell walls of these marine plants (Draget, Smidsrød and Skjåk-Bræk 2005). Alginates  
 93 occur naturally in seaweed mainly in the form of sodium, potassium, calcium and magnesium salts of  
 94 alginic acid (Saltmarsh, Barlow and eds. 2013). “Extraction involves ion exchange in an alkaline medium  
 95 followed by precipitation, purification, recovery of alginic acid and conversion to the appropriate salt”  
 96 (Saltmarsh, Barlow and eds. 2013). For example, ammonium alginate is the ammonium salt of alginic acid;  
 97 potassium alginate is the potassium salt of alginic acid; sodium alginate is the sodium salt of alginic acid  
 98 (World Health Organization 1997).

99  
 100 Alginates also occur as capsular polysaccharides (exopolysaccharides) in soil bacteria, including  
 101 *Pseudomonas aeruginosa* (Draget, Smidsrød and Skjåk-Bræk 2005, Pawar 2012). While alginates can be  
 102 derived from bacteria and algae, commercially available alginates are currently only derived from algae.  
 103 Alginates are extracted from multiple brown seaweed species: *Ascophyllum*, *Macrocystis*, *Lessonia*, *Durvillea*,  
 104 *Ecklonia*, *Sargassum* and *Laminaria* (Saltmarsh, Barlow and eds. 2013, Pawar 2012). The majority of  
 105 commercially produced alginates are extracted from cultivated brown seaweeds with an estimated annual  
 106 production of 30,000 metric tons (Hay, Rehman and Moradali, et al. 2013).

107  
 108 **Table 1.** Polysaccharides derived from seaweeds (Mabeau and Fleurence 1993).

| Seaweed Type                              | Cell-Wall polysaccharides   | Storage polysaccharides    |
|---|---|----------------------------|
| Brown Seaweeds<br>( <i>Phaeophyceae</i> ) | Alginate (guluronic acid,<br>mannuronic acid);<br>Fucans (sulfated fucose)        | Laminarin (glucose)        |
| Red Seaweeds<br>( <i>Rhodophyceae</i> )   | Carrageenans<br>(galactose, sulfate);<br>Agar (galactose);<br>Cellulose;<br>Xylan | Floridean starch (glucose) |
| Green Seaweeds<br>( <i>Clorophyceae</i> ) | Cellulose;<br>Xylan; Mannan;<br>Glucuronoxylorhamnan (sulfated)                   | Starch                     |

109  
 110 The wide industrial application of the three main phycocolloids – agar, alginates and carrageenan – is based  
 111 on their particular properties to form gels in aqueous solution (Zemke-White and Ohno 1999).  
 112 Phycocolloids are hydrophilic, which means water loving (Khotimchenko, et al. 2001). In water,  
 113 phycocolloids swell, causing the solution to thicken and increasing its viscosity (Khotimchenko, et al. 2001).  
 114 Approximately 101 species of seaweed are used for phycocolloid production as a source of agar, alginate  
 115 and carrageenan (Zemke-White and Ohno 1999). Phycocolloid content varies between species, and  
 116 according to growing season and environmental conditions. Table 2 presents the seaweed species used for  
 117 alginate production and the countries in which they are cultivated. Of the species in the class of brown  
 118 seaweeds, *Phaeophyceae*, 41 species are used for extracting alginates (Zemke-White and Ohno 1999).

119  
 120 **Table 2.** Seaweed species in the class *Phaeophyceae* that are used for alginate production and the country  
 121 where each species is predominately grown. Adapted from (Zemke-White and Ohno 1999).

| Species                     | Country             |
|-----------------------------|---------------------|
| <i>Ascophyllum nodosum</i>  | Ireland, Norway, UK |
| <i>Cystoseira barbata</i>   | Egypt               |
| <i>Durvillaea potatorum</i> | Australia           |

|   |                            |
|---|----------------------------|
| <i>Fucus serratus</i> , <i>F. vesiculosus</i>   | Ireland                    |
| <i>Laminaria digitata</i>   | France, Ireland            |
| <i>Laminaria hyperborea</i>   | Ireland, Norway, Spain, UK |
| <i>Laminaria japonica</i>   | China                      |
| <i>Laminaria ochroleuca</i>   | Spain                      |
| <i>Lessonia nigrescens</i>  | Chile, Peru                |
| <i>Lessonia trabeculata</i>   | Chile                      |
| <i>Macrocystis integrifolia</i>   | Peru                       |
| <i>Sargassum crassifolium</i> , <i>S. gramminifolium</i> ,<br><i>S. henslowianum</i> , <i>S. mcclurei</i> , <i>S. siliquosum</i> ,<br><i>S. vachelliannum</i> | Vietnam                    |
| <i>Sargassum ilicifolium</i> , <i>S. myriocystum</i> , <i>S. wightii</i> ,<br><i>Turbinaria conoides</i> , <i>T. decurrens</i> , <i>T. ornata</i>             | India                      |
| <i>Sargassum polycystum</i>   | Indonesia, Thailand        |

122

123 **Properties of the Substance:**

124

125 The physical and chemical properties of alginates render them useful in many food and industrial  
126 applications. These characteristics include: ability to retain water and water-holding capacity; gelling,  
127 viscosifying and stabilizing properties; emulsifying properties; and temperature-independent sol/gel  
128 transition in the presence of divalent cations, such as calcium (Draget, Smidsrød and Skjåk-Bræk 2005).  
129 Alginates bind easily with water and can produce high viscosity thickeners at low levels.

130

131 The chemical composition and resulting physical properties of an alginate varies according to seaweed  
132 species, structure and environmental conditions. "For example, some [species] may yield an alginate that  
133 gives a strong gel, another a weaker gel; one may readily give a cream/white alginate, another may give  
134 that only with difficulty and is best used for technical applications where colour does not matter" (McHugh  
135 2003). Growing environments are influential as well; the ion composition of alginates is determined by the  
136 ion-exchange equilibrium with the seawater in which the algae plant grew (Pawar 2012). Another example,  
137 the amount of guluronate present in an alginate, is dependent on the seaweed sourced: the species, age at  
138 harvest, geographic location of harvest and plant part extracted (Fett and Wijey 1995).

139

140 **Physical:**

141 Alginate salts are odorless, white to yellowish-brown powders. Alginates have no discernable flavor.

142 Forming a viscous, colloidal solution, the salts of alginic acid formed with monovalent cations are soluble in  
143 water [sodium alginate, potassium alginate, ammonium alginate] (Kimica 2009). As a 1% solution, the  
144 resulting pH is between 5.0-7.5 (FMC BioPolymer 2006). Sodium alginate does not have a boiling or melting  
145 point. At temperatures greater than 392°F (>200°C), sodium alginate will auto ignite.

146

147 Alginates are block copolymers comprised of two uronic acids, mannuronic acid (M block) and guluronic  
148 acid (G block), of varying composition and sequence (Yang, Ying-Jian and Wen 2011). There is a correlation  
149 between the arrangement of the uronic acid blocks and the age of the plant and conditions of growth. The  
150 leaves of the same algae, *L. hyperborea*, have a very high content of guluronic acid when the plant grows in  
151 exposed coastal areas, compared to a lower G-content when the leaves float in placid waters (Draget,  
152 Smidsrød and Skjåk-Bræk 2005).

153

154 **Chemical:**

155 The solubility of alginates is influenced by the total ionic strength of the solution, the free calcium  
156 concentration, and pH of the solvent (van den Brink, et al. 2009). Sodium, potassium and ammonium  
157 alginates are soluble in hot and cold water (Saltmarsh, Barlow and eds. 2013, Kimica 2009). Table 3 outlines  
158 the solubility of different types of alginates in various solutions (Kimica 2009). Alginates formed with  
159 divalent cations are insoluble; calcium and magnesium alginates do not dissolve in water (McHugh 2003),  
160 but will swell when placed in water (Khotimchenko, et al. 2001). Ammonium, potassium and sodium  
161 alginates are insoluble in ethanol and ether (World Health Organization 1997). Calcium alginate is slightly  
162 soluble in ethanol and will dissolve slowly in sodium polyphosphate and sodium carbonate (World Health

163 Organization 1997). Alginates selectively bind with divalent cations, especially calcium, making them  
 164 insoluble in high calcium solutions such as milk or hard water with high calcium content (Table 3) (Draget,  
 165 Smidsrød and Skjåk-Bræk 2005). All of the alginate types listed in Table 3 are insoluble in fats, oils and  
 166 organic solvents (Kimica 2009).

167  
 168 Alginates exhibit limited solubility at low pH. The soluble alginates will not hydrate in highly acidic  
 169 systems (pH < 4-5). In more acidic conditions, alginic acid precipitates out of solution. The precipitation of  
 170 alginic acid is caused by an abrupt decrease in pH below the pKa value of the alginate (Draget, Smidsrød  
 171 and Skjåk-Bræk 2005). Alginates with an alternating, heterogeneous structure (MG blocks) precipitate at  
 172 lower pH compared with alginates containing a more homogeneous block structure (MM and GG) (Draget,  
 173 Smidsrød and Skjåk-Bræk 2005). Alginates are stable in alkaline conditions up to a pH of 10, beyond which  
 174 depolymerization occurs (Saltmarsh, Barlow and eds. 2013).

175  
 176 Alginate forms chemically induced gels (Truong, Walter and Giesbrecht 1995). The gel network is formed  
 177 by inter-molecular association of divalent cations, such as calcium, with the polyguluronate sites of the  
 178 alginate molecule (Truong, Walter and Giesbrecht 1995). The cross-linking between carboxyl groups and  
 179 divalent cations is the basis for gel formation (Draget, Smidsrød and Skjåk-Bræk 2005). Therefore, the  
 180 sol/gel transition of alginates is not temperature dependent. Alginate gels can also be heated without  
 181 melting (Draget, Smidsrød and Skjåk-Bræk 2005).

182  
 183 **Table 3.** The solubility of alginates in various conditions (Kimica 2009).

| Type of Alginate   | Acidic Conditions<br><i>Fruit juice, Liquor, Salad dressing, etc.</i> | Alkaline conditions<br><i>Kansui, etc.</i> | In solution with divalent cations<br><i>Hard water, milk, etc.</i> |
|--------------------|---|--|--|
| Alginic acid       | Insoluble   | Soluble                                    | Insoluble  |
| Sodium alginate    | Insoluble   | Soluble                                    | Insoluble  |
| Potassium alginate | Insoluble   | Soluble                                    | Insoluble  |
| Calcium alginate   | Insoluble   | Insoluble                                  | Insoluble  |
| Ammonium alginate  | Insoluble   | Soluble                                    | Insoluble  |
| PGA                | Soluble   | Soluble*                                   | Soluble  |

184 \* In neutral and alkaline conditions, PGA decomposes and forms an alginate salt.

185  
 186 **Propylene glycol alginate:**

187 Propylene glycol alginate is a white to yellowish brown substance that can be produced in filamentous,  
 188 grainy, granular or powdered forms (FoodChem International Corporation 2014). Like alginates, PGA is  
 189 soluble in water and will result in a viscous, colloidal solution (World Health Organization 1997). In a 1%  
 190 solution, the pH ranges from 3.0-4.5 (FoodChem International Corporation 2014). Depending on the degree  
 191 of esterification, which can be ≥80%, PGA is soluble in up to 60% aqueous ethanol (FoodChem International  
 192 Corporation 2014). Most alginates exhibit limited solubility at low pH, but PGA is used as a food stabilizer  
 193 under acidic conditions because PGA is soluble at a low pH (Draget, Smidsrød and Skjåk-Bræk 2005).

194  
 195 **Specific Uses of the Substance:**

196  
 197 In 1881, alginic acid was first isolated and named by a Scottish scientist, Dr. E.C.C. Stanford (K. Draget  
 198 2009). Since then, alginic acid and its derivatives have been utilized as a hydrocolloid in a variety of  
 199 applications such as food additives, pharmaceuticals, cosmetics and textile manufacturing (Kimica 2009).

200  
 201 Alginates are the most widely produced polysaccharide (Brownlee, et al. 2005). They are used in food  
 202 production and handling as an emulsifier or emulsifier salt, firming agent, flavor enhancer or flavor  
 203 adjuvant, formulation aid, processing aid, stabilizer or thickener, surface-active agent and texturizer  
 204 (Truong, Walter and Giesbrecht 1995). Alginates are used in food applications at levels ranging from 0.5-  
 205 1.5% (Brownlee, et al. 2005). "Given the large number of different applications, alginates must be regarded  
 206 as one of the most versatile polysaccharides" (Draget, Smidsrød and Skjåk-Bræk 2005). Table 4 outlines the  
 207 major uses of alginates in food products as a percentage of total production.

208

209 Alginates are used to extend product shelf life and reduce risk of pathogen growth on food surfaces (Rößle,  
210 et al. 2011). Alginates are used as carriers of active or functional food ingredients (e.g., anti-browning  
211 agents, colorants, flavors, nutrients, spices, antimicrobial compounds) (Rößle, et al. 2011). As components of  
212 edible coatings or films, alginates act as a protective barrier to retard food spoilage and extend the  
213 effectiveness of an active ingredient (Datta, et al. 2008). Alginates are used in solid foods “to prevent water  
214 loss, syneresis<sup>1</sup> and phase separation” (Saltmarsh, Barlow and eds. 2013). As selective barriers to moisture,  
215 oxygen, lipid oxidation and loss of volatile aromas and flavors, edible films increase the functionality of  
216 fresh-cut, pre-packaged fruits (Rößle, et al. 2011). Fresh apple wedges coated with alginate resulted in better  
217 retention of polyphenolic compounds than the uncoated wedges (Rößle, et al. 2011). Starch-alginate (SA)  
218 coatings are used to inhibit lipid oxidation and the formation of a “warmed-over flavor” in pre-cooked  
219 meats (Wu, et al. 2001). The barrier properties of SA-films improved with the addition of stearic acid.  
220 Starch-alginate-stearic acid (SAS) coatings were more effective in prohibiting moisture loss than lipid  
221 oxidation (Wu, et al. 2001).

222  
223 Calcium alginate gels combined with antimicrobial agents have been used to preserve a wide variety of  
224 food products. When compared to the application of the antimicrobial agents alone, the use of the edible  
225 coating, calcium alginate gel, retained the effectiveness of two antimicrobial agents, nisin and oyster  
226 lysozyme, against *Listeria monocytogenes* and *Salmonella anatum* by 35 days (Datta, et al. 2008). Lactic acids  
227 added to calcium alginate gels reduced *L. monocytogenes* populations on lean beef tissue more than the acid  
228 treatment alone (Siragusa and Dickson 1992). The ability of alginates to instantly form gels, skins and fibers  
229 renders them useful for restructured foods (onion rings, pet-food chunks). Sodium alginate is commonly  
230 used as a stabilizer of ice cream to control the formation of ice crystals and improve flavor (Saltmarsh,  
231 Barlow and eds. 2013). Sodium alginate impedes the movement of water during melt/freeze cycles, thereby  
232 preventing the formation of ice crystals and fat clump growth in frozen products (Saltmarsh, Barlow and  
233 eds. 2013). Alginates are also used in many dairy products to prevent the attachment of food and packaging  
234 materials to foods such as refined cheese and cream cheese.

235  
236 Sodium, potassium and ammonium alginates are soluble in cold water; these salts can be used  
237 interchangeably in food products for thickening, gelling, stabilizing, formation of films and controlled  
238 release applications (Saltmarsh, Barlow and eds. 2013). Their ability to make gels without the use of heat  
239 distinguishes alginates from other hydrocolloids that require high-temperature processes (i.e., gelatin, agar,  
240 carrageenan, locust bean gum). Alginates are useful when using heat sensitive ingredients (flavors, instant  
241 mixes).

242  
243 Some examples of typical products that utilize alginates include sauces, salad dressings, desserts, fruit  
244 preparations, ice cream and water ices, onion rings, low-fat spreads, bakery filling creams, fruit pies, flavor  
245 capsules, icing and frostings (Saltmarsh, Barlow and eds. 2013). Alginate gels can be heated without  
246 melting, and therefore can be used in baking creams (Draget, Smidsrød and Skjåk-Bræk 2005). When used  
247 in combination, alginate-pectin gels exhibit a higher gel strength than either component alone, and alginate-  
248 pectin gels are heat reversible (Brownlee, et al. 2005). Ammonium alginate is used for can sealing due to its  
249 very low ash content (K. Draget 2009).

#### 250 251 **Propylene glycol alginate:**

252 Propylene glycol alginate is used as a thickener, suspending agent and stabilizer; however unlike alginates,  
253 PGA does not form gels, insoluble films or fibers (Saltmarsh, Barlow and eds. 2013). Propylene glycol  
254 alginate is water-soluble and forms viscous solutions in hot and cold water. The chemical properties of  
255 PGA extend the applicability of alginates to lower-pH foods; PGA remains stable at pH down to 3.  
256 Propylene glycol alginate is more compatible with acidic foods and foods with high calcium content  
257 (Saltmarsh, Barlow and eds. 2013). Due to its stability at low pH levels, PGA is used in more applications  
258 than alginates; yet, the amount used is considerably less (Brownlee, et al. 2005). “Because of the relatively  
259 limited solubility of alginates at low pH, the esterified propylene glycol alginate is applied as a food  
260 stabilizer under acidic conditions” (Draget, Smidsrød and Skjåk-Bræk 2005). Its compatibility is due to the

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<sup>1</sup> The contraction of a gel accompanied by the exudation of liquid. The collection of whey on the surface of yogurt is an example of syneresis.

261 esterification of the reactive carboxylic acid groups, making PGA more acid stable and less sensitive to  
 262 calcium (Saltmarsh, Barlow and eds. 2013). However, PGA cannot dissolve in milk below the boiling point.  
 263 Grades of PGA with a high degree of esterification can interact with proteins and are used to stabilize beer  
 264 foam, meringues and noodles. Given its stability at low pH, PGA is frequently used in salad dressings to  
 265 stabilize oil-vinegar emulsion, in fruit drinks to prevent separation of pulp, and to flavor oils and fermented  
 266 milk drinks (Saltmarsh, Barlow and eds. 2013). Due to its unique suspension and foaming applications,  
 267 PGA is used in beer and soft drink production (Brownlee, et al. 2005).

268  
 269 Alginates are also used in culinary applications in the process of spherification. Alginate spheres consist of  
 270 a very thin, outer gel membrane with a liquid core (Lee and Rogers. 2012). Alginates are most commonly  
 271 used with calcium chloride to make spheres in the formation of faux caviar, egg dishes, gnocchi and ravioli.  
 272 Sodium alginate is added to a liquid, which is dropped into an aqueous solution of calcium chloride (Lee  
 273 and Rogers. 2012). The alginate at the surface of the droplet becomes a gel and forms a thin film around the  
 274 liquid inside (Cassi 2011). Calcium gluconate and calcium lactate are also used as the source of calcium in  
 275 spherification (Lee and Rogers. 2012). The rate of gelation is greatest for calcium chloride (100 s) and  
 276 slowest for calcium gluconate (3000 s). Calcium chloride can lend a bitter taste to food, although it can be  
 277 masked by other flavors (Lee and Rogers. 2012).

278  
 279 The use of alginates is not limited to foods. Industrial applications use alginates to improve the  
 280 performance of products such as paper coating, textiles, adhesives, air freshener gels and ceramics (K.  
 281 Draget 2009). Alginates are also utilized in a variety of ways in the medical field. Examples include wound  
 282 dressings, surgical implants, pharmaceutical preparations, and as a source of dietary fiber (Brownlee, et al.  
 283 2005). Sodium alginate is used as a synthetic inert ingredient in crop pesticide products (OMRI 2014).  
 284 Propylene glycol alginate is used as an inert defoaming agent in pesticides and is allowed for application to  
 285 growing crops (pre-harvest) or to raw agricultural commodities after harvest; residues of PGA are exempt  
 286 from the tolerance limit when used in accordance with good agricultural practices (40 CFR 180.910).

287  
 288 **Table 4.** Common Uses of Alginates in Food Products (Brownlee, et al. 2005).

| Application of Alginate            | % of total alginate food applications | Notes on application  |
|------------------------------------|---------------------------------------|---|
| Premium beer foam stabilizer (PGA) | 21.2                                  | PGA provides better head retention & prevents contamination   |
| Restructured Foods                 | 19.6                                  | Renders food material product thermostability and desired consistency (e.g., onion rings, pimento pieces)   |
| Additional uses of PGA             | 18.9                                  | Due to acid stability and resistance to loss of viscosity, PGA is used in: soft drinks; dressings/condiments; milk drinks; sorbet; ice cream; noodles/pasta         |
| Bakery Products                    | 14.9                                  | Bread and cake mixes: improves shelf life<br>Bakery creams: provides freeze/thaw stability & reduced syneresis<br>Instant flan: provides cold solubility            |
| Fruit Preserves                    | 6.5                                   | Jams, marmalades, fruit sauces: gelling, thickening, stabilizing agent<br>Alginate-pectin gels  |
| Ice Cream                          | 3.8                                   | Prevents crystallization and shrinkage<br>Produces viscosity of ice cream<br>Provides heat shock resistance<br>Provides homogeneous melting without whey separation |
| Other                              | 15.1                                  | Desserts (mousses, instant puddings, ripple syrups)<br>Emulsions and sauces (condiments, low fat dressings & spreads)<br>Extruded foods (noodles and pasta)         |

289

**Approved Legal Uses of the Substance:**

Alginates are classified as Generally Recognized as Safe (GRAS) in food according to good manufacturing processes. The FDA has outlined the specific uses and levels of concentration that are allowed for the different types of alginates (ammonium, calcium, potassium and sodium) in food products (21 CFR Regulations 184.1133, 184.1610, 184.1724, 184.1187). These uses are further described and addressed in Evaluation Question #4 and Table 5. In addition, sodium and propylene glycol alginate are permitted as ingredients per 21 CFR 133.178 and 133.179 in standardized pasteurized neufchatel and processed cheese spreads. PGA is also allowed as a coating for fresh citrus fruit per 21 CFR 172.210, as a defoaming agent in processed foods per 21 CFR 173.240, and as an indirect food additive (components of paper and paperboard) per 21 CFR 176.170.

**Action of the Substance:**

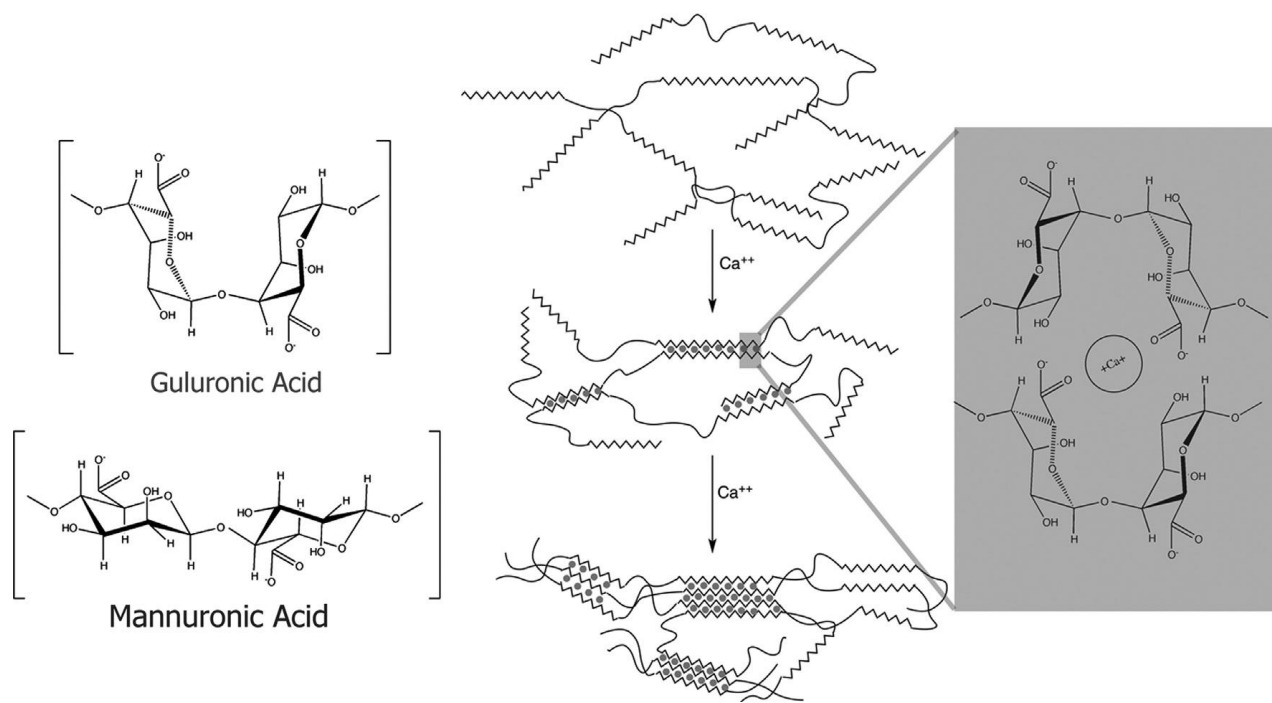
Alginates form chemically induced gels independent of temperature (Truong, Walter and Giesbrecht 1995, McHugh 2003). Once formed, the gels are thermostable and will not melt (Saltmarsh, Barlow and eds. 2013). The degree of thickening or gelling of alginates is determined by two factors:

1. the presence of monovalent or divalent cations in solution (Fernández-Martín, et al. 2009); and
2. the amount of guluronate present in the alginate, which is dependent on the algal species, age at harvest, geographic location of harvest and plant part extracted (Fett and Wijey 1995)

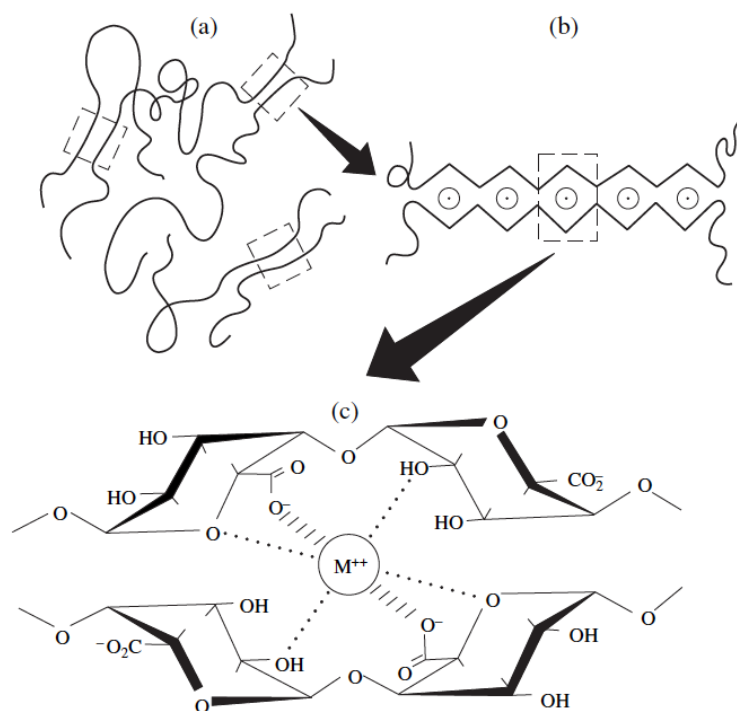
In the presence of monovalent cations, such as potassium and sodium, alginates do not form gels and can be used as thickening agents in foods. In the presence of divalent cations, such as calcium or magnesium, alginates form gels (Fernández-Martín, et al. 2009, Pawar 2012). The order of alginate affinity towards divalent ions is as follows: Pb > Cu > Cd > Ba > Sr > Ca > Co, Ni, Zn > Mn (Datta, et al. 2008). Calcium is the most commonly used cation for inducing alginate gel formation (Datta, et al. 2008). The cation acts as a crosslinker or bridge between the functional groups of the alginate chains (Yang, Ying-Jian and Wen 2011). "Alginate displays particular affinity for calcium, strontium and barium ions which induce a conformational transformation of the polyuronide chains into 'eggboxes' in which the cations are strongly chelated. Aggregation of alginate chains leads to the formation of gels" (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Figure 3 illustrates the eggbox model of alginate gelling and the formation of divalent ion salt bridges (Lee and Rogers. 2012). Hydrogen bonds form between the oxygen (O) atoms and the metallic, divalent ion, and ionic bonds form between the carboxyl groups and the same metallic ion (Khotimchenko, et al. 2001).

The structure of alginates determines the stiffness and strength of the gel formed in the presence of divalent cations. The gelling effect of alginates increases as the ratio of guluronic to mannuronic units grows larger (Fernández-Martín, et al. 2009). Alginates with high concentrations of guluronic acid (G) are used for gelling; alginates with high levels of mannuronic acid (M) are used for thickening and stabilizing (Saltmarsh, Barlow and eds. 2013). Alginate gel is not formed if the guluronic acid content is less than 20-25% (Khotimchenko, et al. 2001). The molecular structure of alginates is arranged in varying proportions of these M and G acid units, as GG, MG and MM blocks (Draget, Smidsrød and Skjåk-Bræk 2005). Alginate contains all four possible glycosidic linkages: diequatorial (MM), diaxial (GG), equatorial-axial (MG) and axial-equatorial (GM) (Yang, Ying-Jian and Wen 2011). Stiffness of the chain blocks increases in the order: MG < MM < GG. Mannuronic acid forms beta (1 → 4) linkages that result in a more flexible, linear conformation. Guluronic acid forms alpha (1 → 4) linkages that produce a steric hindrance around the carboxyl groups yielding a folded, rigid conformation (Yang, Ying-Jian and Wen 2011). The formation and resulting properties of the gel are determined by the interactions between G-blocks (Pawar 2012). In the presence of divalent cations, G-blocks bind with calcium more efficiently to form tightly held junctions that result in a stiff gel (Hay, Rehman and Ghafoor, et al. 2010). MG blocks also interact with divalent cations; however, these are weak junctions that form less stiff gels.





341



342  
 343 **Figure 3.** Chemical structure of monomeric units in alginate (G and M blocks) and representation of the  
 344 “eggbox” model of alginate gelling: a) and b) illustrate the binding zones between alginate molecules; c)  
 345 zooms into single binding zone showing two types of bonds: 1) hydrogen bond between OH groups and  
 346 divalent ion (M<sup>++</sup>) (dotted line); and 2) ionic bond between carboxyl group and M<sup>++</sup> (dashed line)  
 347 (Khotimchenko, et al. 2001, Lee and Rogers. 2012).

348

349 **Combinations of the Substance:**

350

351 Additional ingredients are not commonly added to commercially available forms of alginates. Publicly  
 352 available specification sheets and ingredient lists did not report any ancillary substances (e.g., stabilizers,  
 353 preservatives or anti-caking agents). Sodium alginate and PGA are commercially prepared as 100% freeze-  
 354 dried material (FMC BioPolymer 2012).

355  
356 The following substances are commonly used in combination with alginates. A divalent cation source is  
357 required to induce alginate gelling; calcium is most commonly used to produce stiff gels (Saltmarsh, Barlow  
358 and eds. 2013). Readily soluble in water, calcium acetate provides a soluble source of calcium for reaction  
359 with alginates. Calcium citrate effectively forms acid-based gels with alginates. The solubility of calcium  
360 citrate increases at lower pH values and decreases with increasing temperature. It effectively forms acid-  
361 based gels with alginates. Dicalcium phosphate and calcium chloride serve as a calcium sources to form  
362 gels with alginates (E400-403). Calcium chloride provides a source of calcium ions in solution and is  
363 commonly used to cross-link alginate gels. It is also used in the extraction of alginates from seaweed. In the  
364 production of ice cream, alginates are used in combination with other stabilizers to produce additional  
365 effects (Saltmarsh, Barlow and eds. 2013). To increase thickening and slow melting, alginates are combined  
366 with guar/locust bean gum (Brownlee, et al. 2005).

367  
368 Composite polysaccharide films are increasingly used in the food industry to increase the shelf-life and  
369 reduce flavor loss in fresh fruit (Rößle, et al. 2011) and in precooked meats (Wu, et al. 2001). Sodium  
370 alginate coatings are used as a “carrier of active or functional food ingredients such as antibrowning agents,  
371 colorants, flavors, nutrients, spices, and antimicrobial compounds” (Rößle, et al. 2011). Starch-alginate  
372 coatings have been shown to inhibit lipid oxidation and the formation of a “warmed-over flavor.” In these  
373 applications, starch and alginate are combined at a 2.5:1 ratio and stirred into a water, ethanol and glycerin  
374 solution. The effectiveness of SA-films is increased with the addition of stearic acid. To create the starch-  
375 alginate-stearic acid (SAS) film, 20% stearic acid and 30% lecithin are added to the SA-film solution.  
376 Additionally, tocopherols can be added to produce tocopherol-coated SA and tocopherol-coated SAS films  
377 (Wu, et al. 2001).

378  
379 Alginates are used to improve the texture of processed food. Tetrasodium pyrophosphate and calcium  
380 sulfate are used in combination with sodium alginate in texturized sweet potato puree (Truong, Walter and  
381 Giesbrecht 1995). Alginates are also used in dietary supplements. Fiber supplement formulations use  
382 alginates in combination with other fiber sources, psyllium seed and husk, flaxseed, guar gum and  
383 maltodextrin-soluble fiber, and cleansing agents bentonite, black walnut leaf, lactobacillus and beet root  
384 (Lifeplus 2014). The heavy metal binding property of alginates is utilized in dietary supplements; alginates  
385 are combined with milk thistle, silicon dioxide and rice flour in a hypromellose vegetable capsule (Rockwell  
386 Nutrition 2014).

## Status

### Historic Use:

389  
390  
391  
392 The NOSB voted in April 1995 to allow alginates as synthetic materials for use in organic food processing  
393 (NOSB 1995), and they were included in the National Organic Program Rule published in December 2000.  
394 However, the 1995 Technical Advisory Panel (TAP) report did not include propylene glycol alginate  
395 (Taylor and Theuer 1995); PGA is included in this technical report, however, because PGA is FDA  
396 approved as a food ingredient per 21 CFR §172.858. Following the review of alginates in the 1995 TAP  
397 Report, the NOSB recommended the continued listing of alginates at § 205.605(b) (Agricultural Marketing  
398 Service 2010).

### Organic Foods Production Act, USDA Final Rule:

400  
401  
402 Alginates are currently listed as allowed synthetics at section 205.605(b) in the USDA organic regulations  
403 (USDA National Organic Program 2014). Alginates do not appear in the Organic Foods Production Act.  
404

### International:

#### **Canada - Canadian General Standards Board Permitted Substances List**

405  
406  
407  
408 Certain alginates are permitted under the Canada Organic Regime due to their appearance in the section  
409 titled “Non-organic Ingredients Classified as Food Additives, of the Organic Production Systems Permitted

410 Substances List.” In this section, alginates (alginic acid, sodium alginate and potassium alginate) are  
411 included in Table 6.3 (Canadian General Standards Board 2011).

412  
413 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing**  
414 **of Organically Produced Foods (GL 32-1999)**

415 Certain alginates are permitted. Only potassium (402) and sodium (401) alginates are listed as allowed food  
416 additives in Table 3.1 as an ingredient of nonagricultural origin in the CODEX Alimentarius Commission,  
417 Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (Codex  
418 Alimentarius Commission 2014).

419  
420 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

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

426  
427 **Japan Agricultural Standard (JAS) for Organic Production**

428 Certain alginates are permitted. The JAS for Organic Processed Foods identifies sodium alginate as an  
429 allowed food additive limited to use only in processed foods of plant origin, INS number 401 (The Japanese  
430 Organic Standard 2005).

431  
432 **International Federation of Organic Agriculture Movements (IFOAM)**

433 Certain alginates are permitted. Sodium and potassium alginate are recognized by IFOAM as approved  
434 additives for use in an organic processed products without annotation (IFOAM 2014) (Appendix 4: Table  
435 1).

436

437 **Evaluation Questions for Substances to be used in Organic Handling**

438

439 **Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the**  
440 **petitioned substance. Further, describe any chemical change that may occur during manufacture or**  
441 **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**  
442 **animal, or mineral sources (7 U.S.C. § 6502 (21)).**  
443

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

455 **Extraction of alginates**

456 The extraction of alginates follows the same manufacturing process as alginic acid (Pawar 2012). Alginic  
457 acid is obtained from brown seaweeds, which naturally contain calcium alginate. The seaweeds are mixed  
458 in water with sulfuric acid (OMRI 2014). This leaching converts the alginate in the seaweed into insoluble  
459 alginic acid. The insoluble alginic acid is solubilized by neutralization with an alkali, such as sodium  
460 carbonate (Na<sub>2</sub>CO<sub>3</sub>) or sodium hydroxide (NaOH). The demineralized seaweed is ground in the presence of  
461 sodium alkali. This converts the alginic acid into soluble sodium alginate. The insoluble components are  
462 removed; separation processes to remove particulate matter include sifting, flotation, centrifugation,  
463 flocculation, filtration or a combination of these (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999,

464 Pawar 2012). The alginic acid is precipitated out of solution by adding sulfuric acid to the alginate solution.  
465 The precipitated alginic acid is then rinsed and dried (OMRI 2014). Sodium alginate is precipitated with an  
466 alcohol, sodium chloride (NaCl) or calcium chloride or a mineral acid (Pawar 2012). The dried product is  
467 milled and packaged (Pawar 2012, OMRI 2014). A filtration step is necessary for food grade alginates  
468 Filtration aids include diatomaceous earth and perlite (Hernandez-Carmona, McHugh and Lopez-Gutierrez  
469 1999). Alginates can be processed further by esterification to produce the propylene glycol ester, PGA  
470 (Saltmarsh, Barlow and eds. 2013). Alginates can also be recovered from brown seaweed via acid hydrolysis  
471 (Pawar 2012). The macerated seaweed is dissolved in sulfuric acid and heated to 110°C for four hours. The  
472 product is cooled and diluted with water (Pawar 2012).

473  
474 The following technique is commonly used in the industry to isolate alginates from brown seaweed  
475 (Rahelivao, et al. 2013). Algae is ground and suspended in distilled water. Hydrochloric acid (HCl) is added  
476 to achieve a pH of 3. The mixture is stirred for 24 hours. The supernatant is eliminated by centrifugation.  
477 The seaweed residue is suspended in distilled water. Sodium carbonate and ethylenediaminetetraacetic  
478 acid (EDTA) are added to change the pH to 11. The algae solution is kept at 80°C and stirred for 2 hours  
479 before filtering. The solution is acidified with HCl to pH of 3. The precipitate formed is collected by  
480 centrifugation and suspended in distilled water. Sodium hydroxide is added to adjust pH to 10. Sodium  
481 alginate is precipitated in presence of NaCl. The precipitate is washed with ethanol (Rahelivao, et al. 2013).

482  
483 Achieving high yields of alginates from the raw algal material is important in industrial production.  
484 Alginate yield is lower in the absence of EDTA (10-13%) and higher in the presence of EDTA (~30%)  
485 (Rahelivao, et al. 2013). Higher temperatures and longer extraction times increase yield but decrease the  
486 viscosity of the product (Hernandez-Carmona, McHugh and Lopez-Gutierrez 1999). The type of alkali  
487 used, concentration in solution and duration of extraction have been manipulated in early patents and  
488 subsequent research to evaluate the most efficient extraction methods, which include but are not limited to  
489 the following: a) 4% Na<sub>2</sub>CO<sub>3</sub> solution, 2 hours at 40°C; b) 5-7% Na<sub>2</sub>CO<sub>3</sub> solution, 12 hours; c) Solution of  
490 algae to NaOH at a ratio of 1:50, with a pH below 7; d) 1.5% Na<sub>2</sub>CO<sub>3</sub> at 50-60°C for 1.5 hours (Hernandez-  
491 Carmona, McHugh and Lopez-Gutierrez 1999).

#### 492 493 **Biosynthesis**

494 Bacteria are capable of producing alginate as an exopolysaccharide, which can serve multiple functions  
495 (Hay, Rehman and Ghafoor, et al. 2010). *Pseudomonas* secretes a high volume of alginate to aid in formation  
496 of thick biofilms. In *Azotobacter*, alginates participate in the formation of desiccation resistant cysts. Pindar  
497 and Bucke proposed the first bacterial alginate biosynthesis pathway in 1975 in the species *Azotobacter*  
498 *vinelandii*. Biosynthesis “can be broken down into four stages: (i) precursor synthesis; (ii) polymerization  
499 and cytoplasmic membrane transfer; (iii) periplasmic transfer and modification; and (iv) export through the  
500 outer membrane” (Hay, Rehman and Ghafoor, et al. 2010).

501  
502 The end product of bacterial fermentation is more consistent and can be customized (Draget, Smidsrød and  
503 Skjåk-Bræk 2005). Alginates produced by bacteria are of high quality and are primarily used in medical  
504 applications. “Alginates with a very high content of guluronic acid can be prepared from old algal tissue of  
505 *L. hyperborea* by chemical fractionation or by enzymatic modification *in vitro* using mannuronan C-5  
506 epimerases from *A. vinelandii*” (Draget, Smidsrød and Skjåk-Bræk 2005). Alginates produced by *A.*  
507 *vinelandii* have higher concentrations of G-blocks that form stiffer gels. The isolation of alginates from  
508 bacteria results in alginates of more predictable, consistent composition, such as 100% mannuronate or  
509 guluronate versus a mixture of M and G blocks (Draget, Smidsrød and Skjåk-Bræk 2005). Pharmaceutical  
510 grade alginates have defined molecular weights and M/G ratios. Figure 4 illustrates the steps of bacterial  
511 alginate biosynthesis; ultimately, the bacteria excrete the ‘mature alginate’ (Hay, Rehman and Moradali, et  
512 al. 2013).

513  
514 At present, production by fermentation is possible, but not economically feasible (Draget, Smidsrød and  
515 Skjåk-Bræk 2005). It is significantly more expensive to produce alginates through bacterial biosynthesis  
516 pathway compared with alkali extraction from brown seaweed, at \$100 g<sup>-1</sup> compared to \$5 kg<sup>-1</sup>, respectively  
517 (Hay, Rehman and Moradali, et al. 2013).

518

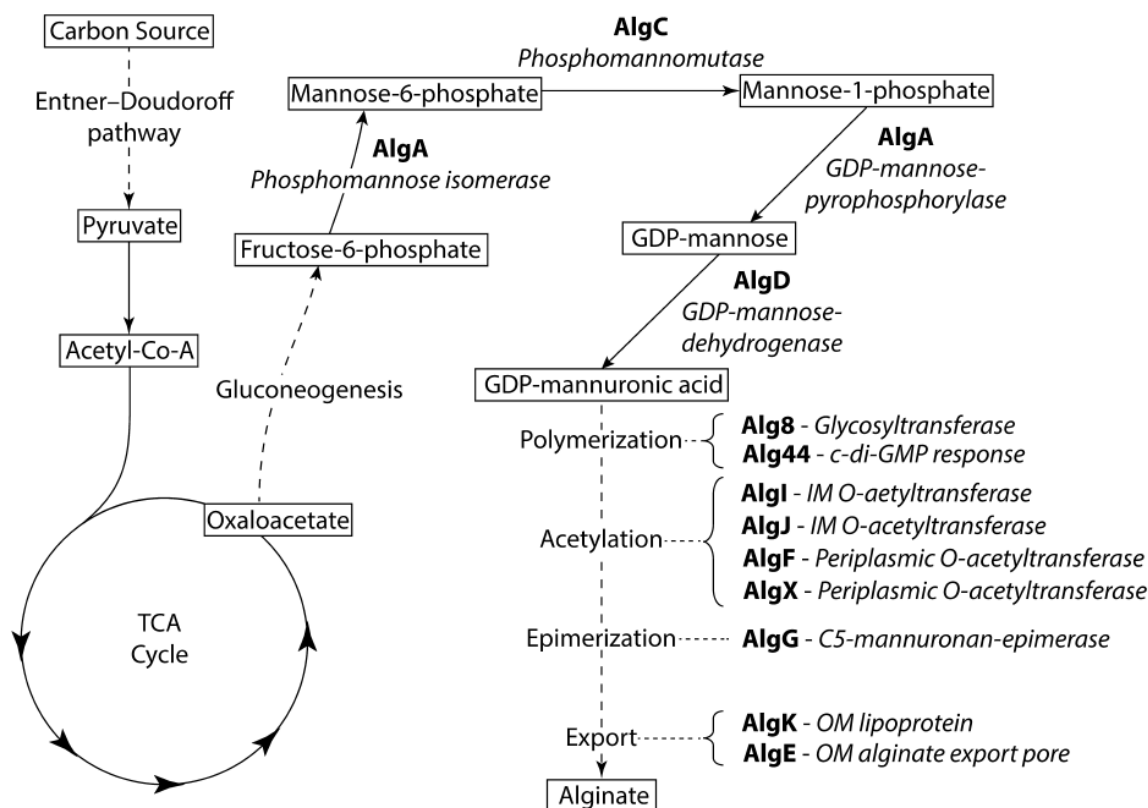


Figure 4. Overview of bacterial alginate biosynthesis (Hay, Rehman and Moradali, et al. 2013).

**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.

Commercial manufacture of alginates utilizes the chemical process of alkali extraction of brown seaweed. The naturally occurring cell-wall polysaccharide present in brown seaweed is chemically altered during extraction and reacted with the appropriate salt to produce a synthetic alginate product. Produced by esterification of alginic acid, PGA is also a product of a chemical process.

While synthetic extraction is the most common commercial production, there is increasing attention and research into the biosynthesis of alginates via bacteria that produce alginate as an exopolysaccharide (Hay, Rehman and Moradali, et al. 2013). This method may be considered a 'naturally occurring biological process' as no further extraction or isolation is required of the alginate excreted by bacteria (Hay, Rehman and Moradali, et al. 2013).

**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)).

There are no nonsynthetic forms of alginates. The polysaccharides that compose alginates are extracted from a nonsynthetic, natural source, brown algae; these algal polysaccharides are not found in any terrestrial plants (Holdt and Kraan 2011). The chemical process of alkali extraction renders alginates synthetic. Alginates are derived from alginic acid. Esterification of alginic acid produces PGA, which is also synthetic. Alginic acid does not exhibit the same chemical properties as alginate. For example, alginic acid is hydrophobic and is not soluble in water. Nor does alginic acid have as many food applications as alginates.

Alternatives to alginates include other nonsynthetic gelling and thickening agents derived from seaweed such as carrageenan and agar. However, these nonsynthetic gelling agents require high-temperature

550 processes for activation whereas alginates do not. See Evaluation Questions 12-13 below for more  
 551 information on alternative substances to alginates.

552  
 553 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**  
 554 **recognized as safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR §**  
 555 **205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**

556  
 557 Toxicological studies have shown that alginates are safe for use in food (McNeely and Kovacs 1975,  
 558 Khotimchenko, et al. 2001, FDA 2014). Ammonium, calcium, potassium and sodium alginates are  
 559 considered GRAS when used in accordance with good manufacturing practice as described in 21 CFR  
 560 Regulation 184.1133, 184.1187, 184.1610, 184.1724 and 172.858 and as presented in Table 5. Propylene  
 561 alginate glycol is approved for use by the FDA as a direct food additive (21 CFR 172.858 and 172.210).  
 562 Ammonium, calcium and sodium alginates are listed at CFR 184, Subpart B, titled “Listing of Specific  
 563 Substances Affirmed as GRAS” with maximum concentrations specified by food use category. Table 5  
 564 outlines the function and maximum allowance of alginates in specific food categories.

565  
 566 Produced by Inovo Biologic, Inc., the substance Polysaccharide Complex KAX is considered GRAS under  
 567 the GRN 407 (FDA, GRAS Notices 2012). It is a polysaccharide complex of konjac glucomannan (konjac),  
 568 sodium alginate and xanthan gum. It is allowed for use “at levels up to seven percent as an ingredient to  
 569 provide dietary fiber or to provide thickening or a stabilizing effect in yogurts, milk shakes and fruit  
 570 smoothie-type drinks, frozen yogurt, ice cream bars, puddings, white and whole wheat breads, cookies,  
 571 breakfast bars, granola-type bars, noodles, whole wheat cereals, meatless lasagna and macaroni/cheese,  
 572 fruit juices, fruit juice bars, cereal beverages, and medical foods.” The FDA had no questions regarding the  
 573 substance (FDA, GRAS Notices 2012).

574  
 575 **Table 5.** Function and maximum allowable level of five different types of alginates in food. Each type of  
 576 alginate can be used in food only within the following specific limitations. Blanks indicate that the alginate  
 577 has not been approved for use in the specified food category by the FDA.

| Food Use Category                                | Ammonium alginate   | Calcium alginate    | Potassium alginate | Sodium alginate                       | Propylene glycol alginate |
|--|---------------------|---------------------|--------------------|---------------------------------------|---------------------------|
| Alcoholic Beverages (170.3(n)(2))                |                     | 0.4% <sup>a</sup>   |                    |                                       |                           |
| Baked Goods (170.3(n)(1))                        |                     | 0.002% <sup>a</sup> |                    |                                       | 0.5% <sup>a,e,g</sup>     |
| Cheeses (170.3(n)(5))                            |                     |                     |                    |                                       | 0.9% <sup>a,g</sup>       |
| Condiments and relishes (170.3(n)(8))            |                     |                     |                    | 1.0% <sup>a,b</sup> ,<br>except<br>** | 0.6% <sup>a,g</sup>       |
| Confections and frostings (170.3(n)(9))          | 0.4% <sup>a</sup>   | 0.4% <sup>a</sup>   | 0.1% <sup>a</sup>  | 0.3% <sup>a</sup>                     | 0.5% <sup>a</sup>         |
| Egg Products (170.3(n)(11))                      |                     | 0.6% <sup>a</sup>   |                    |                                       |                           |
| Fats and oils (170.3(n)(12))                     | 0.5% <sup>a</sup>   | 0.5% <sup>a</sup>   |                    |                                       | 1.1% <sup>a,g</sup>       |
| Frozen dairy desserts (170.3(n)(26))             |                     |                     |                    |                                       | 0.5% <sup>a</sup>         |
| Gelatins and puddings (170.3(n)(22))             |                     | 0.25% <sup>a</sup>  | 0.7% <sup>a</sup>  | 4.0% <sup>a,e,f</sup>                 | 0.6% <sup>a,g</sup>       |
| Gravies and sauces (170.3(n)(24))                | 0.4% <sup>a</sup>   | 0.4% <sup>a</sup>   |                    |                                       | 0.5% <sup>a</sup>         |
| Hard Candy (170.3(n)(25))                        |                     |                     |                    | 10.0% <sup>a</sup>                    |                           |
| Jams and jellies (170.3(n)(28))                  | 0.4% <sup>a</sup>   | 0.5% <sup>a</sup>   |                    |                                       | 0.4% <sup>a</sup>         |
| Pimento Ribbon for Stuffed Olives                |                     |                     |                    | **6.0%<br><sup>a,b</sup>              |                           |
| Processed Fruits and fruit juices (170.3(n)(35)) |                     |                     | 0.25% <sup>a</sup> | 2.0% <sup>b,c</sup>                   |                           |
| Seasonings and flavors (170.3(n)(26))            |                     |                     |                    |                                       | 1.7% <sup>e</sup>         |
| Sweet sauces (170.3(n)(43))                      | 0.5% <sup>a</sup>   | 0.5% <sup>a</sup>   |                    |                                       |                           |
| All other food categories                        | 0.1% <sup>a,d</sup> | 0.3% <sup>a</sup>   | 0.01% <sup>a</sup> | 1.0%<br><sup>a,e,f,g,h,i</sup>        | 0.3% <sup>a,e,i</sup>     |
| <b>21 CFR Regulation</b>                         | <b>184.1133</b>     | <b>184.1187</b>     | <b>184.1610</b>    | <b>184.1724</b>                       | <b>172.858</b>            |

578 <sup>a</sup> Stabilizer, Thickener; <sup>b</sup> Texturizer; <sup>c</sup> Formulation aid; <sup>d</sup> Humectant; <sup>e</sup> Flavor adjuvant; <sup>f</sup> Firming agent; <sup>g</sup>  
579 Emulsifier; <sup>h</sup> Processing aid; <sup>i</sup> Surface active agent

580

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

584

585 A chemical food preservative is defined under FDA regulations at 21 CFR 101.22(a) (5) as “any chemical  
586 that, when added to food, tends to prevent or retard deterioration thereof, but does not include common  
587 salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure  
588 thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties” (FDA, Title 21:  
589 Food and Drugs 2013). The primary function of alginates is not as a preserving agent. Rather, alginates are  
590 used in foods as gelling agents, thickeners, emulsifiers and flavor enhancers, which can have a secondary  
591 effect of stabilizing the food product over time.

592

593 Alginates are used to extend product shelf-life and reduce risk of pathogen growth on food surfaces (Rößle,  
594 et al. 2011). Alginates help to slow the degradation of food products by providing a physical barrier to  
595 moisture, oxygen, lipid oxidation and loss of volatile aromas and flavors (Rößle, et al. 2011). As components  
596 of edible coatings or films, alginates act as a protective barrier to retard food spoilage and extend the  
597 effectiveness of an active ingredient (Datta, et al. 2008).

598

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

603

604 The available literature did not present alginates as substances used to recreate flavors, colors, textures or  
605 nutritive values lost in processing. Alginates do, however, improve these qualities in food. Alginates are  
606 primarily used to produce or enhance the texture during processing of restructured foods, to stabilize or  
607 thicken food products, and as a flavor adjuvant or enhancer (Truong, Walter and Giesbrecht 1995, Draget,  
608 Smidsrød and Skjåk-Bræk 2005). Alginates maintain texture when they are used as a stabilizer to prevent  
609 separation of ingredients (Saltmarsh, Barlow and eds. 2013). Alginates are a source of dietary fiber  
610 (Brownlee, et al. 2005) but there is no indication in the literature that alginates are added to processed foods  
611 in order to restore fiber lost in processing. As a component of edible coatings on fresh-cut fruits, alginates  
612 are used to maintain color and texture and extend the shelf life of the product by preventing moisture loss,  
613 oxidation and loss of aromas and flavors (Rößle, et al. 2011). The use of alginates in these applications is not  
614 intended to restore flavor.

615

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

618

619 The human body does not absorb alginates, making them a low-calorie ingredient that does not provide  
620 metabolic energy (Draget, Smidsrød and Skjåk-Bræk 2005, Saltmarsh, Barlow and eds. 2013). Multiple  
621 sources indicate the use of alginates in diet foods as sources of insoluble fiber (Brownlee, et al. 2005, Burtin  
622 2003, Jimenez-Escrig and Sanchez-Muniz, F.J. 2000, MacArtain, et al. 2007) or as a means of appetite control  
623 (Paxman, et al. 2008). The indigestible fibers of alginates “can increase feelings of satiety and aid digestive  
624 transit through their bulking capacity” (MacArtain, et al. 2007). Alginates are frequently used in fiber  
625 supplements as a polysaccharide bulking agent (Anderson, et al. 1991, Mabeau and Fleurence 1993,  
626 Brownlee, et al. 2005). Seaweeds can provide up to 12.5% of the daily fiber needs in an 8 g serving  
627 (MacArtain, et al. 2007). Fiber supplement products use alginates in combination with other fiber sources:  
628 psyllium seed and husk, flaxseed, guar gum and maltodextrin-soluble fiber, and cleansing agents such as  
629 bentonite, black walnut leaf, lactobacillus and beet root (Lifeplus 2014). The binding nature of alginates  
630 affects the bioabsorption of heavy metals in the human system and has been linked to reduced mineral  
631 availability, namely iron (Bosscher, Caillie-Bertrand and Deelstra 2001, MacArtain, et al. 2007). Alginates

632 are used in dietary supplements, accompanied by marketing claims that they are “beneficial for those  
633 individuals exposed to environmental pollutants or toxins” (Rockwell Nutrition 2014).

634  
635 Seaweeds have high mineral content (calcium, magnesium, phosphorus, potassium, sodium and iron);  
636 however, “the linkage of certain minerals with anionic polysaccharides (alginates, agar or carrageenan)  
637 might limit the absorption of these minerals” (Mabeau and Fleurence 1993). The type of linkage between  
638 the polysaccharide and the mineral determine the availability of the mineral. “The strong affinity of  
639 divalent cations (particularly calcium) for carboxylic polysaccharides limits the availability of associated  
640 minerals” (Mabeau and Fleurence 1993). Experiments in growing rats have shown substantial reductions in  
641 iron absorption with sodium alginate (Bosscher, Caillie-Bertrand and Deelstra 2001).

642  
643 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**  
644 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**  
645 **(b)(5)).**

646  
647 No reports of levels of heavy metals in alginates, including PGA, were found. Alginates do not exhibit  
648 heavy metal levels in excess of FDA tolerances (FDA 2014). Product specification sheets report minimal  
649 concentrations of heavy metals: <3ppm arsenic, <10ppm lead, ≤1 ppm mercury, <1.5ppm (FMC BioPolymer  
650 2012) and <40ppm total heavy metals (FMC BioPolymer 2005). However, studies on bioremediation with  
651 seaweed and seaweed derivatives report their ability to absorb heavy metals (Aderhold, Williams and  
652 Edyvean 1996, Khotimchenko, et al. 2001). Alginates have a high binding capacity for heavy metals and can  
653 sequester metal ions such as arsenic, lead, zinc and copper. In the presence of high concentrations of nickel,  
654 copper, zinc, lead and cadmium, alginates caused a reduction in residual concentrations of all ions except  
655 zinc (Aderhold, Williams and Edyvean 1996).

656  
657 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**  
658 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**  
659 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

660  
661 Annually, more than 3.5 million tons of seaweeds are harvested for food consumption (60%) and  
662 phycocolloid production (40%) (LaHaye 2001); in general, the rate of seaweed harvest has continued to  
663 increase in the 21<sup>st</sup> century (Bixler and Porse 2011). However, the balance of seaweed supply and demand is  
664 increasingly more fragile due to rising seawater temperatures, erratic weather patterns and pollution  
665 (Bixler and Porse 2011). Many of the brown seaweed species used to extract alginates are wild harvested  
666 (McHugh 2003). Table 6 illustrates shifts in the last decade that have occurred in harvest location, species of  
667 seaweed harvested, chemical composition and total seaweed harvest for alginate production in dry tons  
668 (Bixler and Porse 2011). Higher quality species of brown seaweed are found in cold waters (20°C) (Kraan  
669 2012). As the water temperature increases, the concentration of terpenes and other chemical compounds in  
670 the seaweed increases; these compounds are not desirable for alginates used in food production (Kraan  
671 2012). Since the quality and quantity of alginates depend on the algae species, the type and age of tissues  
672 extracted and location of harvest, the structure and properties of alginates harvested from specific locations  
673 has been documented: Madagascar seacoast algae (Rahelivao, et al. 2013), brown seaweed species in  
674 Quebec’s Saint-Lawrence River (Rioux, Turgeon and Beaulieu 2007), substantial resources of *Ascophyllum*  
675 *nodosum* in Ireland, Scotland, Iceland, France and Canada (Bixler and Porse 2011), *Lessonia nigrescens* from  
676 Chile (Bixler and Porse 2011) and several species in the European temperate Atlantic waters (Holdt and  
677 Kraan 2011).

678 **Table 6.** Geographic harvest of seaweeds used for alginate production in 1999 and 2009 (Bixler and Porse  
679 2011).

| Type                  | Harvest Location                        | Extract Type | 1999 Harvest<br>(dry t) | %  | 2009 Harvest<br>(dry t) | %  |
|-----------------------|---|--------------|-------------------------|----|-------------------------|----|
| <i>Laminaria</i> spp. | France, Ireland, United Kingdom, Norway | Med/High G   | 5,000                   | 6  | 30,500                  | 32 |
| <i>Lessonia</i> spp.  | Chile, Peru                             | Med/High G   | 7,000                   | 8  | 27,000                  | 28 |
| <i>Laminaria</i> spp. | China, Japan                            | Med G        | 13,000                  | 16 | 20,000                  | 21 |
| <i>Macrocystis</i>    | U.S., Mexico, Chile                     | Low G        | 35,000                  | 42 | 5,000                   | 6  |



|                    |  |        |        |     |        |     |
|--------------------|--|--------|--------|-----|--------|-----|
| <i>Durvillaea</i>  | Australia                                | Low G  | 4,500  | 6   | 4,500  | 5   |
| <i>Flavicans</i>   | Chile, Peru                              | High G | 3,000  | 4   | 4,500  | 4   |
| <i>Ecklonia</i>    | South Africa                             | Med G  | 3,000  | 2   | 2,000  | 2   |
| <i>Ascophyllum</i> | France, Ireland, United Kingdom, Iceland | Low G  | 13,500 | 16  | 2,000  | 2   |
| <b>TOTAL</b>       |  |        | 84,000 | 100 | 95,000 | 100 |

680  
 681 Seaweed can replicate via vegetative (asexual) reproduction or sexual reproduction; the latter requires a  
 682 cycle of alternating generations between a large sporophyte and a microscopic gametophyte (McHugh  
 683 2003). Many of the brown algae species used for alginate production cannot be propagated by taking  
 684 cuttings from mature plants. In land-based facilities, it is challenging to manage precisely the water  
 685 temperature, light and nutrient conditions necessary to facilitate the sexual reproductive cycle of brown  
 686 algae species; it becomes cost prohibitive to supply the raw material for alginate production in this manner.  
 687 “None of the usual seaweeds for alginate production are cultivated. This makes cultivated brown seaweeds  
 688 too expensive when compared to the costs of harvesting and transporting wild seaweeds” (McHugh 2003).  
 689 Figure 5 illustrates the mechanical harvest of wild seaweeds at sea; each drag of the trawl harvests over 1  
 690 ton of fresh kelp in two minutes (Vea and Ask 2011). It is important to note that cultivation of low-grade  
 691 industrial alginates is possible; wild harvested seaweed has higher levels of G-acid, yielding higher quality  
 692 alginates that form stiff, hard gels (Bixler and Porse 2011). There is growing concern about overharvesting  
 693 wild seaweed and depleting natural resources of seaweed (Vea and Ask 2011). Sustainable harvesting  
 694 management plans have been implemented in Norway consisting of revolving 5-year harvest cycles, set  
 695 harvest volumes for specific areas and monitoring of regrowth (Vea and Ask 2011).



696  
 697 **Figure 5.** Harvest of *Laminaria hyperborea* in Norway (McHugh 2003).  
 698

699 Most commonly, seaweed is wild harvested for manufacture of alginates with medium to high levels of G-  
 700 acid (Bixler and Porse 2011). Although seaweed farming is difficult due to the above mentioned challenges,  
 701 China has been cultivating *L. japonica* on floating rafts since 1952 at rates of 250,000 dry tons per year (Bixler  
 702 and Porse 2011). Seaweed is farmed by tying fronds of seaweed to wooden poles that are dug into the  
 703 ground in shallow intertidal pools or attached to lines, rafts or floats in deeper water (Philips 1990).  
 704 Seaweed cultivation is largely considered to be an environmentally friendly form of aquaculture due to the  
 705 lack of added inputs for fertility, minimal changes in physical landscape and potential for bioremediation  
 706 of polluted or nutrient rich waters (Eklof and Kautsky 2006). Large-scale seaweed cultivation can positively  
 707 and negatively affect coastal waterways (Kraan 2012). Seaweed farming has demonstrated positive effects  
 708 on the environment as a means of mediating eutrophication and other forms of pollution through the filter  
 709 feeding action of seaweed (Eklof and Kautsky 2006). Increased sedimentation has been documented, which  
 710 can have a positive effect on erosion control (Philips 1990). Seaweed farming can cause a number of  
 711 secondary environmental impacts. Large-scale seaweed farming can lead to the depletion of nutrients in the  
 712 coastal waters where the seaweed grows which can affect primary food sources such as phytoplankton  
 713 (Philips 1990). The use of plastic ties to secure seaweed fronds, Styrofoam floats and plastic bottle buoys has  
 714 led to increased garbage and foreign debris on beaches, reefs and mangroves; these materials are seldom

715 recycled or disposed of properly (Zemke-White and Ohno 1999). Advancements in integrated farming of  
716 seaweed, fish, crustaceans and mollusks could resolve issues of nitrogen leaching and eutrophication from  
717 the seaweed system (Titlyanov and Titlyanova 2010). Another example of “integrated mariculture,”  
718 seaweeds can provide nutrient uptake from fish excrement in existing fish farms (Titlyanov and Titlyanova  
719 2010). A significant problem of cultivated seaweed that would not be addressed by integrating systems is  
720 the introduction of non-native seaweed species. The potential introduction of non-native aquatic plant  
721 species from commercial kelp production is a serious bio-invasive risk for nearby marine communities  
722 (Chandrasekaran, et al. 2008). Since seaweed can reproduce asexually, fragments from cultivated seaweed  
723 can escape from seaweed farms and colonize new areas of coral or other features. If colonization occurs on  
724 dead coral reefs, the invasive seaweed can prevent the cycle of coral erosion and resettlement of coral,  
725 leading to reef degradation (Chandrasekaran, et al. 2008). Given the insurmountable challenges of  
726 managing non-native seaweed populations, some researchers claim that it is preferable to focus on  
727 sustainable wild harvest techniques with regard to mitigating environmental impact (Titlyanov and  
728 Titlyanova 2010).

729  
730 Byproducts of industrial extraction of alginate are a potential source of pollution unless properly managed,  
731 utilized in another process, or repurposed as a substrate for another product (Fleury and Lahaye 1993).  
732 Dealginated seaweed waste has been shown to remove heavy metals from solution (Aderhold, Williams  
733 and Edyvean 1996). Rates of cadmium removal by dealginated seaweed have been found to be fast and  
734 effective (91% removal within 5 minutes) (Romero-Gonzalez, Williams and Gardiner 2001). Wastewater  
735 management is an important aspect of the manufacturing process. The first acidic-water effluent from the  
736 alginate manufacturing process contains fucose, uronic acid, sulfate, xylose and galactose. Several thousand  
737 cubic meters of liquid are produced annually. Fucans are sulfated polysaccharides that have nutritional and  
738 biological properties, such as antitumoral, antiviral and anticoagulant properties (Fleury and Lahaye 1993).  
739 The feasibility of using the substrate for methane production has been investigated but the suitability of the  
740 alginate byproducts for the production of gas remains unknown (Edyvean, Stanley and Stanley 1988).

741  
742 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**  
743 **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**  
744 **(m) (4)).**

745  
746 Human endogenous enzymes in the gastrointestinal tract cannot digest algal polysaccharides (Mabeau and  
747 Fleurence 1993, MacArtain, et al. 2007). Seaweed polysaccharides are not metabolized; alginates are only  
748 partly degraded and lead to a substantial production of short chain fatty acids in the colon (Burtin 2003).  
749 Algal polysaccharides reach the large intestine where they are subsequently fermentable in the colon by gut  
750 bacteria (Burtin 2003). The resistance of alginates to bacterial and enzymatic degradation in the human gut  
751 is due to its high concentrations of fucose and sulfate (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). After 6  
752 hours of fermentation and production of gas in the colon, only 65% of the degraded alginates were  
753 metabolized to short chain fatty acids. “Since algal fibre probably retains its physicochemical properties in  
754 the colon, its resistance to fermentation can lead to particular physiological effects” (Jimenez-Escrig and  
755 Sanchez-Muniz, F.J. 2000). Fermentation leads to the production of hydrogen, methane and short chain  
756 fatty acids, which can be a source of metabolic energy and discomfort (Burtin 2003).

757  
758 Alginates that are not degraded by human enzymes are a source of dietary fiber (Burtin 2003). A study on  
759 the dietary effects of sodium alginate in humans concluded that the ingestion of high levels of sodium  
760 alginate caused “no effects other than those normally associated with a polysaccharide bulking agent”  
761 (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Alginates slow digestion as a bulking agent (Anderson, et  
762 al. 1991, Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). The water-holding and water-binding capacity of  
763 alginates decreases the transit time of digested food in the colon; this decrease in “colon transit time” is  
764 considered a positive factor in preventing colon cancer (MacArtain, et al. 2007). Dietary fiber from brown  
765 algae is essentially composed of four families of polysaccharides: laminarins, alginates, fucans and cellulose  
766 (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Dietary fiber decreases the risk of coronary heart disease  
767 “due to its characteristics of dispersibility in water (water-holding capacity), viscosity, binding ability,  
768 absorptive capacity, faecal bulking capacity and fermentability in the alimentary canal. Indigestible viscous

769 seaweed polysaccharides such as alginates, carrageenans and funorans, which are capable of forming ionic  
770 colloids, have shown positive effects on serum lipid levels in rats. The capacity of seaweed polysaccharides  
771 to lower serum cholesterol levels seems to be due to their ability to disperse in water, retain cholesterol and  
772 related physiologically active compounds and inhibit lipid absorption in the gastrointestinal tract”  
773 (Jimenez-Escrig and Sanchez-Muniz, F.J. 2000). Incorporation of alginates into foods or beverages has been  
774 shown to mimic the physiological effects of meal consumption, thereby reducing hunger and food intake  
775 while increasing satiety (Brownlee, et al. 2011). Results also demonstrate improved glycemic control and  
776 reduced fat absorption (Brownlee, et al. 2011).

777  
778 Based on its high biocompatibility, abundance and availability of the algal sources and relatively low cost  
779 to produce, alginates are increasingly being used in the medical field (Brownlee, et al. 2005). Alginates are  
780 used for heartburn prevention (Caestecker 2001). Alginates serve the active ingredient in anti-reflux  
781 therapies (Brownlee, et al. 2005). “Alginate encapsulation has been used successfully as a method to orally  
782 deliver DNA based vaccines” (Hay, Rehman and Ghafoor, et al. 2010).

783  
784 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**  
785 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

786  
787 Alternatives to alginates include other gelling and thickening agents derived from seaweed such as  
788 carrageenan and agar, as well as xanthan gum (Imeson 2010). The ability of alginates to make gels without  
789 the use of heat distinguishes them from other hydrocolloids that require high-temperature processes (e.g.,  
790 gelatin, agar, carrageenan, locust bean gum) (Saltmarsh, Barlow and eds. 2013). See questions below for  
791 more information on alternative substances to alginates.

792  
793 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products, which may be**  
794 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**  
795 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

796  
797 Other food hydrocolloids may be used to obtain the desired emulsifying, stabilizing and thickening effects  
798 of alginates. Examples of such food hydrocolloids include alginic acid, agar agar, gum Arabic, carrageenan,  
799 cassia tora, gelatin, gellan gum, guar gum, karaya, konjac, locust bean gum, pectin, starches, tara,  
800 tragacanth and xanthan gum (Imeson 2010). Currently agar agar, carrageenan, gellan gum and xanthan  
801 gum are listed as nonagricultural (nonorganic) substances that are allowed as ingredients in or on  
802 processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (7  
803 CFR §205.605(a) and (b)). The supply and price of xanthan gum and gellan gum are stable; the price and  
804 supply variability of locust bean gum, guar gum and gum Arabic are well known (Imeson 2010).

805  
806 At the time of this report, there are no certified organic products available that contain PGA.

807  
808 **Evaluation Question #13: Provide a list of organic agricultural products that could be alternatives for**  
809 **the petitioned substance (7 CFR § 205.600 (b) (1)).**

810  
811 Food additives that may be used as alternatives to alginates to achieve a similar functionality include  
812 carrageenan, guar gum, gum Arabic, gelatin, locust bean gum and xanthan gum. Guar gum, gum Arabic,  
813 locust bean gum and gelatin are agricultural processing ingredients. They are listed under the USDA  
814 organic regulations section 205.606 as nonagricultural (nonorganic) substances that are allowed as  
815 ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients  
816 or food group(s))”. Nonorganic forms may be used only when the ingredient has been shown to be  
817 commercially unavailable in organic form. Xanthan gum is synthetic; however, it is allowed for use in  
818 organic processed products (7 CFR §205.605(b)).

819  
820 Certified organic food hydrocolloids include gum Arabic, guar gum, locust bean gum and inulin (National  
821 Organic Program 2014). Table 7 includes the number of certified organic sources of these alternative  
822 hydrocolloids as of January 28, 2015. Products manufactured by TIC Gums are not included in the count; a  
823 search of the substance names on the Agricultural Marketing Services will not yield TIC Gums in the

824 results. TIC Gums manufactures hydrocolloids and stabilizers, including some certified organic products  
825 (<http://www.ticgums.com/products.html>).

826  
827 Gum Arabic, guar gum and locust bean gum are considered GRAS; they are permitted in many food  
828 categories according to maximum usage levels permitted (FDA 2014). Guar gum is allowed as an emulsifier  
829 and emulsifier salt, formulation aid, stabilizer and thickener in "all other food categories" up to 1%. Locust  
830 bean gum is allowed as a stabilizer and thickener in "all other food categories" up to 0.5% (FDA 2014).  
831 Inulin is approved as GRAS under GRN No. 118 and GRN No. 477, allowing for use as "a bulking agent"  
832 and use "in food in general," respectively (FDA 2003, FDA 2013).

833  
834 **Table 7.** List of available organic hydrocolloids certified to processing and handling standards as of 2013  
835 (National Organic Program 2014).

| Certified organic product | # of Sources |
|---------------------------|--------------|
| Gum Arabic                | 4            |
| Guar gum                  | 6            |
| Inulin                    | 31           |
| Locust bean gum           | 3            |

836

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