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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: CITIZEN PETITION REQUESTING THAT FDA AMEND ITS GRAS REGULATIONS AT 21 CFR §§ 184.1610 AND 184.1724 TO PERMIT THE USE OF POTASSIUM AND SODIUM ALGINATE IN PLANT-BASED SHELLFISH ALTERNATIVES FOR HUMAN CONSUMPTION

Dear Sir or Madam:

The undersigned submits this petition under 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to amend its regulations at 21 CFR §§ 184.1610 AND 184.1724, concerning the circumstances under which potassium alginate and sodium alginate are Generally Recognized as Safe (GRAS). The Petition further requests that the Commissioner direct the Food and Drug Administration (FDA), pending a decision on this Petition, to exercise enforcement discretion for the uses of potassium alginate and sodium alginate described herein.

I. ACTION REQUESTED

This Citizen Petition requests that the FDA amend its GRAS regulations at 21 CFR §§ 184.1610 and 184.1724 describing the circumstances under which potassium and sodium alginate are deemed to be GRAS, to permit the use of these ingredients at levels above 0.01% and 1.0%, respectively, as thickeners, firming agents or texturizers in plant-based shellfish-alternative food products for human consumption, provided such use meets all of the following criteria: (1) the alginates are derived from brown seaweed, (2) combined alginate levels in a given product do not exceed 5%, (3) the alginate ingredients do not contain the heavy metals arsenic and lead at levels exceeding 1 mg/kg or cadmium and mercury at levels exceeding 0.2 mg/kg and (4) the ingredients otherwise conform to, or exceed, current specifications established by the Food Chemicals Codex (USP, 2014) and the

Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1997). This Citizen Petition further requests that, pending revision of the GRAS regulations in the manner requested (or a decision to decline to do so), FDA exercise enforcement discretion with respect to the use of potassium alginate and sodium alginate in a manner that conforms with the requested amendments.

II. STATEMENT OF GROUNDS

A. Summary of Grounds

As described in greater detail herein, the requested actions will foster the development of much-needed alternatives to shellfish to provide options for consumers who limit or avoid shellfish for health, environmental, moral or religious reasons. The requested actions will not result in unsafe levels of potassium and sodium alginate in the U.S. food supply.

B. Potassium and Sodium Alginate

Potassium alginate and sodium alginate are the potassium and sodium salts of alginic acid (or algin), a natural polyuronide constituent extracted from brown seaweed,[1] where it occurs in the intercellular mucilage and cell wall as an insoluble gel containing sodium, calcium, magnesium, strontium, and barium ions. Algin is the most abundant polysaccharide in brown algae, comprising up to 40% of the dry matter. Apart from being a structural polysaccharide that provides rigidity to the algae, it also helps prevent the desiccation of those plants when exposed to air at low tide.

Alginic acid is a family of linear copolymers containing blocks of (1,4)-linked β-D-mannuronate (M) and α-L-guluronate (G) residues. The blocks are composed of consecutive G residues (GGGGGG), consecutive M residues (MMMMMM), and alternating M and G residues (GMGMGM) (Figure 1). Alginates extracted from different sources differ in M and G content as well as the length of each block. The G-block content of commercially available alginates is generally in the range of 14–31%. The molecular weight of commercially available sodium alginate ranges between 32,000 and 400,000 g/mol (Lee and Mooney, 2012), although JECFA (1997) gives a broader range of 10,000-600,000. The molecular weight of commercially available potassium alginate ranges between 10,000 and 600,000 g/mol (JECFA, 1997).

Alginates, which are linear biopolymers consisting of 1,4-linked β-D-mannuronic acid (M) and 1,4 α-L-guluronic acid (G) residues arranged in homogenous (poly-G, poly-M) or heterogenous

[1] Several bacteria also produce alginate extracellularly, but at present, all commercial alginates come from algal sources.

(MG) block-like patterns (Szekalska et al., 2016), are prepared by the neutralization of purified alginic acid with appropriate pH control agents.[2] Alginates are widely used in various industries because of their ability to retain water, and also because of their gelling, thickening and stabilizing properties. Commercial alginates may differ in composition and the sequence of G- and M-blocks, depending on the source material.

The basic molecular structures of alginates are shown in figures below from Szekalska *et al.* (2016) and EFSA (EFSA ANS Panel, 2017):

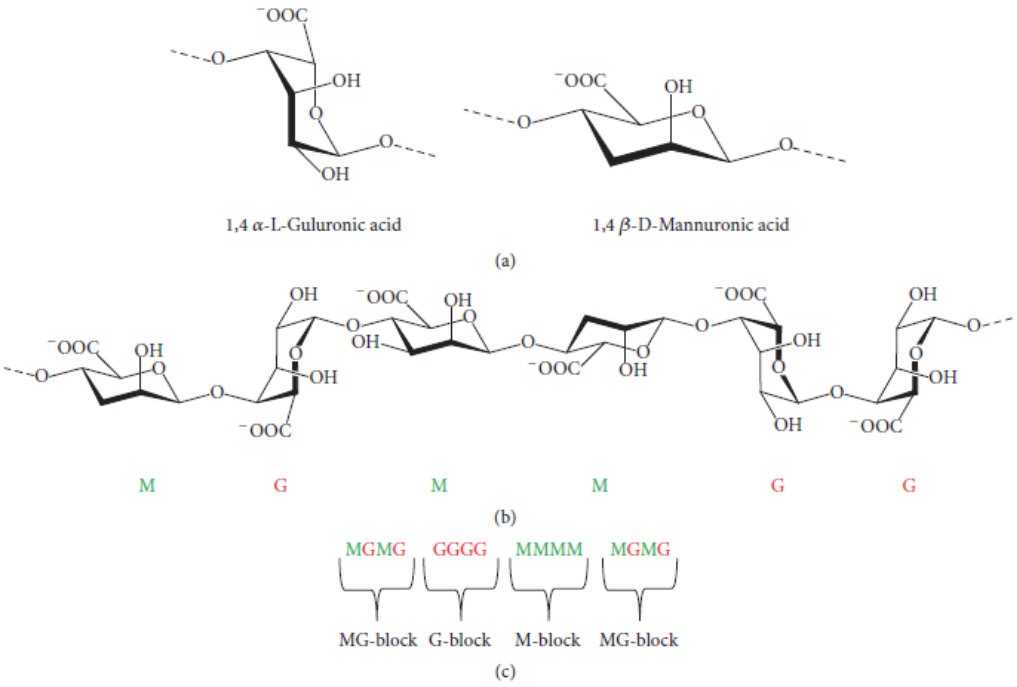

FIGURE 1: The structure of ALG: monomers (a), chain conformation (b), and blocks distribution (c).

[2] 21 CFR §184.1610 and §184.1724.

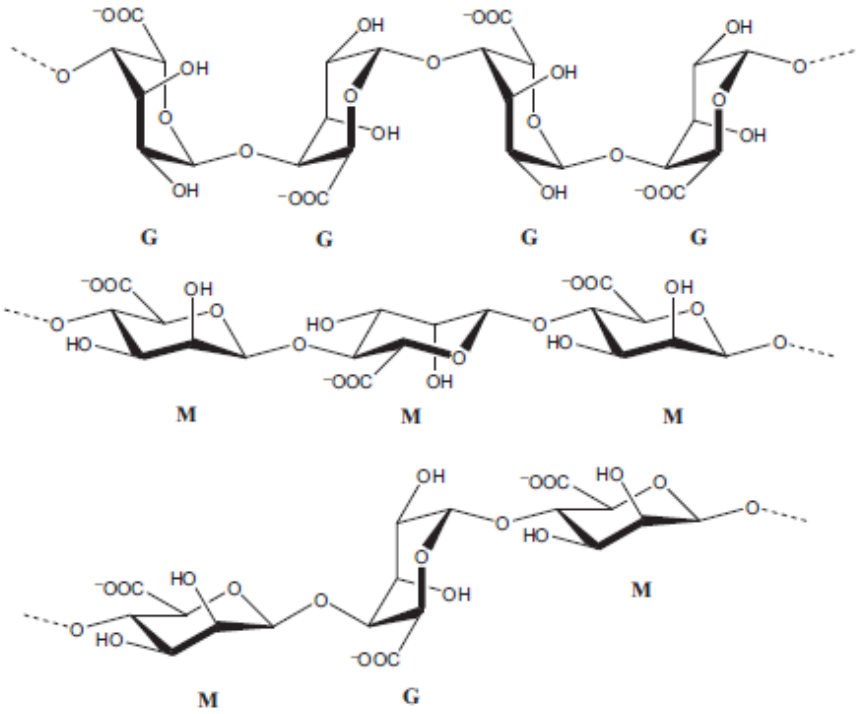

Figure 2: Structural formulae of polymeric blocks of a glycuronoglycan chain consisting of D-mannuronate (M) and L-guluronate (G) units in alginic acid and its salts

Potassium alginate and sodium alginate are prepared by the neutralization of purified alginic acid with appropriate pH control agents (21 CFR §184.1610 and §184.1724). The *Food Chemicals Codex* describes both potassium alginate and sodium alginate as white to yellow-brown, fibrous or granular powders that are the salts of alginic acid.[3] The CAS number of potassium alginate is 9005-36-1 and that of sodium alginate is 9005-38-3.

As indigestible polysaccharides, both alginates function as dietary fiber, a necessary dietary macronutrient.[4] Potassium alginate contains approximately 63% carbohydrates (almost all fiber), 27% ash and 10% water. Sodium alginate contains approximately 70% carbohydrates (almost all

[3] The United States Pharmacopeial Convention, Food Chemicals Codex (13th Ed. 2022), available at https://www.foodchemicalscodex.org/.

[4] FDA, Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates (2018).

fiber), 20% ash and 10% water. The most abundant polymer-bound sugars are D-mannuronic acid and L-guluronic acid.

C. History of Current GRAS Regulations for Potassium and Sodium Alginate

Potassium and sodium alginates are GRAS-affirmed substances with limitations on their use that vary by food category (21 CFR §184.1610 and 21 CFR §184.1724).

Table 1. Potassium alginate may be used in food in the U.S. only within the following specific limitations (21 CFR §184.1610) (relevant portions highlighted)

Category of food	Maximum level of use in food (as served)(percent)	Functional use
Confections and frostings	0.1	Stabilizer, thickener
Gelatins and puddings	0.7	Do
Processed fruits and fruit juices	0.25	Do
All other food categories	0.01	Do

Table 2. Sodium alginate may be used in food in the U.S. only within the following specific limitations (21 CFR §184.1724) (relevant portions highlighted)

Category of food	Maximum level of use in food (as served)(percent)	Functional use
Condiments and relishes, except pimento ribbon for stuffed olives	1.0	Texturizer, formulation aid stabilizer, thickener
Pimento ribbon for stuffed olives	6.0	Do
Confections and frostings	0.3	Stabilizer, thickener
Gelatins and puddings	4.0	Firming agent, flavor adjuvant, stabilizer, thickener
Hard candy	10.0	Stabilizer, thickener
Processed fruits and fruit juices	2.0	Formulation aid, texturizer
All other food categories	1.0	Emulsifier, firming agent, flavor enhancer, flavor adjuvant, processing aid, stabilizer and thickener, surface active agent

These GRAS regulations were promulgated in 1982 and 1983 and have not been amended in the forty years since. In setting the maximum levels permitted for these alginates, FDA relied upon a survey of a "representative cross-section of food manufacturers . . . to determine the specific foods in which the alginates were used and the levels of usage" along with "[i]nformation from surveys of consumer consumption . . . [used] to obtain an estimate of consumer exposure to these ingredients." In addition, the Agency conducted a search of the scientific literature from 1920 to 1978 to provide information about the safety of the alginates under consideration when used at then-current levels.

Based on these information sources, FDA determined that there was "no evidence in the available information on ammonium, calcium, potassium, sodium, and propylene glycol alginates that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public *when they are used at levels that are now current and in the manner now practiced*." Thus, a limitation of 1.0% was set for "all other food categories" because it was sufficient to cover the then-current uses for these ingredients and was viewed as safe in view of anticipated levels of consumption. Although FDA found that it was not possible to determine, without additional data, whether a significant increase in consumption of these substances would constitute a dietary hazard," there was no finding that higher levels of consumption associated with additional food categories or new uses of the ingredients might be unsafe. It is worth noting that the primary safety concern expressed during the rulemaking related to the presence of heavy metals, but ultimately the Agency determined that lead, arsenic and total heavy metal content of alginates were well within the limits prescribed by the then-current edition of the Food Chemicals Codex. The use of sodium and potassium alginate as contemplated by this Petition would expressly apply only where lead, arsenic, as well as cadmium and mercury are below the limits set forth in the Codex.

The action requested by this Petition is consistent with decisions of global food safety agencies with respect to alginates. In 1992, JECFA determined that the appropriate group acceptable daily intake (ADI) for alginates is "not specified." Experts from the EU have recently reviewed the safety of alginates and found no evidence of adverse effects; the European Food Safety Authority (EFSA) ANS Panel concluded that a numeric ADI was not warranted (2017). Similarly, Codex Alimentarius in its General Standard for Food Additives (GSFA) allows sodium and potassium alginate for a variety of uses, including frozen [and frozen battered] fish, fish fillets and fish products including mollusks, crustaceans, and echinoderms" and "cooked mollusks, crustaceans, and echinoderms," limited only by Good Manufacturing Practice (GMP). Codex GFSA Food Categories 09.2.1, 09.2.2 and 09.2.4.2.

As a result of these assessments, many regulatory agencies around the world permit the use of these two alginates (as well as the two other known algin salts, ammonium alginate and calcium alginate) with no restriction or limitations only for certain controlled foods. In the EU, all four alginates are authorized food additives at *quantum satis* levels (i.e., "the amount that is enough") in almost all foodstuffs (69 food categories).[5] Alginate salts have been evaluated in detail by EFSA (EFSA ANS Panel, 2017). Similarly, Canada does not limit its use of algin (the name used by

[5] The only exceptions are peeled, cut and shredded fruit and vegetables (sodium alginate, 0.24%); jam, jellies and marmalades and sweetened chestnut puree (1%); other similar fruit or vegetable spreads (1%); processed cereal-based foods and baby foods for infants and young children (0.05%); dietary foods for infants for special medical purposes and special formulae for **infants** (0.1%); and dietary foods for babies and young children for special medical purposes (depending on the salt; 0.1% or 0.05%) (EFSA ANS Panel, 2017).

Canadian authorities for alginate) and its acid and salts in most food categories, including all "unstandardized foods" commensurate with good manufacturing practice (Health Canada, 2019).

This Petition is necessitated by the confluence of certain idiosyncrasies of the GRAS regulation scheme. When the alginate regulations were published four decades ago, FDA stated that "*[u]ses under development [that] represent potentially expanded levels of consumption . . . must be the subjects of GRAS or food additive petitions*." As the Agency has explained, "when a use of a substance *does not qualify for GRAS status* or other exceptions provided under section 201(s) of the FD&C Act, that use of the substance is a food additive use subject to the premarket approval mandated by the FD&C Act."[6] Thus, companies proposing GRAS uses such as those described herein would have been expected to utilize the GRAS petition process. FDA subsequently eliminated the unwieldy GRAS petition process and instituted a streamlined GRAS notification process in its place,[7] but determined that the notification process would not be available for new uses of substances with existing GRAS affirmation regulations.[8] Instead, a company must submit a food additive petition or petition FDA to amend the GRAS affirmation regulation, even where the new uses are generally recognized by qualified experts as safe based on scientifically derived information. Somewhat ironically, what this means is that small, demonstrably safe increases in well-established food ingredients that have been in the food supply for decades or even centuries require resource-intensive notice-and-comment proceedings, while entirely new ingredients that are often produced through the application of novel and complex technologies and that lack extensive histories of use may be legally marketed using the faster, streamlined, resource-sparing procedure.

D. Use of Potassium and Sodium Alginate in Plant-Based Shellfish Alternative Products

A variety of concerns, including animal welfare, human health, environmental sustainability and religious beliefs, are increasingly causing consumers to reject, or limit their intake of, meat and seafood products. This trend has resulted in an increasing demand for alternative products that look, taste, and feel like their animal-derived counterparts, as evidenced by the growing success of companies with plant-based products that have sensory characteristics that are very similar to

[6] 81 Fed. Reg. 54959 (August 17, 2016).

[7] 21 C.F.R. § 184.1(b)(2).

[8] 81 Fed. Reg. 54959 (August 17, 2016).

beef.[9] From a regulatory perspective, these meat-alternative companies have been able to commercialize their products successfully by establishing that their novel functional ingredients are "generally recognized as safe" (GRAS), using FDA's GRAS notification pathway. Granting this petition will support a similar path to market for shellfish alternative products.

Companies developing seafood alternatives seek to replicate this success for their vegan shellfish replacements. These manufacturers have discovered that sodium or potassium alginate can provide a seafood-like texture to their products as well as thermal stability (with potassium alginate preferred in order to minimize overall sodium levels in the products). The levels of alginate that are functionally required for these products are within levels accepted by other countries and intergovernmental organizations, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and food regulatory authorities in the European Union, Canada, Australia, and New Zealand, and as described in greater detail in the attached report, the industry believes that potassium and sodium alginates are GRAS at levels up to 5%. However, the level of potassium or sodium alginate needed to produce the required texture and stability exceeds the 0.01% or 1% maximum levels, respectively, permitted by FDA's GRAS affirmation regulation. As a result, and unlike the path to market available to developers of beef alternatives, a GRAS notification is not permitted for this use of potassium or sodium alginate. Rather, FDA's regulatory scheme requires that a manufacturer seeking FDA's concurrence with a GRAS determination for an ingredient with an existing, if outdated, GRAS affirmation regulation must either submit a Food Additive Petition asking FDA to issue a new food additive regulation or seek an amendment of the existing GRAS affirmation regulation.[10]

E. Safety of Alginates as Food Ingredients

1. History of Use

Marine algae or seaweed has been used as a human food for at least 14,000 years (Dillehay et al., 2008), and alginate-containing brown seaweeds (class Phaeophyceae) are used today as a human food, as cattle fodder and as a fertilizer (CyberColloids, undated). Alginate was first extracted and patented by the British chemist E.C.C. Stanford in 1881 (UDSA, 2015); algin was isolated by A. Krefting in 1896. Commercial production of algin was initiated by the Kelco Co. in California in the 1920s, with the extracted material used as a boiler compound and for can-sealing purposes. In the 1930s, alginate began to be used in foods (first as a stabilizer in ice cream) and, by the mid-

[9] "The global meat substitutes market is projected to grow from $5.88 billion in 2022 to $12.30 billion by 2029, at a CAGR of 11.11% in forecast period, 2022-2029." Fortune Business Insights (August 2022).https://www.fortunebusinessinsights.com/industry-reports/meat-substitutes-market-100239.

[10] 81 Fed. Reg. 54960, 55030-55031.

20th century, alginate-production plants had been established in the US, Europe and Japan (Nussinovitch 1997). Since then, alginates have been widely used as ingredients in a broad range of food applications because of their ability to retain water, and for their gelling, thickening and stabilizing properties.[11]

As summarized above, potassium alginate and sodium alginate are already affirmed GRAS (21 CFR §184.1610 and §184.1724, based primarily on the findings of the Select Committee on GRAS Substances (SCOGS, 1973). SCOGS found that there was "no evidence in the available information on ammonium, calcium, potassium, sodium, and propylene glycol alginates that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current and in the manner now practiced." Because, at the time the regulation was promulgated forty years ago, these ingredients were present in the U.S. food supply at relatively low levels, FDA's regulations allow the use of potassium alginate (21 CFR §184.1610) and sodium alginate (21 CFR §184.1724) to be added to most foods at only 0.01% and 1%. (For both ingredients, there are slightly higher limits for confections, frostings, gelatins, puddings and processed fruits and fruit juices; in addition, sodium alginate can also be used at substantially higher levels in condiments and relishes, pimento-stuffed olives and hard candy.) FDA also permits the use of alginic acid (21 CFR §184.1011), ammonium alginate (21 CFR §184.1133) and calcium alginate (21 CFR §184.1187) in specific foods with limitations.

2. Estimated Effect of Requested Action on Intakes of Alginates

Recent data on daily intake of alginate salts through food in the U.S. is not available, nor is usage of alginate salts in the American food supply.[12] Data on intake of shellfish alone by the U.S. population are available from the National Marine Fisheries Service (NMFS) and will be discussed below. In addition, there is information on the intake of alginate salts in the EU, estimated by EFSA (EFSA ANS Panel, 2017). Those estimates are used as a conservative indicator of alginate intake in the U.S. since alginates are approved in more food categories and mostly at *quantum satis* levels when compared to the limited current uses in the U.S. Taken together, estimated

[11] Not all brown seaweeds are useful as commercial sources of alginate but of those that are, one of the principal sources is Macrocystis pyrifera harvested off the coasts of southern California and Australia. European alginate production relies mainly on Laminaria hyperborea, Laminaria digitata and Ascophyllum nodosum.

[12]The SCOGS report (1973) estimated an intake of all alginates in the U.S. to be 14.1 mg/p/day (~0.2 mg/kg/day). As the information is very old and the methods used to derive this value were not well documented, this estimate is deemed to be of marginal utility and is not factored into this exposure assessment.

existing intake of alginates and information regarding shellfish intake in the U.S. can be used to assess the impact of granting the enforcement discretion sought by this Petition.

a. Estimated Daily Intake of Alginates in the EU

Alginic acid and its salts are used in a wide range of foods in the EU (appendices to the EFSA ANS Panel, 2017). The EDI of alginates in the EU was estimated by the EFSA ANS Panel (2017) (Table 8), using different exposure scenarios in assessing intake. The regulatory maximum level exposure assessment scenario was based on the Maximum Permitted Levels (MPL) set down in EU regulations and was considered the most conservative. The refined exposure scenario was based on uses and use levels reported by industry based on two different model systems, brand-loyal and non-brand-loyal. EFSA considered that the nonbrand-loyal scenario (at the bottom of the following table) was the appropriate and realistic scenario for risk characterization because it is assumed that a consumer would be exposed long term to alginic acid and its salts present at the mean reported use in food. This exposure estimate was calculated using the mean of the typical reported use level.

Table 8. Summary of anticipated exposure to alginic acid and its salts (E 400–E 404) from their use as food additives in the maximum level exposure assessment scenario and in the refined exposure scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw/day).

	Infants		Toddlers		Children		Adolescents		Adults		The elderly	
	(12 weeks–11 months)		(12–35 months)		(3–9 years)		(10–17 years)		(18–64 years)		(≥ 65 years)	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Maximum level exposure assessment scenario												
Mean	39.7	108.0	110.1	300.3	81.5	210.9	41.5	100.4	36.6	72.0	35.1	68.5
95th percentile	124.1	305.6	193.7	355.0	152.4	388.6	80.4	176.9	68.7	143.3	66.1	120.6
Refined estimated exposure assessment scenarios												
Brand-loyal scenario												
Mean	11.1	68.2	45.3	192.0	42.3	121.6	23.3	57.3	16.1	42.6	14.0	39.0
95th percentile	59.5	276.7	104.1	242.4	86.9	227.6	47.6	116.0	35.7	124.2	31.2	101.3
Non-Brand Loyal												
Mean	5.3	50.6	21.6	99.5	19.7	68.1	12.2	31.9	7.5	22.6	6.2	21.0
95th percentile	32.9	207.5	53.0	142.3	41.6	120.6	23.3	55.8	16.8	41.7	13.6	35.7

Source: EFSA ANS Panel, 2017; Table 11.

Mean maximum intakes of alginic acid and alginate salts by age group do not exceed 100 mg/kg/day. This maximum intake (99.5 mg/kg bw/day) is found in a small group (i.e., toddlers one to three years old) of the entire surveyed population. The 95th percentile intake of

alginic acid and its salts, representative of a heavy user, ranged from 13.6 mg/kg bw/day in elderly to 207.5 mg/kg bw/day in infants. It should be noted that infants and toddlers (< 3 years of age) are not anticipated to be typical users of plant-based shellfish products.

The maximum mean value for children 3-9 years (68 mg/kg/day) is taken to be a reasonable and conservative high intake of alginic acid and alginate salts for users in the U.S. It is three-times the mean maximum intake of the largest two groups (adults and the elderly) and twice that of adolescents in the EU where alginic acid and alginate salts are approved in many more categories than in the U.S. This value is taken to represent the EDI for the 90th percentile intake in the U.S. and is 340 times higher than the estimated intake (0.2 mg/kg bw/day) reported in the 1973 SCOGS report.

b. Estimated Impact of Alginate-Containing Shellfish Alternatives on Daily Intake of Alginates in the US, Based on Current Shellfish Consumption

Based on NMFS estimates, in 2018, Americans consumed approximately 3 kg shellfish/person/yr, or 8.2 g/person/day in 2018 on a *per capita* basis (NMFS 2020), although this number may represent an underestimate. A more accurate estimation of consumption of fish and shellfish was reported by Tran *et al.* (2013). The frequencies of shellfish intake over a 30-day period from National Health and Nutrition Examination Survey (NHANES 1999-2006) were combined with the 24-hour dietary recall data from NHANES 2003-2004 using a Monte Carlo procedure to estimate the "usual intakes" of shellfish which found that over 48% of the overall NHANES subjects are shellfish consumers.[13] The mean per capita shellfish intake was reported to be 3.06 g/day; this estimate is lower than the 8.2 g/day more crudely estimated in the NMFS report cited above.[14] Usual daily shellfish intake (all types combined) for the U.S. population was 6.38 g/day or 0.1 g/kg bw/day. Mean intake was lowest for children 1 to <2 years of age (0.56 g/day or 0.05 g/kg bw/day) and highest for males 21+ years old (8.71 g/day or 0.1 g/kg bw/day). On a g/kg bw/day basis, intake is highest among children 3 - <6 years at 0.18 g/kg bw/day.

This Petition seeks enforcement discretion for the use of potassium alginate and sodium alginate at levels not to exceed 5%, combined, in plant-based shellfish products. At this level and using a mean population *usual intake* of all shellfish of 6.4 g/day for shellfish consumers, it is estimated that consumption of alginates from shellfish alternative products would be 320 mg alginate salt/day (5.3 mg/kg bw/day based on a 60 kg person). The group consuming the highest amount

[13] Subjects who reported consumption of at least one of the shellfish categories in the Food Frequency Questionnaire over the last 30 days were considered shellfish consumers.

[14]The mean usual intake of shellfish (all types combined) is 60.6 g/eating occasion for shellfish consumers (Tran *et al.*, 2013). Intake at the 90th percentile, representing a high intake, is estimated to be 134 g of all shellfish/eating occasion for shellfish consumers (Tran *et al.*, 2013).

of shellfish per day, males 21+ yr., would consume 7.2 mg alginate salt/kg/day, using the same assumptions. For an average *eating occasion*, people would consume approximately 3 g alginate (50 mg alginate salt/kg bw/eating occasion based on a 60-kg person). At the 90th percentile a person would consume 6.7 g alginate salt/eating occasion (110 mg/kg/eating occasion based on a 60-kg person).

Assuming the data from the EU is representative of consumption in the U.S., a conservative estimate of current high intake (approximately the 90th percentile) of alginate salts from all food sources is approximately 68 mg/kg/day. The addition of alginates from shellfish alternative products as described in this Petition would add as much as 5.3 mg/kg/day to that estimate, for a total intake from food sources of approximately 73 mg/kg bw/day (approximately 4.3 g/day for a 60-kg person).

3. Safety Assessments by Authoritative Bodies

The totality of the evidence of publicly available, published, scientific literature regarding alginate salts, including intestinal fermentation, short- and long-term preclinical toxicity, developmental and reproduction toxicity, carcinogenicity, and *in vitro* and *in vivo* mutagenicity/genotoxicity studies, indicates no adverse effects up to the highest levels tested. Accordingly, as described above in Section C, authoritative bodies that have considered food uses of alginates have concluded that alginates do not need a numeric ADI. In short, the entire body of available information relevant to the safety of potassium alginate and sodium alginate, including identity, specifications, manufacturing process, probable consumer exposure, dietary reference intake values for fiber, and toxicology profile, provides a basis upon which to conclude that there is a reasonable certainty that potassium alginate and sodium alginate are not harmful under the intended conditions of use. Based upon the totality of public, generally available data about alginate salts in general and using conclusions by expert bodies from around the world, it is appropriate to conclude that potassium alginate and sodium alginate, at least when used at levels up to 5%, are GRAS for the intended conditions of use described herein.

F. Public Health Benefits of Shellfish Alternative Products

Plant-based shellfish alternatives are a potential solution, at least in part, to the increasingly urgent problem that mankind is rapidly depleting the oceans of global fish stocks to such an extent, according to one report, "that without urgent measures we may be the last generation to catch food from the oceans."

Equally important is the fact that plant-based shellfish alternatives help address the risks associated with consuming shellfish and other seafood products, which have been emphasized prominently on the CFSAN homepage. Seafood – particularly raw or rare fish and shellfish can

transmit a variety of foodborne illnesses, including vibriosis and norovirus infection. Seafood is also a source of ingested man-made contaminants that can be harmful to human health. Indeed, FDA has issued updated advice about eating fish that incorporates the recommendations of the Dietary Guidelines for Americans, 2020-2025. See Advice about Eating Fish (May 3, 2022); Q&As from the FDA/EPA: Advice about Eating Fish for Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1 to 11 Years (February 17, 2022), and FDA Issues Updated Advice about Eating Fish (October 28, 2021). While these resources recognize that that eating fish provides a variety of health benefits, it also acknowledges that certain populations, including those who are pregnant or breastfeeding and children under the age of 12, should limit consumption of fish and shellfish to 3 or fewer servings per week to avoid exposure to mercury. Indeed, FDA has recently announced that it is partnering with the National Oceanic and Atmospheric Administration, U.S. Department of Agriculture, and U.S. Environmental Protection Agency on an independent study by the National Academies of Sciences, Engineering, and Medicine (NASEM) on the Role of Seafood Consumption in Child Growth and Development. The study supports the goals of the FDA's Closer to Zero Action Plan for reducing the exposure of babies and young children to mercury, arsenic, lead, and cadmium from foods. In making its announcement, FDA said:

> Seafood is part of a healthy eating pattern and provides key nutrients during pregnancy, breastfeeding, and/or early childhood to support a child's brain, spinal cord, and immune system development. At the same time, seafood is the primary dietary source of mercury, which is spread throughout the environment by both natural and human-made processes. Mercury can damage the nervous system, and babies and young children are more vulnerable to the harmful health effects of mercury. Seafood can also be a source of exposure for other naturally occurring and human-made contaminants. NASEM will convene a committee of experts to conduct systematic reviews of the scientific literature on seafood nutrition and toxicology; taken together, these data will inform the basis for evaluating how seafood consumption impacts child growth and development.

The availability of a plant-based shellfish alternatives could provide American consumers with a healthy option to substitute or supplement current shellfish intake to improve consumer and environmental health.

The availability of shellfish alternatives will also serve the interests of the significant proportion of the U.S. population affected by fish and shellfish allergies. Shellfish allergies are the most

common food allergies in adults and among the most common food allergies in children. Allergies to shellfish are generally estimated to affect 2.3% of the generally population,[15] but may be as prevalent as 10%.[16]

In light of the foodborne illness and allergy risks associated with the consumption of shellfish, as well as religious, environmental and animal welfare concerns that limit or preclude some individuals' consumption of seafood, the availability of a plant-based alternatives that mimic the taste and texture of shellfish would provide American consumers with a healthy, sensory-pleasing option to substitute for, or supplement, intake of fish and shellfish. In addition, while the main technical effect of potassium alginate and sodium alginate in shellfish alternative products is as a stabilizer and thickener to create a gel that has the texture of fish or shellfish, alginates are also considered to be dietary fiber,[17] a nutrient that most Americans do not consume in sufficient quantities.[18] The Institute of Medicine of the National Academies of Medicine currently recommends an Adequate Intake level of 38 g fiber/day for adult males and 25 g fiber/day for adult females (ages 19-50 years).[19] According to 2009-2010 NHANES data, mean daily dietary fiber intake is 16.2 g[20]. Thus, most people fall short of the recommended intake of fiber (28g).[21] Indeed, dietary fiber is considered a "nutrient of public health concern" because low intakes are associated with potential health risks.[22] Consumption of foods containing fiber,

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[15] *See* website of the Food Allergy and Research Foundation. *See also,* SH Sicherer *et al.,* Prevalence of seafood allergy in the United States determined by a random telephone survey. *J Allergy Clin Immunol* 2004 Jul;114(x), concluding that "Physician-diagnosed and/or convincing seafood allergy is reported by 2.3% of the general population, or approximately 6.6 million Americans."

[16] Rona RJ *et al.*, The prevalence of food allergy: a meta-analysis. *J Allergy Clin Immunol*. 2007 Sep;120(3):638-46

[17] FDA, Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates (June 2018).

[18] Quagliani D and Felt-Gunderson P. Closing America's fiber intake gap: communication strategies from a food and fiber summit. *Am J Lifestyle Med*. 2016 Jul 7;11(1):80-85.

[19] Institute of Medicine, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: The National Academies Press (2005).

[20] Quagliani, *supra*, n.21

[21] FDA, Daily Value on the New Nutrition and Supplement Facts Labels (webpage current as of February 25, 2022; accessed October 9, 2022).

[22] HHS and USDA, Dietary Guidelines for Americans 2015-2020 (8th Ed.) (stating that "some nutrients are consumed by many individuals in amounts below the Estimated Average Requirement or Adequate Intake levels. These include . . . dietary fiber, . . . Of the underconsumed nutrients, calcium, potassium, dietary fiber, and vitamin D are considered nutrients of public health concern because low intakes are associated with health concerns."

even in low amounts, can be beneficial to public nutrition since dietary fiber intake is inadequate in many populations.

III. ENVIRONMENTAL IMPACT

Because the action requested would amend 21 CFR § 184.1610 and § 184.1724, this Petition is categorically excluded under 21 CFR § 25.32(r) from the requirement for an environmental assessment under § 25.40 of this chapter, as the Petition requests revisions of GRAS limitations with respect to substances that occur naturally in the environment, and the action will not significantly alter the concentration or distribution of the alginates, their metabolites, or their degradation products in the environment.

IV. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Georgia C. Ravitz

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Naomi J. L. Halpern

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