Carrageenan
Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Carrageenan, carragheenan, carrageen
iota-Carrageenan
kappa-Carrageenan
lambda-Carrageenan

Other Names:
PES (processed *Eucheuma* seaweed)
Carageenan gum
Chondrus
Carrageenin
Irish Moss, Irish Moss Extract, Irish Moss Gelose
Vegetable Gelatin, Norsk Gelatin
Danish Agar
Carastay, Carastay C
Eucheuma spinosum gum
Marine colloids
Red seaweed (Rhodophyceae) extract

Trade Names:
None

CAS Numbers:
9000-07-1 (general)
9062-07-1 (iota)
11114-20-8 (kappa)
9064-57-7 (lambda)

Other Codes:
232-524-2 (EINECS, general)
232-949-3 (EC No., general)
232-949-3 (EC No., iota)
234-350-2 (EC No., kappa)
232-953-5 (EC No., lambda)

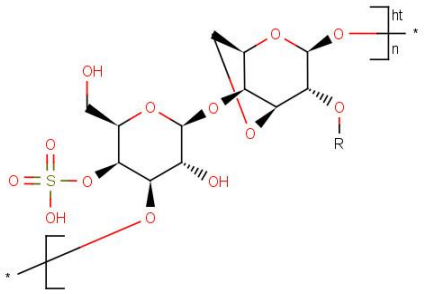
Characterization of Petitioned Substance

Composition of the Substance:

Carrageenan is a generic term referring to a family of linear polysaccharides (i.e., complex carbohydrate chains) that are extracted from species of red seaweeds (Class *Rhodophyceae*) (van de Velde and De Ruiter, 2002). There are several different carrageenans with slightly varied chemical structures and properties (McHugh, 2003). Different *Rhodophyceae* species produce carrageenans in varying nonhomologous polysaccharide mixtures (McHugh, 2003; van de Velde and De Ruiter, 2002).

Individual carrageenans are best described based on the structure of the disaccharide units (i.e., simple carbohydrate chains) that create the polysaccharide molecule (van de Velde and De Ruiter, 2002). Ideally, each disaccharide in the chain contains a beta-delta-galactopyranose (G-unit) with either an alpha-delta-galactopyranose (D-unit) or 3,6-anhydrogalactose (DA-unit). Other carbohydrate residues commonly exist in carrageenan, such as xylose, glucose, and uronic acids. The disaccharide units are variably sulfated, resulting in a sulfate content of 22% to 38% by weight in commercial carrageenan (van de Velde and De Ruiter, 2002). Other cations, such as ammonium, calcium, magnesium, potassium, and sodium, are also often present in the form of galactose esters (FAO, 2007; U.S. Pharmacopeia, 2010). The three most prevalent, and of highest commercial interest, polysaccharides of carrageenan are iota-, kappa-, and lambda-carrageenan (van de Velde and De Ruiter, 2002; FAO, 2007; U.S. Pharmacopeia, 2010). The repeating molecular structure of kappa-carrageenan is shown in Figure 1. Iota- and lambda-carrageenan are similar in structure, but differ in the number and position of the ester sulfate groups (van de Velde and De Ruiter, 2002; FAO, 2007).

Figure 1. Repeating Molecular Structure of Kappa-Carrageenan



(Source: ChemIDplus Advanced, 2011)

Properties of the Substance:

Commercial preparations of carrageenan are nearly odorless powders that are yellowish, tan, or white in color (FAO, 2007). Carrageenan is soluble in hot water (80°C) and variably soluble in room temperature water (20°C), depending on the polysaccharide types present (FMC BioPolymer, 2010). Carrageenan will disperse more readily in water if the powder is first moistened with alcohol, glycerin, or a saturated glucose or sucrose solution (FAO, 2007). Carrageenan is also soluble in boiling milk (FMC BioPolymer, 2010).

The molecular mass of carrageenan varies depending on the sample, but averages 400 to 600 kDa (roughly 6.6×10^{-10} to 10×10^{-10} nanograms) and is no less than 100 kDa in commercial grade mixtures (van de Velde and De Ruiter, 2002). Carrageenan molecules are negatively charged, which allows them to react with positively charged substances like salt ions or proteins (McHugh, 2003). When potassium or calcium salts are added to carrageenan dissolved in boiling water, the solution will form a gel as it cools. The stiffness, resilience, and level of thixotropic flow (i.e., the ability to flow like a thick liquid when stirred, but return to gel when left alone) vary depending on the predominant type of carrageenan (iota, kappa, or lambda) and type of salt used to form the gel. Similarly, carrageenan will form gel matrices through reactions with positively charged proteins such as casein in milk (McHugh, 2003).

Specific Uses of the Substance:

Carrageenan is used as a food additive in the production of a wide range of processed foods, including dairy products, water-based foods, meat products, beverages, condiments, infant formula, and pet food (McHugh, 2003). Carrageenan can function as a bulking agent, carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, or thickener (Codex Alimentarius Commission, 2010). Carrageenan is added to processed foods because it can bind water, promote gel formation, thicken, stabilize, and improve palatability and appearance through interaction with other substances in the food (e.g., proteins, sodium or calcium phosphates, starch, galactomannan, carboxylmethylcellulose) (Piculell, 2006). Table 1 provides a detailed list of different food products in which carrageenan is commonly found, and the purpose for its addition to those products.

Carrageenan is widely used in dairy products to improve texture, thickness, and solubility (McHugh, 2003). Carrageenan can successfully prevent separation and maintain texture in dairy products when added in small amounts—around 0.3% in milk gels (such as custards, flans, and creamy fillings), whipped cream, yogurt, and milkshakes, and 0.03% in frozen desserts and liquid milk products (Piculell, 2006).

Carrageenan can be used as a fat substitute in processed meats, as it improves moisture retention and restores tenderness in low-fat processed meats like hamburgers (McHugh, 2003). For example, recent research showed that ground pork patties with less than 10% total fat and carrageenan at maximum concentrations of 0.75% actually had higher moisture retention after cooking and a similar texture

compared to pork patties containing 20% fat and no carrageenan (Kumar and Sharma, 2004). While carrageenan has been used as a fat replacer in processed meat since at least the early 1990s (Ramirez, 1991), food science researchers are still exploring the use and no information was found to indicate exactly how common this use is today.

Table 1. Uses of Carrageenan in Food Products

Product	Purpose for Addition/Action in Product	Source
Cottage cheese	Prevent separation of whey	McHugh, 2003
Ice cream	Prevent separation caused by addition of gums meant to control texture and ice crystal growth	McHugh, 2003
Flans, custards, cream fillings	Stabilizer, gelling agent	Piculell, 2006
Cheese	Stabilizer	Piculell, 2006
Coffee creamers, evaporated and condensed milk	Prevent separation of fat	McHugh, 2003
Flavored milk (i.e., chocolate milk) and milkshakes	Holds cocoa or other flavoring in suspension	McHugh, 2003; Saha and Bhattacharya, 2010
Whipping cream	Maintain "lightness"	McHugh, 2003
Mousse, pudding, fruit/water gel desserts	Vegetarian substitution for gelatin; stabilizer and emulsifier	McHugh, 2003; Piculell, 2006
Low calorie jellies	Replace pectin and sugar with carrageenan, to help set	McHugh, 2003
Drink mixes (powdered lemonade, fruit punch, etc)	Provide texture when reconstituted in cold water	McHugh, 2003
Sorbet	Provide smooth texture (gelling agent)	McHugh, 2003; Piculell, 2006
Low-fat (i.e. Low-oil) salad dressings	Suspend herbs and provide thicker texture	McHugh, 2003
Low-fat (i.e. Low-oil) mayonnaise	Thicken and stabilize	McHugh, 2003
Relishes	Gelling agent	Piculell, 2006
Pre-cooked poultry products	Injected as brine to improve texture, tenderness and maintain juiciness	McHugh, 2003
Low-fat/low-sodium processed meat and poultry	Improves juiciness and tenderness; behaves like fat and retains moisture through cooking; helps bind meat product during cooking	McHugh, 2003; applegatefarms.com
Fish	Added prior to processing for water retention	Piculell, 2006
Canned pet food	Re-bind meat, create gravy/jelly around meat pieces	McHugh, 2003
Infant formula	Stabilizer	Watson, 2008
Beer	Clarification through precipitating with proteins	McHugh, 2003
Fresh-cut packaged fruits	Slow/control discoloration, maintain texture	Plotto et al., 2006; Bico et al., 2009; Plotto et al., 2010
Tofu	Stabilizer	Saha and Bhattacharya, 2010

One newly-explored use of carrageenan in the food industry is as a protective coating on fresh-cut packaged fruits. Carrageenan coatings function as a gas barrier, adhering to the cut surface of the fruit and reducing respiration, which slows discoloration (Baeza, 2007). Recent studies have shown that carrageenan is successful in controlling discoloration, maintaining texture through shelf-life, and providing antibacterial protection when used as an edible fruit coating on sliced lychee (Plotto et al., 2006), bananas (Bico et al., 2009), and mangoes (Plotto et al., 2010). While research on the use of carrageenan in the fresh-cut, pre-packaged fruit industry is present in the peer-reviewed literature, it is unclear how commonly carrageenan is actually used for this purpose.

There is no indication in the literature that the food uses of carrageenan have changed substantially since the 1995 Technical Advisory Panel (TAP) review for carrageenan (USDA, 1995). However, the distribution of global carrageenan market among different use sectors has changed over the last decade (Bixler and Porse, 2010). Figure 2 shows the changing trends in percentages of global carrageenan market occupied by

various applications from 1999 to 2009. Specifically, the use of carrageenan in dairy products has declined from 40% of total carrageenan use to 31% of total use, although absolute volume usage has increased by nearly 17%. The use of carrageenan in processed meats has increased to 41%, of the total market and absolute volume usage has increased by 85%. The use of carrageenan in water gels has also increased, however this mainly reflects the Asian market and not the U.S., where gelatin is preferred over carrageenan in these products (Bixler and Porse, 2010).

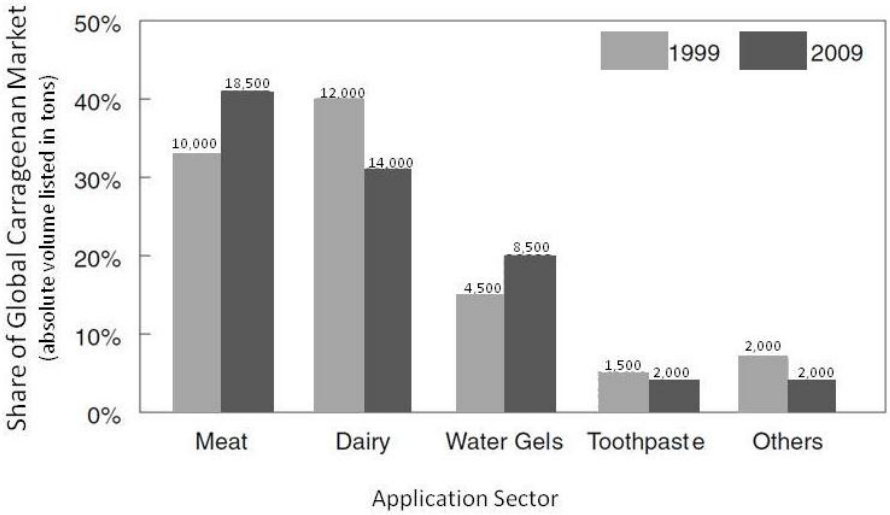


Figure 2. Changing Trends in Global Carrageenan Use by Sector, 1999-2009
(Chart modified from: Bixler and Porse, 2010)

Carrageenan is also used in nonfood applications such as air freshener/odor-absorbing gels, and toothpastes (McHugh, 2003). Recently, the market has opened for nonfood consumer products like cosmetics, pharmaceuticals (i.e., pill coatings and drug capsules) (Bixler and Porse, 2010), sexual lubricants, and topical microbicides to protect against HIV, herpes simplex viruses, and potentially human papillomavirus (Buck et al., 2006).

Approved Legal Uses of the Substance:

Carrageenan was added to the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) on October 31, 2003, allowing its use in organic handling/processing (68 FR 61993). The addition was a technical correction, and it was noted in the Federal Register that carrageenan was included in the proposed National List on December 16, 1997, but accidentally omitted from the National List that was published in the Federal Register on March 13, 2000 (65 FR 13627) and the subsequent final rule (7 CFR § 205) published on December 21, 2000 (65 FR 80548). Per requirements of the Organic Foods Production Act of 1990, carrageenan was reviewed and reauthorized five years later (November 2008), as the Secretary of Agriculture concurred with the National Organic Standard Board's determination that carrageenan is "critical to organic production and handling operations" (73 FR 59481).

According to FDA, carrageenan may be safely used as a direct food additive for human consumption as long as its use is in accordance with 21 CFR § 172.620. This regulation specifies that carrageenan should be prepared by aqueous extraction from the following eight species of *Rodophyceae* seaweeds: *Chondrus crispus*, *Chondrus ocellatus*, *Eucheuma cottonii*, *Eucheuma spinosum*, *Gigartina acicularis*, *Gigartina pistillata*, *Gigartina radula*, and *Gigartina stellata*.

Additionally, 21 CFR § 172.620 specifies that the sulfate content of carrageenan must be within the 20 to 40 percent range, the dominant hexose units must be galactose and anhydrogalactose, and the name carrageenan must be used on the label. Carrageenan must be used or intended for use in the amount

necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

Salts of carrageenan are also permitted for safe use as a direct food additive under 21 CFR § 172.626. "Salts of carrageenan" are defined within this regulation as carrageenan meeting the provisions of 21 CFR § 172.620 that has been modified by increasing ammonium, potassium, calcium, or sodium to the level that it is the dominant salt. Salts of carrageenan must be labeled according to the dominant salt, for example "sodium carrageenan." Salts of carrageenan must be used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

Action of the Substance:

Carrageenan is added to products during handling because it exhibits a number of desired properties, including:

- Ability to bind moisture (i.e., water, salt solutions), therefore retaining fluid in a product;
- Ability to stabilize emulsions, inhibit separation due to thickening action and thixotrophic properties (i.e., flows like a liquid when stirred, but acts like gel when left alone);
- Ability to suspend particles, thereby maintaining uniform distribution of insolubles within a solution (i.e. herbs within oil of salad dressing);
- Displays a minimal viscosity at high temperatures yet thickens and solidifies when cool, which allows for easier processing of certain food products; and
- Produces gel matrices through changes in heat and reaction with various proteins and cations. (FMC Biopolymer, 2010)

Combinations of the Substance:

Carrageenan is often used in combination with other emulsifiers, gelling agents, or stabilizers, including xanthan gum, locust bean gum, and pectin (McHugh, 2003), in order to achieve the desired actions described above. Locust bean gum is a gelling agent, whereas xanthan gum and guar gum are non-gelling agents; all three are thickening agents (Saha and Bhattacharya, 2010).

Status

Historic Use:

Carrageenan-bearing *Chrondrus crispus* seaweed was first used in food processing over 600 years ago, when it was boiled with milk to produce flan in the Irish coastal village of Carraghen (van de Velde and De Ruiter, 2002). While used in a variety of food products throughout history in Europe and the Middle East, use of extracted carrageenan as a food additive in the U.S. did not begin until the late 1930s, when it was discovered that carrageenan extracted from *Chondrus crispus* could stabilize chocolate milk (Watson, 2008).

OFPA, USDA Final Rule:

Carrageenan is currently included on the National List as a nonagricultural (nonorganic), nonsynthetic substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))" (7 CFR § 205.605(a)). There are no annotations or restrictions regarding the origin or use of carrageenan under the National Organic Program.

International:

The International Federation of Organic Agriculture Movements (IFOAM) lists carrageenan as a permissible food additive (IFOAM, 2006).

The Codex Alimentarius Commission of the Joint FOA/WHO Food Standards Programme lists carrageenan as a food additive permitted for use in plant-based foods, dairy products, and dairy analogues (excluding fats, oils, and fat emulsions) within the guidelines for organically produced foods (Codex Alimentarius Commission, 2007).

Carrageenan is permitted for use in Canadian organic handling and processing according to the most recent June 2011 amendment of the Canadian Organic Production Systems Permitted Substances Lists. It is classified on the Lists as a non-organic ingredient allowed in food processing as a food additive (section 6.3) and/or processing aid (section 6.6) (CGSB, 2011).

The European Economic Community (EEC) Council Regulation permits the use of carrageenan as a food additive in preparation of plant-origin organic food products or animal-origin, dairy-based organic food products (Commission of the European Communities, 2008).

The East African Organic Product Standard and the Pacific Organic Standard both list carrageenan as an additive allowed in organic food processing (East African Community, 2007; Secretariat of the Pacific Community, 2008).

Carrageenan is not listed in the Japanese Agricultural Standard for Organic Processed Foods (Japanese MAFF, 2006).

Evaluation Questions for Substances to be used in Organic Handling

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

Carrageenan is extracted from red seaweeds (*Rhodophyceae)* harvested from natural populations or commercially farmed populations (Van de Velde and De Ruiter, 2002). *Euchema cottonii* and *Eucheuma spinosum* are the most common species used, which grow in the warm waters of the Philippines, Indonesia, and Tanzania (Bixler and Porse, 2010) and produce kappa- and iota-carrageenan, respectively (Imeson, 2000). Less common *Chondrus crispus,* which grows in the north Atlantic, *Gigartina* species, from western South America, and *Furcellaria* species, from Northern Europe and Asia, produce both kappa- and lambda-carrageenan (Imeson, 2000).

After seaweed is harvested, a number of processing methods can be used to produce either refined or semi-refined carrageenan. All of the processes follow the same basic steps (Blakemore and Harpell, 2009; McHugh, 2003; Imeson, 2000). First, the seaweed is sun-dried, baled, and brought to a manufacturing site where is it ground and filtered to remove sand and salt. It is then washed to further remove salt, sand, and other contaminants, and processed through an alkaline treatment method. Next, either refined carrageenan can be separated from other seaweed materials using centrifugation, filtration, and a precipitation method, or semi-refined carrageenan (PES) can be produced with simple chopping, bleaching, and water washes that dissolve and wash away other seaweed materials. The final steps in the production of both carrageenan products involve drying, grinding, and blending of the product (Blakemore and Harpell, 2009; McHugh, 2003; Imeson, 2000).

The three main extraction methods used to produce commercial carrageenan, shown in Figure 3, are alcohol preparation, gel press, and semi-refined or PES extraction (Imeson, 2000; Blakemore and Harpell, 2009). The gel-press and alcohol preparation method are the same with the exception of how the

carrageenan is purified and recovered as a solid from a concentrated solution (Imeson, 2000; McHugh, 2003). These methods use an alkali (e.g., sodium hydroxide, potassium hydroxide, or calcium hydroxide) to extract carrageenan from the seaweed into an aqueous solution, then use centrifugation, filtration, and a precipitation method to recover a very pure, solid carrageenan (McHugh, 2003). With the semi-refined extraction process, an alkali is used to dissolve most extraneous seaweed matter (e.g., cellulose, proteins) from the carrageenan, so centrifugation or filtration is not necessary and the solid carrageenan can be recovered simply through drying/evaporation of water (McHugh, 2003). Additionally, the Danisco Company recently developed a fourth method which is similar to the semi-refined method, but more expensive, as the alkali treatment is performed in an alcohol slurry. However, it can be used on a wider variety of seaweed species (CyberColloids, 2011). This method is patented by the Danisco Company, which has used it in carrageenan production since approximately 1996 (Larson, 1996).

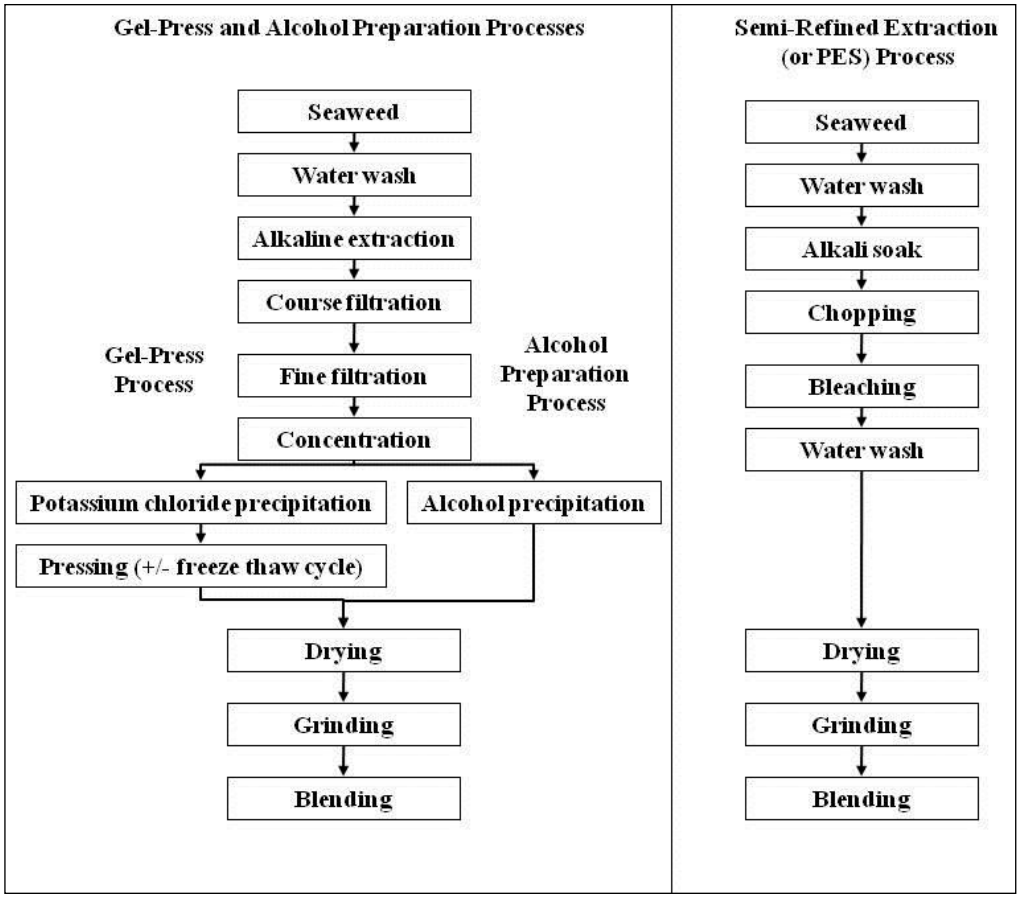


Figure 3. Three Common Carrageenan Production Methods
(Chart modified from: Imeson, 2000 and Blakemore and Harpell, 2009)

The Alcohol Preparation Extraction Method:

Alcohol preparation is the most traditional method, and the only method for extracting lambda-carrageenan (CyberColloids, 2011). Isopropanol is used to precipitate the carrageenan as a fibrous coagulate, which is separated from the solution using centrifugation or a sieve, pressed to remove additional alkaline solvent, and washed again with alcohol to dehydrate (McHugh, 2003). In order for alcohol preparation to be a cost-effective method for carrageenan production, the alcohol must be recovered and recycled (McHugh, 2003).

The Gel-press Extraction Method:

The gel-press method, which has gained popularity in recent years (van de Velde and De Ruiter, 2004; Bixler and Porse, 2010), can only be used to extract kappa-carrageenan (McHugh, 2003), as kappa-carrageenan has a very specific affinity to form gels in the presence of potassium salts (Imeson, 2000). In this method, kappa carrageenan gel is precipitated out of seaweed in a concentrated potassium chloride solution, then pressed to exclude water before being dried and ground to create carrageenan powder (Imeson, 2000). Additionally, freeze-thaw cycles can be used to exclude even more water prior to the drying phase: when a frozen gel solution thaws, the gel contracts and pushes liquid out through a chemical phenomenon known as synaeresis (McHugh, 2003).

The Semi-refined/PES Extraction Method:

The semi-refined extraction method is the fastest-growing technology for carrageenan manufacturing (Bixler and Porse, 2010). In this method, carrageenan is not technically extracted out of the seaweed; rather, water and alkali are used to wash all other compounds (e.g., soluble proteins, carbohydrates, cellulose) away from the carrageenan (McHugh, 2003). Because this method does not involve expensive steps like centrifugation, concentration, and precipitation, it is cheaper than alcohol preparation or gel-press methods (McHugh, 2003).

Semi-refined carrageenan originally had high bacteria counts making it unsuitable for human consumption unless used in canned products, since the canning process kills the bacteria (McHugh, 2003). However, the manufacturing method has been modified and refined (Van de Velde and De Ruiter, 2002). Producers of carrageenan in the Philippines now add an additional step to the semi-refined extraction method so that the product, referred to as processed *Euchema* seaweed or PES, is suitable for human consumption (McHugh, 2003). After alkali treatment, the carrageenan solution is treated with bleach, and drying occurs in a closed dryer system. In some cases, the dried carrageenan is then washed with ethanol and vacuum evaporated, or treated with superheated steam, to eliminate bacterial contamination (McHugh, 2003). PES contains 8 to 15% acid insoluble materials, opposed to only 2% for carrageenan that is produced through the alcohol preparation or gel-press methods (Blakemore and Harpell, 2009). The acid insoluble materials are mostly cellulose and protein materials from the algae that result in different solubility characteristics between PES and carrageenan extracts. Both products are regulated as the food additive carrageenan by the FDA and must adhere to the same standards for microbial contamination and limits for other contaminants such as heavy metals (Blakemore and Harpell, 2009; U.S. Pharmacoepia, 2010). The introduction of PES to the market approximately 25 years ago has reconfigured the geographic distribution of production around the world, and the percentages of total product being produced by each method (Bixler and Porse, 2010).

The alkaline treatment processes used in the manufacture of refined carrageenan and PES cause chemical changes to occur in the algal extracts. Prolonged treatment with alkali promotes internal molecular rearrangements and modifications of the polysaccharide backbone (Imeson, 2000; McHugh, 2003; Blakemore and Harpell, 2009). Some sulfate groups are removed from the molecule, and the proportion of 3,6-anhydrogalactose units is therefore increased (McHugh, 2003). These rearrangements in effect reduce the number of bends in the polysaccharide chain, thereby strengthening the inter-chain associations (Blakemore and Harpell, 2009). The predominant carrageenan present (i.e., kappa, iota, or lamda), and resulting properties of the final product, are determined by the amount of time and the type of alkali used for alkali treatment (McHugh, 2003; Imeson, 2000). For example, kappa carrageenans are modified in a way that allows adjacent chains to form helical structures, resulting in firm, brittle gels (Imeson, 2000). Iota carrageenans are modified to form weak, elastic gels, and lamda carrageenans do not gel but rather form high viscosity liquids (McHugh, 2003). In other words, treatment in an alkaline solution promotes structural changes to the polysaccharide molecule, resulting in a carrageenan product with specifically desirable gel strengths and textures (Imeson, 2000; McHugh, 2003; Blakemore and Harpell, 2009).

There is no indication in the literature that the types of manufacturing methods for carrageenan have changed substantially since the 1995 TAP review for carrageenan (USDA, 1995). However, there have been

changes in the use patterns of those methods. Figure 4 shows the changing percentages of world carrageen market share by production method, including alcohol precipitation, gel press, semi-refined, and PES, from 1999 to 2009. Overall, carrageenan production through PES methods has increased from 22% to 41% (which is an increase from 0% in the early 1970s), and gel-press methods has increased from 20% to 26% (Bixler and Porse, 2010). Conversely, alcohol precipitation methods have declined from 32% of the world market share to 23%, and semi-refined carrageenan production has decreased from 26% to 10% of the global market production. The overall volume increase in carrageenan sales during the same time period was 2 to 3% per year (Bixler and Porse, 2010).

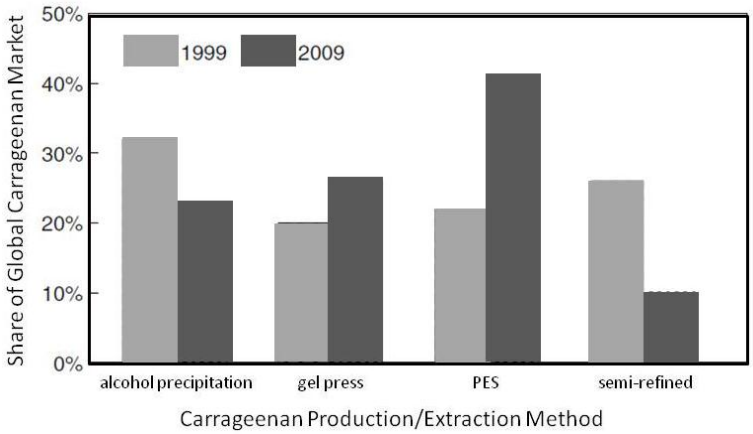


Figure 4. Changing Trends in Global Carrageenan Production Methods, 1999-2009
(Chart modified from: Bixler and Porse, 2010)

Evaluation Question #2: Is the substance synthetic? 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).

Carrageenan is a naturally occurring polysaccharide extracted from seaweed, and therefore considered non-synthetic. As stated in the response to Evaluation Question #1, industrial extraction methods use alkali treatment to facilitate rearrangements and modifications in the chemical structure of the polysaccharide for manufacture of commercial-grade products (Imeson, 2000; McHugh, 2003; Blakemore and Harpell, 2009). Carrageenan that is produced using those methods is considered synthetic.

Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

All carrageenan is obtained from natural sources. Sources of carrageenan are red seaweeds of the class *Rhodophyceae* (Van de Velde and De Ruiter, 2002). There is no indication in the literature that any new species of seaweeds or other (i.e., non-seaweed) sources are being used to manufacture carrageenan since the 1995 TAP review for carrageenan (USDA, 1995). However, there have been shifts in the global regions supplying seaweeds for the production of carrageenan. The Asia-Pacific region has remained the largest source of carrageen-producing seaweed, supplying over 50% of the market from 1999 through 2009, and the Americas have similarly maintained 16-18% of the global market (Bixler and Porse, 2010). However, production levels decreased in Europe and increased substantially in China (Bixler and Porse, 2010).

As stated in the response to Evaluation Question #1, manufacturing of carrageenan results in chemical modifications to the seaweed extract. No information was found to indicate that any form of commercially-available carrageenan is extracted without chemical modifications.

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

Chondrus extract, or carrageenan specifically from *Chondrus crispus,* has been categorized as GRAS since 1958 (Watson, 2008), when used in accordance with good manufacturing practice (21 CFR § 182.7255). Although carrageenan from other sources is not specifically listed as GRAS, in 1960, 21 CFR § 172.620 listed carrageenan as a food additive that can be sourced from eight different seaweed species, including *Chondrus crispus*. A review for carrageenan in general, and not just the extract of Chondrus, was completed in 1973 by the Select Committee on GRAS Substances (SCOGS) (U.S. FDA, 2006). The Committee concluded that "no evidence in the available information on carrageenan demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced," however uncertainties exist and additional studies should be conducted. Therefore, it appears that all forms of carrageenan acceptable as food additives in the U.S. are now considered GRAS. The technical function of carrageenan under 21 CFR § 182.7255 is a stabilizer. 21 CFR § 172.620 lists functions of emulsifier, stabilizer, and thickener.

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

The primary use of carrageenan is to modify and maintain texture and/or consistency in processed foods (Piculell, 2006; McHugh, 2003). Therefore, its primary function or purpose is not as a preservative. However, when used as a protective coating for fresh-cut packaged fruits, carrageenan can be described as a preservative because it functions to slow respiration on the cut fruit surface, thereby controlling discoloration and natural textural changes (Plotto et al., 2010; Bico et al., 2009; Baeza, 2007; Plotto et al., 2006).

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

No information was found to suggest that carrageenan is used to recreate flavors, colors, textures, or nutritive values lost during processing. Carrageenan is mainly used to produce or enhance texture during processing by acting as a thickening, gelling, emulsifying, or stabilizing agent (Piculell, 2006; McHugh, 2003). However, there are no indications that it is added to processed foods in order to restore these qualities where they exist during small batch production. Carrageenan is used to maintain texture when it is used as a stabilizer to prevent separation of ingredients, but is unclear whether this use could be considered to improve or enhance texture. Carrageenan is a source of dietary fiber (Piculell, 2006) but there is no indication that it is added to processed foods in order to restore dietary fiber lost in processing.

When carrageenan is used as a coating on fresh-cut, pre-packaged fruits, it is being used to maintain color and texture that would normally be lost during the product's shelf-life (Plotto et al., 2010; Bico et al., 2009; Plotto et al., 2006) by inhibiting respiration on the fruit's cut surface (Baeza, 2007). This use is not restorative.

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

A study conducted in 1974 found that addition of carrageenan to skim milk at a dietary level of 4% had no influence on growth rate, diet energy efficiency, utilization of iron, or absorption of protein, fat or calcium in rats (Tomarelli et al., 1974). When carrageenan is used in products such as processed meats and sausages, it often functions as a fat replacer and therefore increases the nutritional quality of the food by significantly decreasing the fat content and cholesterol (Kumar and Sharma, 2003).

No other information was found on the effects or potential effects of carrageenan on the nutritional quality of food.

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

No reports of excessive levels of heavy metals or other dangerous contaminants in carrageenan have been identified, and no substances listed on FDA's Action Levels for Poisonous or Deleterious Substances in Human Food have been reported as contaminants of concern for carrageenan. However, carrageenan has a high tendency to sequester metal ions such as arsenic, lead, zinc, and copper (Piculell, 2006). The specifications for carrageenan in the seventh edition of the "Food Chemicals Codex" include that it contain no more than 3 mg/kg arsenic, 2 mg/kg cadmium, 5 mg/kg lead, 1 mg/kg mercury, 0.1% of the residual solvents ethanol, isopropanol, or methanol singly or in combination, and that is contain between 20% and 40% sulfate as ester sulfate (U.S. Pharmacopeia, 2010). The heavy metal content in carrageenan from semi-refined processing (i.e., PES) is higher than the heavy metal content in carrageenan from gel-press or alcohol preparation processing, but is still well below FDA tolerances (Imeson, 2000).

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

Cold water species of red seaweed used to make carrageenan (from Chile, Mexico, Canada, France) are generally harvested from wild populations (Bixler and Porse, 2010); however recent shifts have been seen in cultivated populations of seaweed in waters near South America (Buschmann et al., 2008). As with any collection from wild populations, harvest levels must be in check to ensure that population size remains at sustainable levels and that the surrounding ecosystem is not negatively affected. For example, overharvesting of Gigartina species at its northernmost limit in Chile resulted in a severe reduction in population size and a complete crash in the total number of seaweed landings in the early 2000s (Faugeron et al., 2004). Overall biomass was reduced and individual plants were smaller, resulting in many infertile plants (Faugeron et al., 2004).

Warm water species of red seaweed used to make carrageenan are mainly cultivated in the Philippines, Indonesia, and Tanzania using vegetative growth methods to produce and maintain seaweed populations (Bixler and Porse, 2010). To create a seaweed farm, fronds of seaweed are tied to strings between wooden poles dug into the ground of shallow intertidal lagoons (Bryceson, 2002). In some cases where water is deeper, floating lines and rafts are used. Cultivation of non-native seaweed presents serious bio-invasive risks for nearby marine communities (Chandrasekaran et al., 2008). Fragments of seaweed often escape from cultivation sites, presumably through physical forces like wave action, storms (including seasonal monsoon patterns), or strong tides, and disperse to other areas of the ocean. The fragments can catch on coral or other oceanic features, and vegetatively propagate to establish new colonies that overtake the existing ecosystems (Chandrasekaran et al., 2008). For example, a Philippine-derived species introduced to Hawaii in the 1970s was recently shown to be spreading from the cultivation site at a rate of 250 meters per year and is competing with native corals for space (Conklin and Smith, 2005). The same species was introduced at a single site in the Gulf of Mannar, South India, in 2002 and by 2007 had invaded and completely covered coral reefs 100 meters away, smothering and shadowing the corals and hindering the coral's ability to support other species in the system (Chandrasekaran et al., 2008). Invasive seaweed also poses a risk in systems where the coral reef is already dead: dead coral undergo a natural cycle of erosion and resettlement of coral onto the reef from nearby thriving coral communities. When seaweeds take over, they prevent this process and contribute to reef degradation (Chandrasekaran et al., 2008).

Seaweed farming is generally considered to be the most environmentally friendly type of aquaculture, as it requires no fertilizers, does not cause major physical landscape changes, and can even serve to mediate eutrophication and other forms of pollution (Eklof and Kautsky, 2006). However, seaweed farming is not

without environmental impacts; the presence of a seaweed farm has been shown to affect aquatic community composition by inducing population dynamic changes in bacteria, meiofauna, benthic macrofauna, fish, and corals (Eklof and Kautsky, 2006). Establishment of a cultivation plot can disrupt benthic community structure, as existing seagrass is cut, as well as disrupt general marine ecosystems, as existing niches are interrupted by the presence of new seaweed plants (Zemke-White and Smith, 2006). While large landscape modifications are not made, crops of seaweed tied low to the ground can result in abrasion of the sea floor and changes to sedimentation. Seaweed farms can increase shade of underlying habitats, and in some places lines or poles are purposefully anchored to corals (Zemke-White and Smith, 2006). Moreover, *Euchema* species, which are most commonly used in seaweed farming, can experience physiological stress due to fluctuations in environmental conditions such as temperature or salinity (Bryceson, 2002). When under stress, these species produce and release volatile halogenated organic compounds which can inhibit growth and survival of epiphytes or other organisms in the ecosystem (Bryceson, 2002).

A recent review and analysis of various mariculture models by Tityanov and Tityanova (2010) argued that sustainable management of monodominant natural seaweed populations is preferable to farming of seaweeds from an environmental impact standpoint. Cultivated non-native species, especially when they escape the cultivation plot and bioinvade corals and other marine areas, are not susceptible to controls by the naturally present grazing fish, physical clearing methods (i.e. natural tidal motions), or aquatic chemistry of the ecosystem, and so populations grow unchecked (Chandrasekaran et al., 2008). Management of indigenous species for carrageenan production, rather than introduction of exotic species, may yield less carrageenan product but does not pose the ecological risk (Chandrasekaran et al., 2008).

However, advancements in methods of integrated farming of seaweed, fish, mollusks, and crustaceans could help make seaweed farming more sustainable (Titlyanov and Titlyanova, 2010). Integrated seaweed cultivation can result in some positive impacts on the ecosystem. For example, combined mussel and seaweed cultivation areas in Brazil have been shown to improve water quality through decreasing the dissolved inorganic nitrogen concentration, which helps mitigate eutrophication of the system (Pellizzari and Reis, 2011). Further, experiments that discharged fish tank water into seaweed cultivation areas showed that the seaweed acted as a biofilter to remove 80% of the ammonium and 26% of the phosphate from the water (Hayashi et al., 2006), suggesting a benefit to cultivating seaweed in existing fish farms.

The industrial manufacture of carrageenan is a process that produces large amounts of alkaline waste water which may pose environmental problems. For example, the Shemberg plant, which is the largest plant in the Philippines, creates 2361 m^3 of waste water with a pH of 12-13, and a biochemical oxygen demand of 1539 kg (Zemke-White and Smith, 2006). While the Philippines' Department of Environment and Natural Resources regulates discharge of effluent from these plants, many plants either operate at levels that are above the level that would allow standards to be met, or simply choose to forgo expensive water treatment and pay fines instead (Zemke-White and Smith, 2006).

Additionally, the act of farming seaweed can result in a number of secondary environmental impacts, such as increased pollution on beaches and physical damages to reefs, coastal ecosystems, and mangroves (Zemke-White and Smith, 2006). Many farmers use plastic "straws" to tie the seaweed to lines and plastic bottles and Styrofoam as floats—and seldom are these materials recycled or disposed of properly. Processing operations build raised platform structures on which to dry harvested seaweed in a way that limits contamination with sand. In some areas of the Philippines, the platforms are constructed on stilts on the reef, resulting in damage to the reefs. In other areas, the platforms are built on shore and can disrupt coastal habitat. Regardless of where the platforms are built, mangrove wood is often preferred for use in platforms and for tie-down stakes, since it does not rot as fast as other wood alternatives—resulting in a need for regulation and active enforcement to prevent damage to the biologically important mangrove forest (Zemke-White and Smith, 2006).

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

Despite a long history of approved use as a food additive, carrageenan has been alleged to pose human health risks. In 1969, degraded carrageenan was shown to induce cecal and colonic ulceration in guinea pigs (Marcus and Watt, 1969), the first report of such potential adverse effects (Watson, 2008). Since then, many studies have been published showing that exposure to degraded carrageenan causes bleeding and ulceration of the colon in some laboratory animals (EC SCF, 2003). Degraded carrageenan, also called poligeenan, has an average molecular weight of 20 to 30 kDa and has been widely used in immune system experiments to induce inflammation in immune system experiments (Benford et al., 2008). As a result of these findings, the FDA proposed regulations that commercial-grade carrageenan could not have a molecular weight under 100 kDa (Watson, 2008), though these regulations were never amended and the proposal was withdrawn in 1979 (Tobacman, 2001). Still, the presence of degraded carrageenan in commercially available carrageenan decreased from approximately 25% in 1983 (Benford et al., 2008) to undetectable levels by 2001 (EC SCF, 2003). The molecular weight average of commercially-available carrageenan ranges from 453 to 652 kDa (Uno et al., 2001).

Today, both concern and debate exists over human health hazards from not only direct use of degraded carrageenan in foods, but also based on the idea that acid hydrolysis in the stomach following consumption of non-degraded carrageenan could result in formation of degraded carrageenan, which could then potentially promote colon cancer (Tobacman, 2001; Carthew, 2002). In 2001, Joanne K. Tobacman published a review of 45 studies dated from 1969 through 1997, that showed that exposure to degraded and/or undegraded carrageenan was associated with intestinal lesions such as ulcerations and neoplasms in several different animal models, including ferret, guinea pig, monkey, mouse, rat, and rabbit (Tobacman, 2001). Animal studies published since 1997 that were not included in Tobacman's review have shown conflicting results. While some studies have verified that carrageenan is associated with induction or promotion of gastrointestinal tract inflammation, ulcerations and/or neoplasms in animal models (e.g., Benard et al., 2010 and human tissues (e.g., Borthakur et al., 2007; Bernard et al., 2010), other studies have contradicted this finding (e.g., *in vivo:* Weiner et al., 2007; and *in vitro:* Tobacman and Walters, 2001).

As stated in the response to Evaluation Question #4, carrageenan is listed as GRAS by the FDA (U.S. FDA, 2006). The toxicology of carrageenan has been reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the group acceptable daily intake (ADI) for carrageenan and processed *Eucheuma* seaweed was categorized as "not specified" in 2001 (Benford, 2001). This means that the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect in food and from its acceptable background levels in food, does not, in the opinion of JEFCA, represent a hazard to health (Benford, 2001). JECFA has since maintained the "not specified" ADI classification at the 64th meeting in 2008 they stressed that this classification applied to food additive uses other than infant formula (Benford et al., 2008). JECFA advised that carrageenan should not be used in infant formula intended for children under 13 months of age based on a concern over the narrow margin of exposure between the level of carrageenan consumed through infant formula and the lowest doses reported to cause inflammatory responses in laboratory rats and mice (Benford et al., 2008). Similarly, the European Commission Scientific Committee on Food (now the European Food Safety Authority) concluded in 2003 that there is no evidence of adverse effects in humans from exposure to food-grade carrageenan, yet advised against use of carrageenan in infant formula due to a lack of information regarding possible absorption of carrageenan in the immature gut and effects of carrageenan on the immature immune system (EC SCF, 2003). While the committee noted there was insufficient evidence for lowering the ADI or otherwise limiting carrageenan intake levels, they did suggest a limit be specified that no more than 5% of food-grade carrageenan should fall below 50 kDa (EC SCF, 2003). Conversely, the US FDA does permit carrageenan in infant formula, because it concluded that the health benefit (preventing fat separation and therefore provides uniform nutrition) outweighs the potential risks (Watson, 2008).

Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

Potential food additives that may be substituted for carrageenan to achieve a similar functionality when used either alone or in combinations include alginates, guar gum, gum Arabic, locust bean gum, and xanthan gum (Tobacman, 2001). Gelatin can also be used in some products, such as water gel desserts (Bixler and Porse, 2010).

Guar gum, gum Arabic, locust bean gum, and gelatin are agricultural processing ingredients. They are listed under the NOP final rule section 205.606 as "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic'" (7 CFR § 205.606). To be allowed in organic processed foods they must be water-extracted and not produced or handled with the use of sewage sludge, genetic engineering, genetically modified organisms, or ionizing radiation (7 CFR § 205.105). Nonorganic forms may only be used when the certifier determines that the ingredient is not commercially available in organic form (7 CFR § 205.606).

Xanthan gum and alginates, including ammonium, calcium, potassium, and sodium alginate, are synthetic, nonagricultural processing ingredients. However, they are allowed for use in organic processed products (7 CFR § 205.605(b)).

It is also possible to substitute fats for carrageenan in some products (Tobacman, 2001).

In fresh-cut, pre-packaged fruits, the non-agricultural but allowed substances citric acid and ascorbic acid can be used instead of carrageenan to prevent discoloration, and calcium chloride or calcium citrate can be used as firming agents to maintain texture (Plotto and Narciso, 2006).

No organic agricultural alternatives for this use of carrageenan were identified.

References:

Baeza, R. 2007. Comparison of technologies to control the physiological, biochemical and nutritional changes of fresh cut fruit. A report for completion of the Masters of Science degree. Kansas State University: Manhattan, Kansas. Available online at http://krex.k-state.edu/dspace/bitstream/2097/494/1/RitaBaeza2007.pdf.

Benard, C., Cultrone, A., Michel, C., Rosales, C., Segain, J. -P., et al. 2010. Degraded carrageenan causing colitis in rats induces TNF secretion and ICAM-1 upregulation in monocytes through NF-κB activation. PLoS ONE 5(1): e8666.

Benford, D. J. 2001. Carrageenan and processed Eucheuma seaweed (addendum). In: WHO Food Additive Series: 48. Safety evaluation of certain food additives and contaminants. Prepared by the Fifty-seventh meeting of the Joint FAO/WHO expert committee on food additives (JECFA). World Health Organization, Geneva, 2002. Available online at http://www.inchem.org/documents/jecfa/jecmono/v48je08.htm.

Benford, D. J., Harrison, R. A., Strobel, S., Schlatter, J., Verger, P. 2008. Carrageenan and processed Eucheuma seaweed (addendum). In WHO Food Additive Series: 59. Safety evaluation of certain food additives and contaminants. Prepared by the Sixty-eighth meeting of the Joint FAO/WHO expert committee on food additives (JECFA). World Health Organization, Geneva, 2008. Available online at http://libdoc.who.int/publications/2008/9789241660594_eng.pdf.

Bico, S. L. S., Rapaso, M. F. J., Morais, R. M. S. C., Morais, A. M. M. B. 2009. Combined effects of chemical dip and/or carrageenan coating and/or controlled atmosphere on quality of fresh-cut banana. Food Control 20(5):508-514.

Bixler, H. J. and Porse, H. 2010. A decade of change in the seaweed hydrocolloids industry. J Appl Phycol. 23(3):321-335.

Bryceson, I. 2002. Coastal aquaculture developments in Tanzania: Sustainable and non-sustainable experiences. Western Indian Ocean Journal of Marine Science 1(1):1-10.

Borthakur, A., Bhattacharyya, S., Dudeja, P. K., Tobacman, J. K. 2007. Carrageenan induces interleukin-8 production through distinct Bcl10 pathway in normal human colonic epithelial cells. AJP – GI 292(3):G829-G838.

Buck, C. B., Thompson, C. D., Roberts, J. N., Muller, M., Lowry, D. R., and Schiller, J. T. 2006. Carrageenan is a potent inhibitor of papillomavirus infection. PLOS Pathog 2(7): e69.

Buschmann, A. H., Hernandez-Gonzalez, M. C., Varela, D. 2008. Seaweed future cultivation in Chile: Perspectives and challenges. International Journal of Environment and Pollution 33(4): 432-456.

CGSB (Canadian General Standards Board). 2011. Organic Production Systems Permitted Substances List. CAN/CGSB-32.311-2006. Amended October 2008, December 2009 and June 2011. Available online at http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/internet/bio-org/index-eng.html.

Carthew, P. 2002. Safety of carrageenan in foods. Environ Health Perspect 110:a176-a176.

Chandrasekaran, S., Arun Nagendran, N., Pandiaraja, D., Krishnankutty, N., Kamalakannan, B. 2008. Bioinvasion of Kappaphycus alvarezii on corals in the Gulf of Mannar, India. Current Science 94(9): 1167-1172.

ChemIDplus Advanced. 2011. (database). National Institutes of Health, Department of Health and Human Services, U.S. National Library of Medicine. Available online at http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp. Accessed on July 18, 2011.

Codex Alimentarius Commission. 2007. Guidelines for the production, processing, labeling and marketing of organically produced foods (GL 32 – 1999, Rev. 4 – 2007). Joint FAO/WHO Food Standards Programme. Available online at http://www.fao.org/organicag/doc/glorganicfinal.pdf.

Codex Alimentarius Commission. 2010. GSFA Online: Food Additive Details, Carrageenan (407). Available online at http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=49.

Commission of the European Communities. 2008. Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products with regard to organic production, labeling and control. Official Journal of the European Union. Available online at http://www.organic-world.net/35.html?&tx_ttnews[tt_news]=111&cHash=b1bc05316718066deadd4c1f9e54549d.

Conklin, E. J., Smith, J. E. 2005. Abundance and spread of the invasive red algae, Kappaphycus spp., in Kane'ohe Bay, Hawai'i and an experimental assessment of management options. Biological Invasions 7:1029-1039.

CyberColloids. 2011. Carrageenan. Website. Viewed July 2011, available online at http://www.cybercolloids.net/category/library-tag/carrageenan.

East African Community. 2007. East African organic products standards. EAS 456:2007. Available online at http://www.ifoam.org/partners/projects/pdfs/EAS%204562007_Organic%20products%20standard_w_cover.pdf.

EC SCF (European Commission Scientific Committee on Food). 2003. Opinion of the Scientific Committee on Food on carrageenan. SCF/CS/ADD/EMU/199 Final. Available online at http://ec.europa.eu/food/fs/sc/scf/out164_en.pdf.

Eklof, J. S., and Kautsky, H. N. 2006. Effects of tropical open-water seaweed farming on seagrass ecosystem structure and function. Marine Ecology Progress Series 325:73-84.

FAO. 2007. FAO JECFA Monographs 4. Specifications: Carrageenan. Available online at http://www.fao.org/ag/agn/jecfa-additives/details.html?id=830.

Faugeron, S., Martinez, E. A., Correa, J. A., Cardenas, L. 2004. Reduced genetic diversity and increased population differentiation in peripheral and overharvested populations of Gigartina skottsbergii (Rhodophyta, Gigartinales) in southern Chile. J Phycol 40:454-462.

FMC BioPolymer. 2010. Carrageenan. Website. Viewed July 2011, available online at http://www.fmcbiopolymer.com/Food/Ingredients/Carrageenan/Introduction.aspx.

IFOAM (International Federation of Organic Agriculture Movements). 2006. The IFOAM Norms for Organic Production and Processing. Version 2005. Corrected version 2009. Available online at http://www.ifoam.org/about_ifoam/standards/norms/norm_documents_library/norms_documents_library.html.

Hayashi, L., Yokoya, N. S., Ostini, S., Pereira, R. T. L., Braga, E. S., Oliveira, E. C. 2008. Nutrients removed by Kappaphycus alvarezii (Rhodophyta, Solieriaceae) in integrated cultivation with fishes in re-circulating water. Aquaculture 277:185-191.

Imeson, A. P. 2000. Ch. 5 Carrageenan. In G.O. Phillips, P.A. Williams (Eds.). Handbook of Hydrocolloids, pp. 87-102. Boca Raton, FL: CRC Press.

Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF). 2006. Japanese Agriculture Standard for Organic Processed Foods Notification No. 1464 of 2006). Established: Notification No. 60 of January 20, 2000. Partial revision: Notification No. 1885 of November 18, 2003. Full revision: Notification No. 1606 of October 27, 2005. Partial revision: Notification No. 210 of February 28, 2006. Partial revision: Notification No. 1464 of October 27, 2006. Available online at http://www.maff.go.jp/e/jas/specific/criteria_o.html.

Kumar, M. and Sharma, B. D. 2003. The storage stability and textural, physico-chemical and sensory quality of low-fat ground pork patties with carrageenan as a fat replacer. International Journal of Food Science and Technology 39(1): 31-42.

Larsen, P.F. 1996. "Carrageenan product and a method of producing same." U.S. Patent number 5,502,179.

Marcus, A. J., Watts, J. 1969. Ulcerative colitis in the guinea-pig caused by seaweed extract. J Pharmaceut Pharmacol 21:187.

McHugh, D. J. 2003. Ch. 7 Carrageenan. In A guide to the seaweed industry: FAO fisheries technical paper 441. Food and agriculture organization of the United Nations, Rome. Available online at http://www.fao.org/docrep/006/y4765e/y4765e0a.htm.

Minich, D. 2003. Position paper on carrageenan. Metagenics, Inc. Available online at http://www.metaproteomicslabs.com/positioncomment.asp.

OMRI. 2011. (database). Materials List: Vegetable Gums. Retrieved July, 2011, from http://www.omri.org/simple-gml-search/results/vegetable%20gums.

Pellizzari, F., Reis, R. P. 2011. Seaweed cultivation on the southern and southeastern Brazilian coast. Brazilian Journal of Pharmacognosy 21(2):305-312.

Piculell, L. 2006. Chapter 8: Gelling Carrageenans. In A. M. Stephen, G. O. Phillips, and P. A. Williams (Eds.) Food polysaccharides and their applications, 2nd edition pp. 239-288. CRC Press. Boca Raton, FL.

Plotto, A., Narciso, J. A. 2006. Guidelines and acceptable postharvest practices for organically grown produce. HortScience 41(2):287-291.

Plotto, A., Narciso, J., Baldwin, E. A., Rattanapanone, N. 2006. Edible coatings and other surface treatments to maintain color of lychee fruit in storage. Proc Fla State Hort Soc 119:323-331.

Plotto, A., Narciso, J., Rattanapanone, N., Baldwin, E. A. 2010. Surface treatments and coatings to maintain fresh-cut mango quality in storage. J Sci Food Agric 90:2333-2341

Ramirez, A. 1991. "Fast food lightens up but sales are often thin." New York Times, March 19, 1991. Available online at: http://www.nytimes.com/1991/03/19/business/fast-food-lightens-up-but-sales-are-often-thin.html?src=pm.

Saha, D. and Bhattacharya, S. 2010. Hydrocolloids as thickening and gelling agents in foods: A critical review. J Food Sci Technol 47(6):587-597.

Secretariat of the Pacific Community. 2008. Pacific Organic Standard. Available online at http://www.ifoam.org/partners/projects/pdfs/Pacific_Organic_Standard.pdf.

Titlyanov, E. A., Titlyanova, T. V. 2010. Seaweed cultivation: Methods and problems. Russian Journal of Marine Biology 36(4):227-242.

Tobacman, J. K. 2001. Review of harmful gastrointestinal effects of carrageenan in animal experiments. Environ Health Perspect 109:983–994.

Tobacman, J. K., Walters, K. S. 2001. Carrageenan-induced inclusions in mammary myoepithelial cells. Cancer Detect Prev 25(6):520-526.

Tomarelli, R. M., Tucker, W. D., Bauman, L. M., Savini, S., Weaber, J. R. 1974. Nutritional quality of processed milk containing carrageenan. J Agric Food Chem 22(5): 819-824.

USDA (United States Department of Agriculture). 1995. Technical Advisory Panel Report: Carrageenan. Available at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateJ&page=NOPPetitionedSubstancesDatabase.

U.S. FDA (Food and Drug Administration). 2006. (database). Database of Select Committee on GRAS Substances (SCOGS) Reviews. Last updated 10/31/2006. Accessed on July 19, 2011. Available online at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=scogsListing.

U.S. Pharmacopeia. 2010. 2010-2011 Food Chemical Codex. Seventh Edition. The United States Pharmacopeial Convention, Rockville, MD.

Watson, D. B. 2008. Public health and carrageenan regulation: A review and analysis. J of App Phyc 20(5):505-513.

Van de Velde, I. F., De Ruiter, G. A. 2002. Chapter 9: Carrageenan. In S. De Baets, E. J. Vandamme, A. Steinbuchel (Eds). Biopolymers Volume 6, Polysaccharides II: Polysaccharides from Eukaryotes, pp. 245-273. Weinheim, Germany: Wiley-VCH.

Weiner, M. L., Nuber, D., Blakemore, W. R., Harriman, J. F., Cohen, S. M. 2007. A 90-day dietary study on kappa carrageenan with emphasis on the gastrointestinal tract. Food and Chemical Toxicology 45(1):98-106.

Zemke-White, W. L. and Smith, J. E. 2006. Environmental impacts of seaweed farming in the tropics. In A. T. Critchley, M. Ohno and D. B. Largo (Eds.). World Seaweed Resources: An authoritative reference system. Available online at: http://www.nceas.ucsb.edu/~jsmith/PDFs/Zemke-White%20and%20Smith%202006.pdf.