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Carrageenan Remains on the US National List of Allowed Substances in Organic Food Products

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ABSTRACT

Carrageenan, a non-agricultural, non-synthetic substance derived from certain red seaweeds and allowed as ingredient in organic foods, is one of the main export products of the Philippines. However, the country's carrageenan export, particularly to the United States, has declined due to several attempts to remove it from the National List of Allowed Substances under the Organic Foods Production Act of the United States of America. This paper presents information from two technical papers submitted by the Philippine government to the US Department of Agriculture to address concerns raised by the US National Organic Coalition regarding the health and environmental impacts of carrageenan use and production and to establish that there are no suitable alternatives to carrageenan in its use in organic food products. It aims to emphasize the need to keep carrageenan on the list of allowed substances in organic foods.

Keywords:
carrageenan,
seaweed,
organic food products,
allowed substances

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INTRODUCTION

The Philippines, being an archipelago, is considered as one of the countries in the world with the longest coastlines, at 36,289 kilometers (World Bank 2005). Approximately 60% of its total population lives in coastal areas (Asian Development Development Bank 2014). By applying this percentage to the most recent total population reported by the Philippines Statistics Authority (PSA 2018), the estimated number of Filipinos residing in coastal zones in 2018 is 60.6 million.

Transactions NAST PHL 41 No. 2 (2019)
doi.org/10.57043/transnastphl.2019.1956

One of the sources of livelihood in these coastal communities is seaweed production. In 2018, the top three seaweed-producing regions were ARMM (669,013.44 MT), MIMAROPA Region (344,606.77 MT), and Zamboanga Peninsula (196,638.56 MT), with their combined outputs accounting for 81.87% of the country's total production (PSA 2019). These seaweeds are exported either in raw forms (fresh or dried seaweeds) or processed forms (semi-refined chips/carrageenan and refined carrageenan). The major commercial seaweeds in the Philippines are *Eucheuma, Kappaphycus, Gracilaria* spp. and *Caulerpa lentillifera*. *Kappaphycus alvarezii* and *Eucheuma denticulatum* are the major species cultivated [Bureau of Fisheries and Aquatic Resources (BFAR) 2010], which are known sources of carrageenan.

The Philippines is one of the main exporters of carrageenan in the world, with 28,018 MT export in 2018 valued at US$185.061 million (BFAR, 2018). Table 1 shows the top 15 Philippine seaweed and carrageenan importing countries in 2018. The country's main carrageenan export destination is the United States, accounting for 35% of carrageenan export in 2018 (BFAR 2018). However, carrageenan exports, particularly to the US, suffered a decline these past years mainly due to successive attempts to remove carrageenan from the National List of Allowed Substances under The Organic Foods Production Act of the United States of America (TOFPA-USA).

This paper recounts the issues raised against carrageenan, and the steps taken by the Philippine government to address these issues. It provides a summary of the country's position as indicated in two technical papers that were developed with the aid of the Bureau of Fisheries and Aquatic Resources (BFAR) and submitted to the US Department of Agriculture.

Table 1. Top 15 Philippine Seaweed and Carrageenan Importing Countries in 2018.

Destination Country	Quantity in Metric Tons	FOB in US$
USA	11,485,003	40,297,770.00
China	5,062,137	6,529,606.00
France	1,731,078	7,390,075.00
Mexico	1,676,585	11,084,935.00
Spain	1,627,469	11,949,503.00
Belgium	1,637,062	11,010,068.00
Thailand	1,332,074	11,107,946.00
Denmark	1,112,245	10,246,798.00
Australia	979,489	7,914,581.00
Brazil	937,501	7,052,826.00
Russia	881,796	7,080,891.00
UK	841,526	5,311,369.00
Vietnam	751,608	4,893,147.00
Argentina	650,574	5,625,059.00
Netherlands	634,420	5,116,646.00

Source: Philippine Statistics Authority (2021)

CARRAGEENAN AND THE US ORGANIC FOOD PRODUCTS MARKET

Carrageenan (CGN) is a non-agricultural, non synthetic substance allowed as ingredient in organic foods (CFR 205.605), which is obtained from certain members of the algal class Rhodophyceae (red seaweeds). It has three principal classifications: the gelling fractions, iota (i)- and kappa (k)- and the non-gelling lambda (l)-carrageenan. Current product applications for carrageenan include meat (37%), dairy (28%), water gels (17%), pet food (10%), and household products (e.g., toothpaste, 4%), with a global market of $0.7B/year (Bixler and Porse 2011).

Carrageenan and the Health and Environmental Concerns on its Use and Production

On April 14, 2016, the National Organic Coalition (NOC) submitted a letter to the National Organic Standards Board of the US Department of Agriculture (NOSB-USDA) proposing the removal of carrageenan from the National List of Allowed Substances under TOFPA-USA. NOC is a national alliance of organizations working to provide a

Transactions NAST PHL 41 No. 2 (2019)
doi.org/10.57043/transnastphl.2019.1956

voice for farmers, ranchers, environmentalists, consumers, and industry members involved in organic agriculture while NOSB is a Federal Advisory Board comprised of public volunteers from across the organic community that makes recommendations to the United States Secretary of Agriculture on issues concerning organic food and products. The NOC recommendation to delist carrageenan was based on three (3) health-related concerns and two (2) environmental-related perceptions. To address this matter, BFAR facilitated the development of a 14-page rebuttal that was submitted to the Agricultural Marketing Service National Organic Program of USDA on October 24, 2016. The issues and respective responses are detailed below:

Issue No.1: NOC claims that carrageenan is causing low-level, long-term inflammation (a precursor to many diseases e.g., ulcerative colitis-like disease, intestinal lesions, and intestinal ulcerations, promoter of colon tumor).

The NOC claims that carrageenan can cause low-level, long-term inflammation was based on the scientific papers of Dr. J. K. Tobacman and her colleagues in the University of Illinois (Bhattacharyya et al. 2008a, 2008b; and Borthakur et al. 2007). In their studies, normal human and rat colonic/ileal epithelial cells were cultured in a controlled environment (*in vitro*) and directly exposed to extremely high amounts of CGN (1.0 µg/ml and 10.0 µg/ml, which is equivalent to 1.0 to 10.0 ppm, respectively), that are unlikely to be observed in a living body (*in vivo*). This model, which was argued to be flawed in a review by Weiner (2016), represented a tissue edema-induced inflammation model (Tsuji et al. 2003; Cuzzocrea et al. 2004) and not exposure to carrageenan as food ingredient.

Issue No.2. NOC mentioned that degraded carrageenan is a List 2B carcinogen according to the World Health Organization's International Agency for Research on Cancer (IARC).

Degraded carrageenan is a low molecular weight carrageenan (i.e., primarily referred to as poligeenan with a molecular weight of 20–30 kDa). NOC's claim that it is listed under the List 2B carcinogen according to the World Health Organization's International Agency for Research on Cancer (IARC) is correct. However, to associate native carrageenan (or food-grade carrageenan) with the degraded carrageenan and its associated risk is incorrect.

A survey published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2015 on 29-food grade carrageenan samples showed that their molecular weights ranged from 453 to 652 kDa with a mean of 530 kDa. No degraded product (or poligeenan) was detected at 5% level. Thus, food-grade carrageenan is not contaminated by the carcinogenic poligeenan and should not be confused with the carcinogenic degraded carrageenan.

Issue No. 3: Carrageenan allegedly contributes to insulin resistance and to the development of Type 2 Diabetes.

Contrary to the allegations that CGN can contribute to insulin resistance and to the development of Type 2 Diabetes, food-grade CGN can cause lowering of blood glucose and may help manage metabolic conditions, such as diabetes. The human study on CGN supplementation by Dumelod et al. (1999) in a randomized crossover design on 10 fasting normal human subjects fed with CGN-experimental (2.03% total fiber) and control (0.68% total fiber) diets, showed lower mean postprandial glycaemic responses for experimental versus control, indicating a hypoglycaemic effect of CGN.

Additionally, the bases for the NOC claim, which were derived from the study of Bhattacharyya et al. (2012), is deemed to be flawed. In their study, male mice were given CGN (10 mg/L) in their drinking water, and subjected to glucose tolerance test (GTT), insulin tolerance test, and ante-mortem intraperitoneal insulin injection. Similarly, liver cancer cells (HepG2) were exposed to CGN (1 mg/L for 24 h) and insulin, and the activity of insulin signalling enzymes was determined. The higher glucose in GTT and its persistence during ITT for CGN-treated mice, and the inhibited activity of insulin signalling enzymes in HepG2 cells, were used as bases for suggesting that CGN in the human diet may contribute to the development of diabetes. However, these bases for the claim were flawed, for CGN is not normally consumed as pure CGN in water but incorporated to the food ingredients and used only in small amount. Further, the GTT and ITT test results in mice are not useful in the extrapolation of type 2 diabetes development in mice and much less in humans. Type 2 diabetes arises from persistent long-term elevated blood-glucose level, not incidental high glucose levels (i.e., 90–120 minutes) in a GTT or ITT test. In addition, according to the International Diabetes Federation (IDF 2012), the global guideline for clinical diagnosis of type 2 diabetes is as follows: fasting plasma glucose (FPG) ≥ 7.0 mmol/L; oral GTT using 75 g glucose for FPG ≥7.0 mmol/L and PG at 2 hours post-challenge ≥ 11.1 mmol/L; and glycated hemoglobin test (HbA1c) ≥ 6.5%. In the experiment of Bhattacharyya et al. (2012), the FPG levels of both mice treatments were below diabetic levels; the GTT showed similar pattern for both control and CGN-treated but no data for 2 hours post-challenge; and no HbA1c data was presented. Thus, the experimenters did not follow the global standard for clinical diagnosis of type 2 diabetes.

Issue No. 4: NOC claims that seaweed farmers are overharvesting wild seaweeds to produce raw materials for carrageenan production.

Contrary to NOC claims, the case of over-harvesting of *Kappaphycus* spp. and *Eucheuma* spp., the primary raw materials in CGN production, is not likely to happen. The current Philippine seaweed industry is not solely dependent on harvesting wild stocks. The commercially important species (e.g., *Kappaphycus* spp. and *Eucheuma* spp.) are actually farmed (Trono et al. 2000). The primary source of seaweed seedlings comes from existing cultured seaweeds by way of seedlings bank and/or branch-cuttings culture. Farmers commonly exchange and/or buy seaweed cultivars form existing plots to supply year-round planting materials. In addition, broken-off seaweed branches from cultured plots become seedlings to the wild, as commonly observed by coastal dwellers, and thus contribute to the replenishment of the wild seaweed stocks rather than their depletion from overharvesting as claimed by NOC.

Issue No. 5: It was alleged by NOC that carrageenan processing plants are dumping potassium hydroxide (KOH) liquid laden wastes in receiving waters.

The dumping of wastewater with high amounts of potassium hydroxide (KOH) from carrageenan processing plants as alleged in the NOC claims does not apply under the Philippine context. The industrial waste discharges from seaweed processing plants in the Philippines are regulated by the Philippine environmental laws implemented by the Department of Environment and Natural Resources (DENR). The updated DENR Administrative Order (DAO 2016-08) or the "Water Quality Guidelines and General Effluent Standards" and encompassing pertinent issued DAOs are implemented in compliance with the Philippine Clean Water Act (Republic Act No. 9275) and the Philippine Environmental Impact Statement System (Presidential Decree No. 1586). These national laws aim to protect the country's bodies of water from pollution from land-based sources and to provide comprehensive and integrated strategy to prevent and minimize pollution through a multi-sectoral and participatory approach involving all stakeholders. For a processing facility to operate, an Environmental Compliance Certificate (ECC) should be obtained. Such ECC, requires the factory to treat the wastewater before its release to the environment to comply with the DENR AOs 2016-08, and to conduct regular monitoring of the compliance to such AOs. Hence, the quality of wastewater from seaweed processing facilities are monitored to prevent pollution of receiving waters.

Carrageenan and its Purported Alternatives

In November 2016, the NOSB-USDA reported that *"the body of scientific evidence does not support claims of widespread negative human health impacts from consumption of carrageenan in processed foods"*, establishing the safety of CGN use in food products. However, despite being proven

Transactions NAST PHL 41 No. 2 (2019)
doi.org/10.57043/transnastphl.2019.1956

as safe for use in food products, the NOSB-USDA recommended the removal of CGN from the National List of Allowed Substances based on the availability of alternatives [Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA 6518(m)(6)]. To address this issue, BFAR submitted another paper which was endorsed by the Philippine Agriculture Secretary to USDA Secretary Sonny Perdue. This position paper put together science-based information providing evidence that no alternative could replicate the distinct physico-chemical and functional properties of carrageenan in its current product applications as summarized in the succeeding paragraphs. It aimed to support the advocacy to keep carrageenan on the US National List of Allowed Substances in organic products.

Carrageenan is a multifunctional substance with superior properties when used alone or in combination with other food additives in various food categories. Currently, it is being used as humectant, thickener, glazing agent, gelling agent, and bulking agent in meat products; stabilizer, thickener, gelling agent, and bulking agent in dairy products; clarifying agent in beer and wine; stabilizer in soymilk and almond milk; and thickener in soft candy.

A survey of literature from North America (USA, Canada, and Mexico), Europe (Germany, Greece, Poland, UK, Spain, Brazil, Turkey, Norway, and Ireland), and Asia (Iran, China, and Korea) showed that the **distinct physico-chemical and functional properties of CGN are not fully replicated by other hydrocolloids**, which makes it an essential, irreplaceable food ingredient in organic foods. Table 2 summarizes the physico-chemical and functional properties of CGN as it is applied in various food products. The succeeding paragraphs expound on these observations.

Several studies have proven that CGN is excellent in preventing the separation of the components of skimmed milk, while locust bean (LBG), guar, and xanthan gums cannot carry out the same function without CGN (Thaiudom and Goff 2003; Schorsch et al. 1999). In addition, non-fat dry milk emulsions have superior stability with CGN, which gelatin and high-methoxyl pectin as stabilizers failed to demonstrate (Tippetts and Martini 2012). Due

Table 2. Physicochemical and Functional Properties of Carrageenan in Various Food Products.

Property	Example of Food Product/s
Emulsion stabilization	Skimmed milk, Non-fat dry milk emulsions, Ice cream, Soy milk
Foam formation & stabilization	Ice cream, Whipped dairy cream, Mousse, Marshmallow, Meringue, Egg white protein foams
Crystallization inhibition	Ice cream
Freeze-thaw stabilization	Surimi gels, Whipped dairy cream
Water retention	Ground beef patties, Meatballs, Frankfurters, Sausages, Surimi gels, Noodles and Pasta
Texturization	Ground beef patties, Meatballs, Frankfurters, Sausages, Surimi gels, Non-fat dairy beverages, Whipped dairy cream, Fat-free cheese, Noodles and Pasta
Bulking agent	Ground beef patties, Meatballs, Frankfurters, Sausages
Gel formation	Surimi gels, Cheese and cheese-like products
Thickening	Fermented milk, Follow-up formulae, Ready-to-drink hot cereal and grain beverages, Batter coatings, Sauces and dressings
Glazing	Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms

Transactions NAST PHL 41 No. 2 (2019)
doi.org/10.57043/transnastphl.2019.1956

to its strong interaction with milk proteins, CGN prevents the formation of lumps in ice cream mixes (*wheying-off*), which other stabilizers [e.g., carboxymethylcellulose (CMC), LBG, guar gum, agarose] promote (Syrbe et al.1998; Bahramparvar and Tehrani 2011; Fox 1997; Spagnuolo et al. 2005). It is also known that CGN is the best stabilizer for soymilk (Krawczyk et al. 2004; Wang et al. 2001; Mukherjee et al. 2017). When purported alternatives, such as gum arabic, sodium alginate, xanthan gum, and LBG were used, the integrity of the soy beverages was not preserved as seen in the formation of semi-solid lumps and the settling of chocolate powder (Wang et al. 2001; Mukherjee et al. 2017).

CGN is also vital for the enhancement of the amount of air incorporated (*overrun*) in ice cream mixes, which influences the stability, texture, meltdown, and sensory perception of ice cream (Soukoulis et al. 2008). Several authors have indicated that CGN is crucial in maintaining the quality of ice cream during extended freezer storage (Spagnuolo et al. 2005; Soukoulis et al. 2008; Bahramparvar et al. 2013). Without CGN, separate addition of guar gum and CMC in the mix resulted in large ice crystals, producing a grainy ice cream after extended frozen storage (Soukoulis et al. 2008).

CGN has also been reported to prevent collapse of food foams, such as whipped dairy cream, mousse, marshmallow, and meringue (Żmudziński et al. 2014; Camacho et al. 1998, 2001; Miquelim et al. 2010). In the absence of CGN, other hydrocolloids cannot perform their role as stabilizers in maintaining the structure of food foams. Lambda-CGN (l-CGN) is exceptional at stabilizing whipped dairy cream with LBG during storage in chilled conditions and when subjected to freeze-thaw cycle regardless of LBG level (Camacho et al. 1998; 2001). CGN is a better stabilizer than guar and xanthan in egg white and sugar-based foods (e.g., mousse, marshmallow, meringue) at low pH. Pure xanthan produces egg white protein foams that are difficult to handle during further processing, and only the addition of CGN enables pure xanthan to fully preserve the native properties of egg white protein foams (Miquelim et al. 2010).

CGN exhibits superior performance over other hydrocolloids when added in low-fat meat products (e.g., ground beef patties, meatballs, frankfurters, and sausages), improving color, cooking and storage yields, juiciness, overall texture, and taste (Bullock et al. 1995; Cierach et al. 2009; Ulu 2006; Solheim and Ellekjær 1993; Xiong et al. 1999). In contrast, other gums were less effective and exhibited negative effects on these products. For instance, microcrystalline cellulose (MCC) increased moisture loss, while CMC reduced most textural parameters in low-fat frankfurters (Barbut and Mittal 1996; Lin et al. 1988). Alginate resulted in poor flavor intensity in low-fat ground beef patties while guar gum was ineffective in improving the texture of cooked low-fat meatballs (Bullock et al. 1995; Ulu 2006). Xanthan gum/LBG mixture exhibited higher cooking loss and lower water-holding capacity although comparable with i-CGN in terms of overall acceptability in low-fat ground beef patties (Bullock et al. 1995). Alginate, LBG, guar, and xanthan proved to be unsuitable for low-fat sausages, resulting in products with off-odor and with compromised textural attributes such as loss of bind, increased crumbliness, and softer, more deformable, and slippery texture (Solheim and Ellekjær 1993; Xiong et al. 1999).

Only CGN enhances quality of fabricated seafood products or surimi without introducing negative effects on their sensory properties. CGN enhances the gelling potential and freeze-thaw stability of surimi from Atlantic pollock (*Pollachius virens*) and red hake (*Urophycis chuss*) and improves the juiciness and prevents the toughening of raw minced cod during frozen storage (Ramírez et al. 2011; Park et al. 2014; Hunt and Park 2013). In contrast, fish gelatin and pectins failed to improve the texture of Alaska pollock and silver carp surimi gels, respectively (Hernández-Briones et al. 2009; Barrera et al. 2002); while alginates, xanthan and LBG tend to have negative effects on surimi gel texture when added separately (Ramírez et al. 2002; 2011; Park et al. 2014).

Further, **CGN-containing products have excellent sensory quality** (appearance, texture, mouthfeel, and flavor), which is an important

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factor for consumer acceptability in organic food consumption, **compared to those that contain other hydrocolloids**. For example, thickened and sweetened non-fat dairy beverages with CGN were creamier and smoother than similar beverages containing minimal dairy fat (Flett et al. 2010). Moreover, addition of CGN in low-calorie chocolate-flavored milk drink resulted in better release of flavor compared to sodium alginate (Yanes et al. 2002). The use of CGN in chocolate-flavored soymilk prevented the production of off-flavor, while sodium alginate, xanthan gum, and LBG bring out an undesirable "beany" flavor in similar products (Wang et al. 2001). CGN allows whipped dairy cream to demonstrate exceptional consistency (hence, palatability and appearance) even when exposed to repeated freezing and thawing (Camacho et al. 1998; 2001). Outstanding gastronomic properties of processed meat and fish products are enhanced with the addition of CGN. For instance, low-fat processed meat products with CGN are juicier, more tender, and have better color and flavor (Ulu 2006; Solheim and Ellekjær 1993; Xiong et al. 1999; Huffman and Egbert 1990). On the other hand, guar and xanthan gums yield off-odor, producing sausages that are less firm and elastic than ordinary sausages (Xiong et al. 1999). Konjac, on the other hand, causes a strong off-odor and an increase in undesirable yellow hue in surimi gels (Park et al. 2014; Park 1996; Xiong et al. 2009; Liu et al. 2013).

The above-cited glaring differences in performance and range of applications, in favor of the use of carrageenan, guarantees product shelf-life, superior product presentation, and consistency, while ensuring overall positive impact on consumer acceptance. The arguments presented here emphasize that there is **no suitable alternative to carrageenan in its current product applications**.

THE ACTION

In April 2018, after much deliberation, the US Department of Agriculture, in the conclusion of its 2018 Sunset Review, decided to keep carrageenan on the National List of Allowed Substances under the US Organic Foods Production Act despite the recommendation by the National Organic Standards Board (NOSB) in 2016 to remove it from the list. In a statement published in the Federal Register (Vol. 83, No. 65), the USDA says it *"found sufficient evidence in public comments to the NOSB that carrageenan continues to be necessary for handling agricultural products because of the unavailability of wholly natural substitutes (§ 6517I(1)(ii)). Carrageenan has specific uses in an array of agricultural products, and public comments reported that potential substitutes do not adequately replicate the functions of carrageenan across the broad scope of use. Therefore, carrageenan continues to meet the OFPA criteria for inclusion on the National List."*

CONCLUSION

As the country celebrates the victory of carrageenan's renewal among the "allowed substances" in the National List of the USDA National Organic Program, there is a need for continued vigilance among stakeholders as certain groups continue to lobby against carrageenan. Another sunset review is set for May 2023 and it is likely that the call for public comments to review the status of carrageenan is in the year 2021. There is wisdom in the call to action of Bixler (2017) for the carrageenan industry to be more proactive and skillful in getting the message out about carrageenan's safety and benefits to its consumers rather than continuing to "reduce the noise in the public domain" about the controversies surrounding carrageenan. As delineated in this paper, <u>there is much scientific evidence on carrageenan's safety and superior performance in its current product applications that cannot be fully replicated by purported alternatives.</u>

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