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National Organic Standards Board
USDA-AMS-NOP
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Re. HS: Carrageenan

These comments to the National Organic Standards Board (NOSB) on its Fall 2021 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

The NOSB voted in 2016 to remove carrageenan from the National List. In 2018, NOP announced that it was refusing to remove carrageenan. If, as argued below, carrageenan is a synthetic substance, then §6517(d)(2) of the Organic Foods Production Act (OFPA) prohibits NOP from relisting it. §6517(d)(1) requires that “The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board.” The National List is not “based on” the recommendations of the NOSB if it is directly contradictory to those recommendations. NOP based its decision on testimony received by the NOSB and should not be second-guessing the advisory board for which establishing the National List is an expressly stated responsibility. Below, we repeat the reasons leading us to oppose relisting of carrageenan.

We oppose the relisting of carrageenan on §205.605(a) and believe that the substance should be removed from the National List. Carrageenan should be classified as a synthetic, and hence must be removed from §605(a) and considered for §605(b) if it is to remain on the National List. As we will explain below, this use does not meet the requirements of the Organic Food Production Act —carrageenan may have adverse effects on the health of consumers, its production results in adverse ecological impacts, there are alternatives to its use, and its use is inconsistent with a system of organic and sustainable production.

Carrageenan may have adverse effects on the health of consumers.

We refer the NOSB to the detailed analyses of industry and independent science submitted by Joanne Tobacman, M.D., Cornucopia Institute, and Consumer Reports, which critique studies reviewed by the HS. Although we support those analyses, for the purpose of these comments we choose to concentrate on results that have been reviewed in the technical reviews commissioned for the NOSB.

Carrageenan is synthetic.

The 2011 Technical Review (TR) says, “[I]ndustrial extraction methods use alkali treatment to facilitate rearrangements and modifications in the chemical structure of the polysaccharide for manufacture of commercial-grade products. Carrageenan that is produced using those methods is considered synthetic.”¹ “[M]anufacturing 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.**”² In view of these statements from the commissioned technical report, the NOSB must justify its classification decision.

Carrageenan may have adverse effects on the health of consumers.

After a discussion of the impacts of “degraded carrageenan,” the 2011 TR continues,³ 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. In 2001, Joanne K. Tobacman, M.D. 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. Animal studies published since 1997 that were not included in Dr. 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 and human tissues, other studies have contradicted this finding.

Even taking into account the two negative studies, this is a considerable weight of evidence of harm to humans from carrageenan. The standards of the Organic Foods Production Act are distinct from the Federal Food Drug and Cosmetic Act and the determinations of FDA, requiring that a hazard analysis be incorporated into a decision-making process that is precautionary. The TR contains several cautions beyond the two studies cited above. “JECFA [Joint FAO/WHO Expert Committee on Food Additives] 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

¹ Lines 369-372.

² 2011 TR lines 386-388. Emphasis added.

³ Lines 571-582.

laboratory rats and mice.” “[C]arrageenan has a high tendency to sequester metal ions such as arsenic, lead, zinc, and copper.”

The more recent (2015) technical review specifically examined potential health impacts of carrageenan. The review came up with a verdict of mixed results on virtually every issue. On the question of whether less hazardous high molecular weight carrageenan can be degraded in the digestive system to more hazardous lower molecular weight forms: “The research is not fully conclusive but seems to suggest that degradation is possible.”⁴ On the association between food-grade carrageenan and inflammation or ulceration: “Several conclusions in the literature for animal feeding studies did not associate food-grade carrageenan fed in the diet with inflammation or ulceration, although some research does suggest an association.”⁵ On the impact of carrageenan administered through drinking water: “Results are mixed in animal studies that administered carrageenan through drinking water.”⁶ On effects on cell-signaling leading to inflammation: “Several in vitro studies have been performed to investigate carrageenan-induced effects on cell signaling pathways that contribute to inflammation, but without consensus among the reviewed research.”⁷ On the inflammatory effects of carrageenan in humans, “Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature.”⁸ On absorption of carrageenan: “Although these studies indicate that there may be a small percentage that is not excreted, there is no apparent evidence in the literature of animal feeding studies that carrageenan fed in the diet is absorbed in the gastrointestinal tract in toxicologically significant quantities.”⁹ On carcinogenic risk: “From the above studies on the role of carrageenan in tumor promotion of existing carcinogenic activity, it is difficult to draw conclusions about how carrageenan may contribute hazardous risk to humans.”¹⁰ And, “Carrageenan-induced cell signaling pathways that contribute to proliferation disorders have been studied in human colonic epithelial cells. A mechanism of carrageenan-induced Wnt signaling can lead to proliferative disorders and contribute to colon carcinogenesis as demonstrated in a study by Bhattacharyya, Feferman, Borthakur, et al..”¹¹ On insulin resistance and diabetes, the results appear more definitive: “The mechanisms of the cell-signaling pathway are demonstrated in a recent study by Bhattacharyya, Feferman, and Tobacman, wherein carrageenan-induced inflammatory and transcriptional cell-signaling cascades impair glucose tolerance resulting in insulin resistance.”¹² On the relevance of non-dietary studies in which the link between carrageenan and inflammation is non-controversial: “The relevancy of nearly all of the in vitro studies performed on the health effects of carrageenan is contested by McKim, an in vitro toxicologist, in a review article prepared for and funded by FMC Corporation,

⁴ Lines 40-41.

⁵ Lines 103-104.

⁶ Line 138.

⁷ Lines 146-147.

⁸ Lines 173-174.

⁹ Lines 202-205.

¹⁰ Lines 228-230.

¹¹ Lines 238-241.

¹² Lines 247-250.

a manufacturer of carrageenan.”¹³ **Virtually every study purporting to refute findings of health effects was performed by the same group of industry-supported scientists.**

The NOSB must take a precautionary approach in light of these studies. Even giving equal weight to industry-supported and independent research, the NOSB must accept the existence of science pointing to serious health consequences associated with the consumption of carrageenan and act to protect organic consumers.

A point of agreement

Although there is some disagreement, as pointed out by the TRs, there is agreement that poligeenan (aka “degraded carrageenan” or “low molecular weight carrageenan”) causes adverse health effects. It is important, therefore, that **when faced with the recommendation from the European Commission Scientific Committee on Food (now the European Food Safety Authority) that carrageenan with molecular weight below 50 kilodaltons be limited to no more than 5% of food-grade carrageenan, the industry was unable to comply.**¹⁴ The 2015 TR states,¹⁵ “It is possible that food-grade carrageenan may contain some low molecular weight fractions that are equivalent to poligeenan, although **validated analytical methods to accurately measure the low molecular weight distributions of carrageenan are not fully developed or available to the industry.** An analysis of the molecular weight distributions of 29 types of commercially available food-grade carrageenan demonstrated that none of the food-grade samples contained molecular weight fractions equivalent to poligeenan **at a detection limit of about 5%.**”

Thus, **regardless of other disagreements, the NOSB must assume a presence of 5% or more of poligeenan**, which is generally accepted to cause “ulcerations of the cecus and proximal colon in experimental animals, leading to its classification by the International Agency for Research on Cancer [IARC] as a possible human carcinogen.”¹⁶ IARC classified poligeenan as a Class 2B carcinogen.¹⁷ For reference, other chemicals that IARC has classified as 2B carcinogens include chlordane, chloroform, 2,4-D, hexachlorobenzene, and parathion.¹⁸ **Since**

¹³ Lines 299-302.

¹⁴ Marinalg International, 2008. Status Report on the Work of Marinalg International to Measure the Molecular Weight Distribution of Carrageenan and PPESi n Order to Meet the EU Specification: Less Than 5% Below 50,000 Daltons. p. 2.

¹⁵ 2015 TR lines 31-36. Emphasis added.

¹⁶ 2015 TR lines 26-28.

¹⁷ IARC, List of Classifications, Volumes 1-116. http://monographs.iarc.fr/ENG/Classification/latest_classif.php.

¹⁸ IARC, List of Classifications, Volumes 1-116. http://monographs.iarc.fr/ENG/Classification/latest_classif.php.

Class 2B “is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.”

<http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>.

there is in general no safe level of exposure to a carcinogen,¹⁹ poligeenan at 5% of the total carrageenan should not be dismissed.

The production of carrageenan results in adverse ecological impacts.

The 2011 TR examined ecological impacts of carrageenan production in detail. Overharvesting of a cold water species of seaweeds used to make carrageenan resulted in a population crash of the wild species. Warm water species are cultivated and present “serious bio-invasive risks for nearby marine communities” —not only spreading beyond cultivation sites, but also smothering coral ecosystems and contributing to reef degradation. Other adverse impacts are detailed in the TR.²⁰ Furthermore, “The industrial manufacture of carrageenan is a process that produces large amounts of alkaline waste water which may pose environmental problems.”²¹

More recently, the NOSB commissioned a TR on Marine Plants and Algae, which also documented some impacts of carrageenan production.²² This TR discusses site-specific overharvesting of *Chondrus* (cool water species), including potential regulation by the Canadian government.²³ This comment is also relevant to cultivated species used for carrageenan. Distributions of similar algal species can naturally vary geographically and over time. Habitat change producing conditions not well tolerated by resident species, can often lead to colonization by new species. Lack of competition or their inability to adjust to environmental changes can lead to the disappearance of one resident species from a particular region and replacement by another. Sometimes, the algae themselves cause these changing conditions. Many of the invasive algal species produce alien biomolecules that control competitive organisms in the new habitat.

A brief by the United Nations University and the Scottish Association for Marine Science also highlighted impacts of production of seaweed products.²⁴ In relation to cultivated species, it says,

For example, the red seaweed *Kappaphycus* is one of the most valuable crops grown for its carrageenan content, a product used widely in food, pharmaceuticals and nutraceuticals. As a result, the cultivation of this crop has been promoted in over 30

¹⁹ See, for example: Wigle, D. T., & Lanphear, B. P. (2005). Human Health Risks from Low-Level Environmental Exposures: No Apparent Safety Thresholds. *PLoS Medicine*, 2(12), e350. <http://doi.org/10.1371/journal.pmed.0020350>.

²⁰ Lines 469-551.

²¹ Lines 533-534.

²² 2016 TR Marine Plants and Algae.

²³ 2016 TR lines 588-596.

²⁴ Cottier-Cook, E.J., Nagabhatla, N., Badis, Y., Campbell, M., Chopin, T, Dai, W, Fang, J., He, P, Hewitt, C, Kim, G. H., Huo, Y, Jiang, Z, Kema, G, Li, X, Liu, F, Liu, H, Liu, Y, Lu, Q, Luo, Q, Mao, Y, Msuya, F. E, Rebours, C, Shen, H., Stentiford, G. D., Yarish, C, Wu, H, Yang, X, Zhang, J, Zhou, Y, Gachon, C. M. M. (2016). Safeguarding the future of the global seaweed aquaculture industry. United Nations University (INWEH) and Scottish Association for Marine Science Policy Brief. ISBN 978-92-808-6080-1. 12pp. <http://voices.nationalgeographic.com/files/2016/08/Final-unu-seaweed-aquaculture-policy-for-printing.pdf>.

countries worldwide. The occurrence of ‘ice-ice’ disease - a bacterial infection causing whitening of the sea - weed branches (Figure 2) and epiphyte infestations, however, have led to dramatic declines in the productivity of this crop in the Philippines, where this seaweed originated, in many of the other countries where it has been introduced (e.g. Madagascar and Tanzania). In the Philippines alone, disease caused a 15% loss in production of *Kappaphycus alvarezii* between 2011 and 2013 (a reduction of 268,000 tonnes), equating to a loss of over US\$ 310 million based on a value of 1.09 USD/kg (farm-gate price).²⁵

At the Fall 2020 NOSB meeting, the board passed a recommendation designed to protect marine ecosystems from damage associated with harvesting marine macroalgae. The NOSB recommended an annotation to listings of synthetic macroalgae products used in crop production:

Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules², holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

In addition, “A new listing at 205.602 is further recommended to prohibit marine macroalgae unless harvested to the same parameters, with an exemption for non-commercial harvests.” These protections should also be applied to macroalgae used for organic food inputs.

“Sensitivity” to carrageenan differs from food allergies.

The HS has suggested that varying sensitivity to carrageenan makes it similar to food ingredients to which consumers may be sensitive or have allergies. This suggestion ignores the fundamental difference between an unnecessary food additive and a food ingredient like “gluten, dairy, legumes, and many other foods.” Gluten, dairy, and legumes are foods or food components that may be produced organically and do not require an exemption from a general OFPA rule to be allowed in organic food. Carrageenan is not an agricultural product. It is a highly processed food additive that is only allowed in organic food by virtue of its listing on the

²⁵ Cottier-Cook, E.J., et al. (2016). Safeguarding the future of the global seaweed aquaculture industry. United Nations University (INWEH) and Scottish Association for Marine Science Policy Brief. ISBN 978-92-808-6080-1. 12pp. <http://voices.nationalgeographic.com/files/2016/08/Final-unu-seaweed-aquaculture-policy-for-printing.pdf>.

National List –a list of exceptions to the general rule that “organic” applies only to foods composed of organic ingredients.

Carrageenan is unnecessary.

The use of carrageenan is widespread, but that does not make it necessary. The 2011 TR lists a number of substitutes that “may be substituted for carrageenan to achieve a similar functionality when used either alone or in combinations.” The Cornucopia Institute has published a shopping guide showing that **every product made with carrageenan can be made without it.**²⁶ Food processors have been removing carrageenan from organic food since the sunset decision in 2012.

The use of carrageenan is inconsistent with a system of organic production and handling.

Carrageenan is an unnecessary synthetic material. Volatile synthetic solvents are used in at least some of its manufacturing processes.²⁷ Depending on the production method, it may contain residues of other synthetic materials including polysorbate 80 and epichlorohydrin.²⁸ In some cases, it is used as a preservative.²⁹

Conclusion

Therefore, we ask that the NOSB remove carrageenan from the National List. The evidence summarized by the 2015 Technical Review came up with a verdict of mixed results on virtually every issue regarding food grade (high molecular weight) carrageenan. However, there is widespread agreement that poligeenan, which contaminates food grade carrageenan at unknown and uncontrollable levels, does cause adverse effects, including cancer. The production causes adverse environmental impacts. And it is not necessary –organic processors have been moving away from the use of carrageen because of consumer pressure since it was last considered for sunset. This is made more urgent by the fact that the National Organic Program ignored the recommendation of the NOSB in spring of 2012 to remove carrageenan from infant foods, as well as the 2016 recommendation to remove carrageenan from the National List altogether.

Thank you for your consideration of these comments.

Sincerely,



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²⁶ <http://www.cornucopia.org/shopping-guide-to-avoiding-organic-foods-with-carrageenan/>.

²⁷ 2011 TR lines 287-294.

²⁸ TAP review pages 3, 4, 7.

²⁹ 2011 TR line 415.