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Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave., SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Carrageenan

These comments to the National Organic Standards Board (NOSB) on its Fall 2016 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.

In reviewing this substance, the NOSB must apply the criteria in the Organic Foods Production Act (OFPA), that its use—

- (i) would not be harmful to human health or the environment;
- (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and
- (iii) is consistent with organic farming and handling.¹

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 reclassified as a synthetic. 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.

We refer the NOSB to detailed analyses of industry and independent science by Dr. Joanne Tobacman, Cornucopia Institute, and Consumer Reports, which critique studies on which the HS relies. Although we support those analyses, for the purpose of these comments we have

¹ OFPA §6517(c)(1)(A). Further details at OFPA §6518(m).

chosen to concentrate on results that have been reviewed in the technical reviews commissioned for the NOSB.

Carrageenan is synthetic.

The 2011 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.”² “[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.**”³ 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,⁴

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).

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

² Lines 369-372.

³ 2011 TR lines 386-388. Emphasis added.

⁴ 2011 TR lines 571-582.

the lowest doses reported to cause inflammatory responses in laboratory rats and mice.” “[C]arrageenan has a high tendency to sequester metal ions such as arsenic, lead, zinc, and copper (Piculell, 2006).”

The more recent (2015) technical review specifically examines 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.”⁵ 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.”⁶ On the impact of carrageenan administered through drinking water: “Results are mixed in animal studies that administered carrageenan through drinking water.”⁷ 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.”⁸ 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.”⁹ 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.”¹⁰ 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.”¹¹ 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. (2014).”¹² 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 (2015), wherein carrageenan-induced inflammatory and transcriptional cell-signaling cascades impair glucose tolerance resulting in insulin resistance.”¹³ 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

⁵ 2015 TR lines 40-41.

⁶ 2015 TR lines 103-104.

⁷ 2015 TR line 138.

⁸ 2015 TR lines 146-147.

⁹ 2015 TR lines 173-174.

¹⁰ 2015 TR lines 202-205.

¹¹ 2015 TR lines 228-230.

¹² 2015 TR lines 238-241.

¹³ 2015 TR lines 247-250.

carrageenan is contested by McKim (2014), an in vitro toxicologist, in a review article prepared for and funded by FMC Corporation, a manufacturer of carrageenan.”¹⁴ **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 HS and 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.**¹⁵ The 2015 TR states,¹⁶

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** (Cohen and Ito 2006). 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%** (Uno, Omoto, et al. 2001a).

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 as a possible human carcinogen.”¹⁷ IARC classified poligeenan as a Class 2B carcinogen.¹⁸ For reference, other chemicals that IARC has classified as 2B carcinogens include chlordane, chloroform, 2,4-D, hexachlorobenzene, and parathion.¹⁹ **Since there is in general no safe level**

¹⁴ 2015 TR lines 299-302.

¹⁵ 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.

¹⁶ 2015 TR lines 31-36. Emphasis added.

¹⁷ 2015 TR lines 26-28.

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

¹⁹ 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*

of exposure to a carcinogen,²⁰ 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 seaweed 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.²¹ Furthermore, “The industrial manufacture of carrageenan is a process that produces large amounts of alkaline waste water which may pose environmental problems.”²²

More recently, the NOSB commissioned a TR on Marine Plants and Algae, which also documented some impacts of carrageenan production.²³ This TR discusses site-specific overharvesting of *Chondrus* (cool water species), including potential regulation by the Canadian government.²⁴ 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 recent brief by the United Nations University and the Scottish Association for Marine Science also highlighted impacts of production of seaweed products.²⁵ In relation to cultivated species, it says,

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>.

²⁰ 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>.

²¹ 2011 TR lines 469-551.

²² 2011 TR lines 533-534.

²³ 2016 TR Marine Plants and Algae.

²⁴ 2016 TR lines 588-596.

²⁵ 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

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 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).²⁶

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 organic product made with carrageenan can be made without it.**²⁷ Food processors have been removing carrageenan from organic food since the last sunset decision in 2012.

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

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.²⁸ Depending on the production method, it may

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>.

²⁶ 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>.

²⁷ <http://www.cornucopia.org/shopping-guide-to-avoiding-organic-foods-with-carrageenan/>.

²⁸ 2011 TR lines 287-294.

contain residues of other synthetic materials including polysorbate 80 and epichlorohydrin.²⁹ In some cases, it is used as a preservative.³⁰

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.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors

²⁹ TAP review pages 3, 4, 7.

³⁰ 2011 TR line 415.