Association Mondiale des Producteurs d'Extraits d'Algues Marines
World Association of Seaweed Processors

National Organic Program
USDA-AMS-NOP
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Room 2646-So.
AgStop 0268
Washington, DC 20250-0268

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Subject: Docket ID: AMS-NOP-12-0017

Comments: Sunset – carrageenan

Technical Evaluation Report (October 3, 2011)

Dear ….

The membership of Marinalg believes the status of carrageenan as a non-synthetic allowed for use in organic products should be maintained during this Sunset review for the following reasons.

- Carrageenan is a naturally occurring polysaccharide from red seaweed.
- Seaweeds are agricultural products predominately farmed with minimal environmental impact in South East Asia on family farms.
- The alkali extraction of carrageenan from red seaweed increases the yield minimizing the use of energy, seaweed and other inputs. The NOSB permits the use of strong alkalis in the process of making dutched cocoa, pretzels and organic soaps without deeming these products synthetic.

- Finally, carrageenan has been determined to be safe for use in food by the US FDA and FAO/ WHO (World Health Organization)/ JECFA (Joint Evaluation Committee for Food Additives) in their review of the data from numerous dietary feeding studies.

Based on the nature of seaweed farming, internationally established carrageenan safety and the precedence set by the processing of other organic products using alkali, Marinalg carrageenan producers group believes that there is no reason to change the status of carrageenan.

First, carrageenan is derived from red seaweed that is cultivated in an environmentally friendly and sustainable manner. Most red seaweed is produced in Southeast Asia by small family farms without the need for fertilizer, pesticides or fresh water. In the three countries that produce the more than 80% of cultivated seaweed; Indonesia, Philippines and Tanzania, seaweed farms would cover less than 0.3% of the coral reefs in these countries. Further, most seaweed farming is done on a floating line systems with the seaweed lines safely above the corals or in areas without coral present. Therefore, the impact of the overall seaweed industry creates minimal impact on the coral reefs and should not weigh against carrageenan remaining a non-synthetic.

Second, the assertion that the alkali extraction creates a significant structural change on the carrageenan molecule is incorrect. Seventy to ninety-five percent of the rearrangement of the carrageenan backbone occurs in the seaweed during its lifecycle. The effect of the hot alkali extraction only increases the rearrangement already occurring in the plant to at least ninety percent and allows carrageenan to be processed economically.

The NOSB/USDA NOP has set a precedence to allow the use of chemicals to moderate natural plant processes or make chemical changes in products labeled organic.

- One example is the use of ethylene on the control of blooming of pineapples. Ethylene allows the grower to manage the blooming cycle and efficiently use their land, water and labor to economically produce organic labeled pineapples.

- A sodium hydroxide wash to treat organic pretzels prior to baking is allowed to change the surface of the dough to make it sticky, hold salt, and brown during baking. This is obviously a chemical change to a portion of the dough which is no different than a converting a portion of the carrageenan through the alkali extraction process.
- The NOSB has allowed the use of alkali to effect changes in cocoa. Dutched cocoa can be labeled organic even though it has been treated with an alkalizing agent to neutralize the acids found in cocoa in order to alter the flavor and the color of the cocoa. Neutralization is a chemical change initiated by the alkali source on the molecules within the cocoa.
- Finally, the NOSB has given guidance that soaps maybe labeled organic even though the saponification of organic oils irreversibly transforms the original oil molecules into soap, glycerine, water and other by-products. The products of the saponification reaction bear no resemblance to the original oils or the original agricultural products that were the source of the oils.
- NOSB Guidance issued on August 31, 2009 "The processing of agricultural products in accordance with NOP regulation often results in chemical or physical changes, many of which may involve the synthesis of new compounds. For example, the process of baking bread or cooking meat creates changes in the products that may involve the creation of new compounds. However, neither of these common products are viewed as synthetic under regulations." The alkali extraction process used to extract carrageenan is far milder than the saponification process.

Carrageenan has been used for hundreds of years and is a common product within the food industry and carrageenan is derived from the processing of an agricultural product. By this definition, as given in guidance of organic soap, carrageenan should remain a non-synthetic.

Because the NOSB is still in the process of finalizing the guidance for synthetic/non-synthetic definition, Marinalg believes that any decision regarding the non-synthetic status of carrageenan should not be made at this time.

Third, the use of carrageenan is widespread throughout the production of organic certified products globally. Carrageenan is used at low use levels and provides significant functional advantages to food processors. Carrageenan is unique among hydrocolloids; it can be used to thicken, to create suspensions, or to create an infinite range of gel textures. Furthermore, carrageenan can interact with both proteins and other gums to create unique textures. Hydrocolloids are not drop in replacements for one another they are alternatives; each with its own strengths and weaknesses. Typically hydrocolloids are used in combination with one another and carrageenan is a highly efficient hydrocolloid thus organic food producers have the ability to combine multiple gums and still produce products that meet the 95% organic limitation.

Using hydrocolloids allows food manufacturers to enhance the nutritional profile of their products by reducing sugars or fats without negative changes to texture, changing processing profiles to minimize exposure to extreme hot or cold conditions, eliminating gluten, meeting dietary or cultural or religious restrictions. Finally, carrageenan in combination with other hydrocolloids provides; processing efficiency improvements that can reduce energy or water usage, can reduce food waste through improved shelf life, reduce or eliminate the need for refrigeration through aseptic packaging and improved stability at ambient conditions. The industry information supports that the use profile, benefits derived from using carrageenan and the negative impact on a change to the classification of carrageenan presents a favorable argument that carrageenan should remain a non-synthetic ingredient.

Fourth, the safety of carrageenan has been brought up as an issue under this review. Both the US FDA and WHO/FAO/JECFA have concluded that carrageenan is - safe for use in foods and beverages, etc. Their assessment was conducted using data that has been published and peer-reviewed by the scientific community including toxicologists and food safety experts.

- There has been confusion in the distinction of carrageenan (the food additive) and poligeenan (also known as degraded carrageenan) in discussions on carrageenan's safety. The food additive carrageenan is a naturally occurring polysaccharide that meets

the food chemical codex definition with an average molecular weight of approximately 400,000 to 700,000 daltons.

- Poligeenan is made by processing red seaweed extract at very high temperatures, above 90° C (194°F) and at low pH (1). None of these conditions are met in the human body. Poligeenan has an average molecular weight of approximately 10,000 to 20,000 daltons and is not allowed for use in food. Furthermore it does not function in food to provide either; gelling, thickening or suspension. Poligeenan is used in medical imaging as a dispersing agent.
- Reports have erroneously attributed adverse health reactions to carrageenan when in fact the effects were caused by poligeenan.
- At the fifty-first meeting of JECFA "...if the native carrageenan were sufficiently degraded to cause ulceration or tumor growth, this would have been detected in the animal feeding studies." (Benford et al, 2008, page 79)
- Finally, an animal feeding study (Weiner et al, 2007) was done with carrageenan altered to have a high percentage of low molecular weight. The feeding study concluded that there was no effect of high percentage of low molecular weight tail.

Marinalg understands that the NOP uses the US FDA safety and toxicology data and evaluation for determining safety of a material for the purposes of the National List and US FDA reviewed the totality of the science on carrageenan when making its decision that carrageenan is safe for use in foods. Safety should not be a factor in the decision to change the classification of carrageenan.

Carrageenan has been used for hundreds of years. It is a common product across the food industry derived from an agricultural source, and has been determined to be safe for use in food by the United States FDA and World Health Organizations (JEFCA). Carrageenan is alkali extracted but in comparison to other products that have the organic seal, carrageenan is minimally processed. Carrageenan provides food producers a number of advantages due to its low use level and can enable beneficial processing properties reducing carbon footprint. Organic producers are able to take advantage of these benefits to develop cost effective and

environmentally friendly products. Carrageenan is produced sustainably from red seaweed that primarily comes from small family farms in developing economies. Finally, guidance for determination of synthetic/non-synthetic is in the draft format. Marinalg believes that NOSB should not review the synthetic issue during Sunset but rather wait for a process to review all materials on an even platform with approved guidance.

For these reasons the classification of carrageenan should remain a non-synthetic allowed for use in organic products.

William B. MATAKAS
President of MARINALG International