



May 3, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-12-0017

RE: Handling Committee – Carrageenan

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comment on the NOSB Handling Committee Recommendation on Carrageenan.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

The comments OTA offers on carrageenan focus on its classification as synthetic, the sunset process, available alternatives, and the outcome the final Board vote may have on products currently using carrageenan. OTA is supportive of the sunset process and the role it plays in driving innovation and the development of alternatives in the marketplace. We are confident that the Board will carefully consider the comments received, and base its final decision on the force of evidence as presented by Board members, public comments and scientific data from other sources.

Background

Carrageenan is scheduled to sunset on November 3, 2013. In light of the scheduled sunset date, we offer a quick review of the advance notice and recommendation provided to-date.

- On June 1, 2011, the National Organic Program (NOP) released an Advance Notice of Proposed Rulemaking (ANPR) on whether carrageenan should continue to be allowed. Several comments were submitted in favor of its re-listing. There were no comments against the re-listing of carrageenan.
- The Handling Committee in its February 21, 2012, Recommendation voted in favor of reclassifying carrageenan as synthetic and re-listing on the National List under § 205.605(b). The recommendation also noted that the Technical Evaluation Report (TER) of October 3,

2011, showed that while new uses are being explored for carrageenan, its food uses have not changed substantially.

Given the lack of comments against the re-listing of carrageenan in response to the ANPR and the unanimous decision by the Handling Committee to re-list carrageenan on the National List, OTA expects the Board to also vote to re-list carrageenan. Because carrageenan is critical to the handling of many organic processed products, a decision to de-list a material with an expiration date of November 3, 2013, could cause considerable disruption of well-established organic products. OTA makes this comment in anticipation of the transition time that would likely be needed above and beyond the November 3, 2013, deadline in order to adequately research alternatives, reformulate, and bring products into compliance.

Classification of Carrageenan as “Synthetic”

Carrageenan is currently classified as a non-agricultural nonsynthetic substance. The Handling Committee has recommended re-classifying (and re-listing) carrageenan as an allowed non-agricultural synthetic substance. This determination was based on the information provided in the Technical Evaluation Report (TER). The TER points to structural changes to the polysaccharide molecule as a result of treatment in alkaline solutions, and concludes that carrageenan produced under these conditions is considered synthetic. OTA is not prepared to agree or disagree with the science presented in the TER at this time. Accordingly, we urge the Board to hold back from reclassifying carrageenan until the NOP Draft Guidance on Classification of Materials is finalized.

There are several hydrocolloid gums on the National List. When considering their agricultural source material and how each one is made, their classification appears to be rather inconsistent. High-methoxy pectin, for example, is listed as “agricultural” on § 205.606 of the National List yet the manufacturing process used is almost identical to the process used to make carrageenan. The difference between the two is the use of an acid treatment to extract pectin instead of the alkaline treatment used for carrageenan. To further confuse the matter, the current definition of ‘non-agricultural’ includes “gums” as an example, yet we see gums classified on the National List as both “agricultural” and “non-agricultural.”

OTA believes the most orderly approach would be for NOSB to address the re-classification of gums and other similar substances derived from agricultural material, including pectin, alginates, agar-agar and gelatin, as a group once the NOP guidance on the Classification of Materials is finalized. Considering their current allowance, we do not see the necessity is rushing a reclassification decision during sunset. We believe the focus should simply be on the essentiality of the materials and any new and valid information presented since the last sunset review cycle.

Sunset Process & Evaluation Criteria

OTA recognizes the following National List Criteria used by the Board during its sunset evaluation of National List materials:

- (1) The substance cannot be produced from a natural source and there are no organic substitutes;
- (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
- (3) The nutritional quality of the food is maintained when the substance is used, and the substance itself or its breakdown products do not have an adverse effect on human health as defined by applicable federal regulations;

- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
- (5) The substance is listed as generally recognized as safe (GRAS) by the U.S. Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP), and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA.

The NOSB committee did not express concern on any of the above criteria. The TER points to several alternative gums that are on the National List including agricultural ingredients that are allowed on § 205.606 of the National List, specifically guar gum, Arabic gum, locust bean gum and gelatin. OTA believes that organic guar gum, organic Arabic gum and organic locust bean gum are available. However, we do not know the specifics of how and if they function as replacements to carrageenan. We also don't know if the quantity available would meet current demand. Determining whether alternatives to carrageenan are available is especially important, and we expect this will be a central area of discussion during this meeting. See "Available Alternatives" below.

In regards to the Handling Committee's acknowledgement that carrageenan may be safely used as a food additive for human consumption as long its use in accordance with 21 CFR 172.620, OTA would also like to highlight the applicable National List Criteria #5 and its reference to FDA. Carrageenan (specifically aqueous extracted non-degraded form) is a globally approved food additive, and is generally recognized as safe (GRAS) by FDA. It is permitted for use by federal and international food safety agencies including FDA, Health Canada and the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Available Alternatives

OTA is confident that the Board will carefully consider the comments received from certified operators currently using carrageenan in their products. We need to understand whether any non-synthetic or organic alternatives sufficiently replace the use of carrageenan; this needs to be true for all of the applications it's currently used in.

OTA is aware of at least three applications where we are unaware of an acceptable alternative at this time:

- One use is as a clarifying agent (processing aid) during the brewing processing. Certified breweries often rely on carrageenan to clarify organic beer, particularly if they are not filtering the beer. Carrageenan binds to proteins and pulls the proteins out of solution.
- A second use is in Organic Ultra Pasteurized Whipping Cream. Carrageenan is used to prevent the cream from separating, and to prevent the fat portion from becoming solid (i.e., butter). Even with shaking, this layer would most likely not break apart or go back to its liquid form.
- A third use is in dairy applications where carrageenan acts as a suspension aid. Specifically, carrageenan is commonly used in organic chocolate milk applications to keep the chocolate in suspension because the carob particles have a tendency to fall out of solution. This is also the case for organic chocolate pudding.

We do not know of any organic or non-synthetic gums other than carrageenan that can be used for these types of applications.

We expect there are several more applications where an alternative to carrageenan doesn't exist, but these are the three examples we have specifically received feedback on. OTA commends the efforts of

certified operators actively engaged in sourcing and researching non-synthetic and organic alternatives. We also recognize that many companies that have been using carrageenan for years have searched but have been unable to find alternatives that will work. OTA believes in this process, and appreciates the future innovation it continues to bring about.

In closing, we thank the Board for the time and commitment on this round of sunset materials and wish to respectfully remind the Board that any decision must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. Any decision to remove a material from the National List during sunset must be made on the force of evidence as presented by Board members, public comments and scientific data from other sources.

Again, on behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment.

Respectfully submitted,



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Organic Trade Association (OTA)

CC: Laura Batcha
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