April 25, 2012

National Organic Standards Board
c/o USDA–AMS–NOP
Washington, DC 20250–0268

Re: Carrageenan Sunset Review

Members of the National Organic Standards Board,

I wish to comment on carrageenan, a substance up for Sunset Review at the NOSB meeting in New Mexico in May 2012.

I was a member of the inaugural NOSB, serving a three-year term from 1992 to 1995, during which time I was Chair of the Processing, Handling, and Labeling Committee, the forerunner of the current Handling Committee. After leaving the Board, I was a TAP reviewer for numerous processing materials reviewed by the Board at its 1995 meetings. I was one of the three individuals on the Technical Advisory Panel that reviewed carrageenan.

An important element of the recommendation of the Handling Committee with respect to carrageenan is reclassification of its nature, from nonsynthetic to synthetic. The 1995 TAP Review shows that each of us three reviewers classified carrageenan as "natural" – i.e., nonsynthetic. I have no argument with the Handling Committee's reclassification. Each of us interprets the definition of synthetic in the OFPA as best we can and new information arises. My concern is the potential effect of the "message" conveyed by moving carrageenan from the list of nonsynthetic substances to the list of synthetic substances. I fear that someone will assume that now 'any' synthetic carrageenan can be used in organic foods. 'Any' might include "degraded carrageenan."

In my review in the 1996 TAP Report, I alerted the NOSB to issues relating to carrageenan not otherwise mentioned in the carrageenan TAP report:

- the existence of a different substance, called "degraded carrageenan," with an adverse toxicological profile compared to high molecular weight 'undegraded' carrageenan; and
- my judgment that "degraded carrageenan" should not be allowed in foods labeled as "organic."

I wrote the following: *"Carrageenan has a high molecular weight and must be distinguished from lower molecular weight "degraded carrageenan" which may have adverse health effects."*

This statement was valid in 1995 and remains so today: it is important to distinguish between carrageenan of high molecular weight and "degraded carrageenan." I believe that an annotation for carrageenan should state that degraded carrageenan is not included in the allowance of "carrageenan" as an ingredient in or on food labeled as "organic," to make it clear that degraded carrageenan is not an acceptable synthetic carrageenan and should not be used.

Degraded carrageenan has toxic properties. The science available in 1995 included a 1992 study of epithelial cell proliferation in a rat model of colonic neoplasia. The verbatim abstract of the 1992 study by Wilcox et al.[1] reads as follows.

[1] http://www.ncbi.nlm.nih.gov/pubmed/1357233 . Accessed April 6, 2012.

Lab Invest. 1992 Sep;67(3):405-11.
Colonic epithelial cell proliferation in a rat model of nongenotoxin-induced colonic neoplasia.
Wilcox DK, Higgins J, Bertram TA.

Abstract

BACKGROUND:

The effect on colonic cell proliferation of poligeenan[2], a nongenotoxic polysaccharide that induces colon tumors in rats, was compared with guar gum and carrageenan.

EXPERIMENTAL DESIGN:

Fischer 344 rats were fed a basal diet supplemented with carrageenan and poligeenan fibers for up to 91 days. The quantitative levels of proliferation, location of the proliferating cells, and the ability of the mucosa to readapt by removing the experimental fibers from the diet were tested.

RESULTS:

The mucosal epithelium exhibited a 5-fold increase in thymidine kinase activity in both the carrageenan and poligeenan groups. Proliferating cells appeared at the luminal surface only in the poligeenan-treated rats, and the number of proliferating cells in the upper third of the crypt increased 35-fold. A second and third set of animals were fed one of the three test diets for either 28 or 64 days, followed by a 28-day recovery period. Proliferation in the guar- and carrageenan-treated groups returned to basal levels. In poligeenan-treated rats, thymidine kinase levels, and proliferating cells in the upper third of the crypt remained 2- and 11-fold, respectively, above controls.

CONCLUSIONS:

The difference in recovery time between the poligeenan group and the others, and the luminal location of proliferating cells may prove useful as markers in understanding early events in the carcinogenic process induced by a nongenotoxin.

It is clear that only those animals receiving the degraded carrageenan "poligeenan" had permanent cell proliferation. Thymidine kinase is a marker for cell proliferation but these results show that an increase in thymidine kinase activity can occur and abate in the absence of permanent cell proliferation.

Another 1992 scientific publication[3], this one by U.S. Food and Drug Administration scientists, documented that, despite changes in thymidine kinase activity, no histological changes were associated with any level of carrageenan feeding in rats consuming diets containing carrageenan at levels designed to simulate (on a milligram-per-kilogram basis) 25, 50, and 100 times the maximal human carrageenan intake.

The Technical Evaluation Report dated October 3, 2011, summarizes on lines 553-569 newer information that has become available on degraded carrageenan since 1995. The fact that the

[2] Degraded carrageenan.
[3] Nutrition. 1992 Jul-Aug;8(4):252-7. Effects of graded levels of high-molecular-weight carrageenan on colonic mucosal thymidine kinase activity. Calvert RJ, Satchithanandam S. http://www.ncbi.nlm.nih.gov/pubmed/1498457. Accessed April 25, 2012.

food regulations were never amended to specifically identify degraded carrageenan as an unacceptable component of carrageenan is an additional good reason for the NOSB to add an annotation forbidding degraded carrageenan to the listing of carrageenan when it reclassified as "synthetic."

Regarding the continued listing of carrageenan, I must admit to a personal interest in seeing carrageenan removed from the National List. In the past ten years I discovered that I am allergic to carrageenan in foods, so I would be very happy to see this substance removed from all foods. Fortunately for the rest of humanity, allergy to carrageenan appears to be rare. I found only a single report in the world's medical literature of proven allergy to carrageenan consumed orally[4]. Thus, there may be less than a handful of us idiosyncratically afflicted individuals, woefully inadequate evidence to justify banning the use of this ingredient in food.

I hope that the NOSB finds my comments useful in its deliberations on carrageenan.

Sincerely,

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[4] J Allergy Clin Immunol. 1995 May;95(5 Pt 1):933-6. Anaphylaxis to carrageenan: a pseudo-latex allergy. Tarlo SM, Dolovich J, Listgarten C.