



May 29, 2013

Dr. Miles McEvoy
Deputy Administrator
USDA National Organic Program
1400 Independence Avenue, SW
Washington, DC 20250-0268

Re: Comments on Proposed Rule: AMS-NOP-11- 0003; NOP-10-13PR, RIN 0581-AD13

Dear Sir:

We are writing in support of NOP's decision to maintain the status quo for section 205.605(a) of the National List and not restrict the use of carrageenan in organic infant formula, also suggested by the National Organic Standards Board (NOSB) in May 2012 as a secondary recommendation.

[Marinalg International](#) is a global association supporting the interests of seaweed farmers and the seaweed-based hydrocolloids industry. Marinalg's primary efforts include the delivery of sound science and technical expertise related to the safety and efficacy in the production and use of hydrocolloids from seaweed to family tables. Marinalg represents the regulatory interests of the seaweed-processing industry before various international bodies such as Codex Alimentarius, and national regulatory authorities including the European Food Safety Authority, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

NOP DECISION ON CARRAGEENAN

We agree with the NOP that the NOSB erred in making its initial 2012 recommendation to restrict the use of carrageenan in organic infant formula, which was based solely on a statement about newborn infants expressed in 2003 by the European Union Scientific Committee on Food (SCF), but without scientific studies. The NOP correctly noted that the SCF had concluded in that document that "there is no evidence of any adverse effects in humans from exposure to food-grade carrageenan, or that exposure to degraded carrageenan from use of food-grade carrageenan is occurring."

In the U.S., carrageenan is allowed under FDA regulations at 21 CFR 172.620 as a direct food additive and is considered safe when used in the amount necessary as an emulsifier, stabilizer, or thickener in foods. The FDA, as the U.S. food safety authority, has not prohibited the use of carrageenan in infant formula under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(a)). The NOP proposed rule to

continue carrageenan use without restriction is a wise decision, because there is strong evidence from dietary studies that carrageenan is a safe food ingredient.

CARRAGEENAN HAS A LONG HISTORY OF SAFE FOOD USES

Carrageenan (CAS# 9000-07-1) is a family of high-molecular weight, strongly anionic, linear sulfated polysaccharides extracted from several species of red seaweed that is often used as a thickening agent much in the same way ingredients such as flour, cornstarch and tapioca are used to thicken or bind other ingredients. It is halal-, kosher- and vegan-approved, and is used in place of chemically-produced additives or animal-based products, like gelatin, which is extracted from animal byproducts.

Carrageenan has been used in the kitchens of Ireland for more than 600 years. Use of extracted carrageenan as a food additive in the U.S. dates back to the late 1930s, when it was discovered that carrageenan could stabilize chocolate milk. Today carrageenan is used in food processing to bind water, promote gel formation, thicken, stabilize, and substitute for fat. Carrageenan improves palatability and appearance of a very long list of organic and conventional processed foods, including dairy products, water-based foods, meat and fish products, beverages, condiments, infant formula, and pet food (McHugh, 2003).

Carrageenan is an important component of thousands of organic and conventional food products enjoyed by millions of people daily around the world. Carrageenan is used widely in food because it can impart the following properties:

- Produces gels through changes in temperature and [interactions](#) with various proteins and cations in foods;
- Displays a minimal viscosity at high temperatures yet thickens and solidifies when cool, allowing easier processing;
- Suspends particles within a solution, such as herbs suspended within oil of salad dressing;
- Stabilizes emulsions, inhibits separation, flows like a liquid when stirred but acts like a gel when left alone;
- Binds moisture, retaining fluids in thousands of food products; and
- Substitutes for animal-based products, such as gelatin, in specialty foods.

CARRAGEENAN HAS A LONG HISTORY OF REGULATORY APPROVAL

Carrageenan's widespread use is based on decades of safe use coupled with repeated regulatory approval as a safe food additive for use in conventional foods and organic foods. Examples of such approvals follows:

- 1961 – FDA approved carrageenan as a safe direct food additive for human consumption, specifying that the name “carrageenan” must be used on the label¹
- 1969 - Joint FAO/WHO Expert Committee on Food Additives reviewed carrageenan
- 1973 – FDA assigned Chondrus extract (“carrageenan”) to Generally Recognized As Safe (GRAS) list (GRAS ID Code 9000-07-1; 21CFR§182.7255
- 1977 – European Commission Scientific Committee for Food approved carrageenan as food additive
- 1995 – European Directive 95/2/EC listed carrageenan as permitted additive
- 1999 – Carrageenan is listed as permitted additive in Codex Alimentarius Commission CAC/GL 32, “Guideline for the Production, Processing, Labeling and Marketing of Organically Produced Foods.”

- 2003 – USDA added carrageenan to the National List of Allowed and Prohibited Substances (68 FR 61993; October 31, 2003) reviewed and reauthorized November 2008 as a “Nonsynthetic Allowed”
- 2005 – Carrageenan was listed as an approved additive by the International Federation of Organic Agriculture Movements (IFOAM)
- 2006 – Carrageenan was listed in the Pacific Organic Standard as a permitted additive in organic food processing
- 2006 – Canadian General Standards Board approved carrageenan for use in organic handling and processing (Permitted Substances List CAN/CGSB-32.311-2006)
- 2007 – East African Organic Product Standard listed carrageenan in its Organic Product Standard as an additive approved in organic food processing
- 2008 – European Commission Regulation (EC) No 889/2008 permitted the use of carrageenan as a food additive in preparation of plant-origin organic food products or animal-origin, dairy-based organic food products (Commission of the European Communities, 2008); and

The NOP’s proposed continuation of carrageenan use in U.S. organic foods is supported by both the U.S. FDA and regulatory bodies of dozens of foreign countries.



Carrageenan is acceptable for use in food in all countries highlighted in green

CARRAGEENAN'S SAFETY IN FOOD IS WELL DOCUMENTED

Decades of research on carrageenan safety have been conducted by food scientists, toxicologists and medical researchers. We are not aware of any confirmed adverse effects on human health due to the use of carrageenan in food. Studies indicate that carrageenan, when ingested as a food additive, passes through the gastrointestinal (GI) tract tightly bound to food proteins; is not absorbed across the GI tract (Nicklin and Miller, 1989; Weiner, 1988); passes through the body intact (Arakawa et al., 1986, 1988; Uno et al., 2001); and does not trigger GI tract inflammation or other adverse conditions (Weiner, et al., 2007). Monkeys fed carrageenan at various dosages for 7.5 years showed no adverse effects and no evidence of storage in various GI tract tissues or internal organs (liver, lymph nodes) (Albany Medical College, 1983). Orally administered carrageenan is not digested into small molecular-weight forms; is not absorbed or distributed systemically, and does not cause adverse effects until extremely high dose levels (>5% in diet) are administered (Cohen and Ito, 2002; IFAC and Marinalg, 1997; IARC, 1983; JECFA, 1999, 2002, 2007).

Evaluation of carrageenan as a safe food ingredient has been documented by many oral feeding studies involving ingestion of carrageenan in the diet. Examples include:

- Long-term multigenerational studies conducted by FDA, feeding rats with a diet containing carrageenan at 5% in diet found no effects on reproduction, fertility, average litter size, average number of liveborn animals, viability or survival of offspring, weight gain, or any specific external, skeletal or internal soft-tissue anomalies (Collins, Black, Prew, 1977);
- Studies of male and female infant baboons raised from birth to 112 days of age on infant formula, containing concentrations of carrageenan up to 5x the concentration of commercially-available formulas for human infants, had no effects on infant baboon development. Carrageenan concentration of the formula did not affect growth, characteristics of urine and feces, findings on physical examination, hematological variables, blood clinical chemical analyses, organ weights, or the macroscopic and microscopic appearance of the GI tract (McGill, et al., 1977);
- Studies of rats fed a simulated milk powder diet, containing carrageenan mixed into skim milk, for 6 months had no abnormalities to growth rate; diet energy efficiency; absorption of protein, fat or calcium; utilization of protein or iron; or gross and microscopic effects on the cecum and colon (Tomarelli, et al. 1974).

CARRAGEENAN MUST BE EVALUATED AS A FOOD INGREDIENT

It is important that determinations of carrageenan safety as a food ingredient be based on oral feeding studies performed in compliance with regulatory guidelines, using oral dietary administration (consistent with the route of human ingestion), large groups of animals and several dosage groups. Criticisms of carrageenan based on studies evaluating other routes of carrageenan exposure are not germane to the assessment of dietary safety. Examples include:

- Irrelevant exposure studies: Studies involving injection of carrageenan into animal paws (Winter et al., 1962) or other tissues, or injecting carrageenan intravenously into animal blood veins have no place in the evaluation of carrageenan as a food ingredient (Cohen & Ito, 2002). Animal studies which report systemic effects following administration of carrageenan at high concentrations in drinking water for laboratory animals are not relevant to dietary applications, where carrageenan is tightly bound to food proteins, and hence, not available for direct interaction with tissues.

- Studies with isolated cells or tissue culture: In recent years, there have been numerous *in vitro* studies, incubating carrageenan with isolated human intestinal cell lines, human hepatoma cells, human monocytic cells, and human breast cells grown in culture. The vast majority of these *in vitro* experiments has come from a single laboratory, which has suggested in a very public manner that carrageenan can trigger inflammation, diabetes, breast cancer and adversely alter the immune system. It is not uncommon for investigators to see events in test tubes that have little or no relationship to events in laboratory animals or humans. In 2012 the FDA rejected a citizen's petition from the principal investigator of this laboratory research, concluding such experiments are of "limited value" to the determination of dietary carrageenan safety.¹ Today there is no evidence supporting the extrapolation of such test tube studies to *in vivo* experiences of carrageenan ingestion as a food ingredient.
- Confusion of carrageenan with poligeenan (often referred to as "degraded carrageenan.") Poligeenan is a synthetic compound that is intentionally created for medical uses using strong acids and high temperatures over an extended period of time to alter carrageenan. Poligeenan is not produced naturally, nor is it produced when carrageenan is extracted from seaweed. Poligeenan has no value as a food ingredient; is not allowed in food, and is not present in food that contains carrageenan. Many older studies, however, tested "degraded carrageenan"/poligeenan toxicology under the incorrect theory that degradation of carrageenan to poligeenan "might occur" during ingestion. Even today, some critics of carrageenan intentionally refer to those older studies incorrectly. Unlike poligeenan, carrageenan does not cause adverse GI tract effects; it is a family of large-molecule polysaccharides (200,000 to 800,000 Da or larger) that is not degraded when produced or when ingested in the diet.

CARRAGEENAN IS A SAFE, VALUABLE FOOD INGREDIENT

Carrageenan continues to be an important food ingredient that many millions of people ingest daily. It has been an important food ingredient for centuries and is used worldwide in thousands of food, pharmaceutical and other consumer products. Carrageenan is used to bind water, promote gel formation, thicken, stabilize, substitute for fat, and improve palatability and appearance of a very long list of organic and conventional processed foods (McHugh, 2003). Throughout all of this, carrageenan continues to meet regulatory expectations for food safety. NOP has correctly determined U.S. organic standards should continue to include carrageenan.

Thank you for the opportunity to submit these comments for the record.

Sincerely,



William B. Matakas
President
Marinalg International

¹ <http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0347-0003>