

Summary of USDA Proposed Rule to Continue Use of Carrageenan

The Agricultural Marketing Service (AMS) is an agency in the US Department of Agriculture and it oversees the National Organic Program (NOP). The National Organic Standards Board (NOSB) is an advisory panel whose members are from the “organic” community who are appointed to the NOSB by the Secretary of Agriculture. The NOSB makes recommendations on the conduct of the organic program. Recommendations made by the NOSB are not official policy until they are approved and adopted by USDA.

On May 3, 2013 the U.S. Department of Agriculture (USDA) published in the Federal Register (FR) its proposed actions pursuant to recent recommendations of the [National Organics Standards Board](#) (NOSB) regarding the status of carrageenan as a substance allowed in organic food. The NOSB recommends that carrageenan be listed again as an allowed substance in foods labeled organic in the U.S. However, the NOSB also recommends that due to safety concerns, carrageenan should be excluded from use in organic infant formula. Thankfully, in their proposed rule the USDA has decided to accept the NOSB recommendation to continue to allow carrageenan as a non-synthetic substance permitted in organic foods and has decided to reject the NOSB recommendation to exclude carrageenan from organic infant formula. The publication of the proposed rule establishes a 30-day period for stakeholders to file public comments. The deadline for filing comments to the docket is June 3, 2013.

Basis for NOP’s carrageenan decision: The NOSB’s justification for the recommendation to exclude carrageenan from use in organic infant formula was based, in part, on the NOSB’s erroneous interpretation of a 2003 opinion of the European Commission’s Scientific Committee for Food – and – improper reference to the AAP’s Pediatric Nutrition Handbook. The NOP concluded that the NOSB erred in making its 2012 recommendation to restrict the use of carrageenan in organic infant formula, a recommendation based solely on a statement about newborn infants expressed in 2003 by the European Union Scientific Committee on Food (SCF). In that document, however, the SCF had concluded 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.” NOP noted this, and also that 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, for there is strong evidence from dietary studies that carrageenan is a safe food ingredient.

Carrageenan is a natural product: The production and separation of carrageenan from red seaweed is non-synthetic. The process is carefully controlled under alkaline conditions to avoid degradation or chemical changes to the three types of naturally-occurring carrageenan produced. Carrageenan is composed of high-molecular weight long-chain polysaccharides of galactose sugars, which, like cellulose, form non-digestible molecules. The three types of carrageenan (lambda, kappa, and iota) convey differences in physical properties as food ingredients. As a group, carrageenan is used worldwide in thousands of food products for traditional and organic markets, and additionally as a vegetarian and vegan alternative to gelatin. Carrageenan does its job before it is ever consumed in food:

- Produces gels through changes in temperature and reactions 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; and
- Binds moisture, retaining fluids in thousands of food products.

Feeding studies establish carrageenan’s dietary safety: The question of whether dietary carrageenan passes through the body without effect or provokes an inflammation response is an important aspect to the NOP decision. Despite arguments to the contrary in the social media, oral feeding studies confirm that carrageenan in food passes through the human body essentially unaltered; is not significantly absorbed; is not carcinogenic; does not induce tumor formation in the colon, and does not induce GI tract inflammation (Weiner et al., 2007). Studies indicate that food-grade carrageenan passes through the body quantitatively (Uno et al., 2001; Tomarelli et al., 1974). Male and female infant baboons showed no adverse effects when raised from birth to 112 days on infant formula containing up to 5x the level of carrageenan typically present in human infant formula (McGill et al., 1977). Multi-generational studies with rats fed up to 5% carrageenan showed no adverse effects (Collins et al., 1977). Lifetime studies of rats and hamsters fed up to 5% carrageenan had showed no adverse effects (Rustia et al., 1980). A 40-week study of rats fed up to 5% carrageenan in the diet showed no adverse effects (Abraham et al., 1985). A 90-day study of rats fed up to 5% carrageenan (containing 7% mean low molecular weight tail) showed no adverse effects (Weiner et al., 2007). Studies indicate that carrageenan passes through the GI tract tightly bound to proteins in ingested foods. The unique structure of carrageenan resembles that of cellulose, which is not recognized by the digestive enzymes of the gut. Acid hydrolysis does not occur either, for studies indicate the conditions necessary to break down carrageenan do not exist in the GI tract.

Dietary safety cannot be based on “test tube” studies: Effects of injection of carrageenan into tissues or into the blood of animals are irrelevant in discussions of carrageenan food safety, for these methods bypass the normal limits on ingestion present in the GI tract. Similarly, “test tube” or “petri dish” studies conducted with isolated cells or tissues incubated with carrageenan for the evaluation of effects on whole-body function must be viewed with caution. A vast majority of these studies have come from a single laboratory, and have been used by these authors to suggest that carrageenan can bind to and activate cellular activities to trigger inflammation, diabetes, breast cancer and immune responses. It is not uncommon for investigators to see events in cell models that have little or no relationship to events in animals or humans. It is important to view these studies as informative but they have not been tied to physiological events that occur naturally in animals.