Executive Summary
Based on an evaluation of the available scientific evidence and a review of the safety data, it is the position of Metagenics that carrageenan is a safe additive for incorporation into food products at levels necessary to achieve the desired functional result.

Review of the Evidence
Carrageenan is a carbohydrate extract composed of sulfated galactose units from a number of seaweeds of the class Rhodophyceae. The three main types of carrageenan used commercially—iota-, kappa-, and lambda-carrageenan—differ slightly in their structure and degree of sulfation.

For centuries, carrageenan has been used in food products and was patented as a food additive for use in the United States in the 1930s. It is a naturally sourced material with little taste or odor, and has a long history of safe use in food products. Carrageenan is used widely by the food industry in relatively minor quantities to assist with stabilizing and texturizing functions. For example, carrageenan is often used to thicken and improve the texture of foods such as yogurt, salad dressings, infant formulas, and soymilk.

In addition to food, carrageenan has been used as an ingredient in pharmaceuticals and personal care products, such as toothpaste and cosmetics. The predominant role of carrageenan, however, has been in food preparations where it is used across a wide variety of food groups because of its ability to substitute for fat and combine easily with milk proteins to increase solubility and improve texture.

Earlier work in animal models such as rats, mice, rabbits, and guinea pigs has suggested that carrageenan, and in particular, degraded carrageenan, may cause gastrointestinal complications. In 2001, Joanne Tobacman from the University of Iowa published a review of these 45 studies and concluded that carrageenan may be associated with the formation of ulcers and tumors in the gastrointestinal tract. However, comparable evidence does not exist in humans. The findings reported in animals may not apply to humans for the various reasons:

1) On average, the doses of carrageenan reported in these studies are not representative of usual human dietary intake. Doses as high as 10% carrageenan were used to demonstrate effects.
2) In animal studies, carrageenan was commonly provided in the water supply, causing difficulty in the extrapolation of results as it applies to eating a mixed diet. The bulk of the diet itself, possibly in conjunction with the high level of nutrients in foods, may negate any potential effects that carrageenan can have on the gastrointestinal tract.
3) The difference in intestinal bacterial strains between animals and humans may play a significant role in how dietary carrageenan is metabolized. In their meeting report from 2000, the FAO/WHO Expert Committee on Food Additives (JECFA; an independent, international panel of expert scientists and government authorities) reported on an abstract of a conference that indicated that tumor promotion does not occur in rats in which the intestinal microflora are derived from human donors who have been ‘adapted’ to carrageenan. This finding might suggest that promotion of colon carcinogenesis in the rat is dependent on the presence of normal microflora of the gastrointestinal tract.
4) Carrageenan in food comes in a different form than the form used in the animal studies. A majority of the reported studies used degraded carrageenan, also known as poligeenan, to evoke negative health effects. Carrageenan does not have the same
effects as poligeenan because it is not degraded, not degraded to the same molecular mass, or not degraded in a similar fashion to poligeenan. Although poligeenan lacks the thickening or stabilizing properties of carrageenan, it was nevertheless confused with the food-grade carrageenan. Due to this confusion, the U.S. Adopted Names Council determined that “poligeenan” was a more accurate, descriptive name for the chemically degraded form of carrageenan. While poligeenan has shown unfavorable health effects in animal studies, food-grade carrageenan has no known toxicity or carcinogenicity and is Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration.

As food additives are subject to periodic review, the safety of carrageenan was confirmed most recently on June 2001 at the 57th meeting of JECFA. They affirmed their earlier conclusion that carrageenan may be used safely in the diet, and is only limited by the amount necessary to achieve its technical function. They performed a multiple-year review of all of the relevant safety data on carrageenan, including a specific analysis of colon cancer promotion. Based on studies which included a three-generation study of reproductive toxicity, short- and long-term studies of toxicity in rats at dietary concentrations up to 5%, and short- and long-term studies in hamsters, guinea pigs, and monkeys, they concluded that carrageenan may be used safely in the diet and recommended an Acceptable Daily Intake of “not specified,” which is the highest possible classification from a toxicological point of view. This term is used to refer to a food substance of very low toxicity, which on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects, and from its acceptable background levels in food, does not in the opinion of the Committee represent a hazard to health. This recommendation was significant since the review was based on extensive safety studies.

**Conclusion**

Authorities worldwide such as JECFA, Scientific Community on Food (SCF), and International Food Additives Council (IFAC) have extensively evaluated the safety of carrageenan. In contrast to the findings presented by Tobacman, all of these authorities agree that carrageenan is safe for use in foods. In addition, the positive effects of carrageenan on human health are beginning to be explored. For example, a number of preliminary in vitro studies suggest that carrageenan may have anti-viral properties. Furthermore, carrageenan has recently been shown in a clinical trial to significantly reduce serum cholesterol and triglyceride levels.

**References**