

May 2, 2012

Docket No. AMS-NOP-12-0017; NOP-12-06 Public comments on the Handling Committee recommendations concerning **choline and inositol.** 

The Hain Celestial Group is one of the largest producers of organic products in the world. We make a wide variety of organic products that are manufactured at many different food processing facilities located throughout the United States and other countries. We market organic infant formula that contains both choline and inositol.

First, we wish to strongly support the handling committee's recommendation to add both choline and inositol to the National List 205.605 (b) for use in infant formula labeled organic or made with organic.

Second, the handling committee recommended that choline and inositol be added to the National List 205.605 (b) for products other than infant formula labeled "made with organic" and prohibited in products labeled "organic."

We do not agree with this second recommendation. We believe that these two nutrients are important to human health, and "organic" products other than infant formula should have the option of being fortified with these nutrients. In a survey conducted by the Organic Trade Association in conjunction with Kiwi magazine, 78% of organic food consumers said that choosing fortified foods for their family is either "very important" or "somewhat important." Consumers should be able to purchase an organic product with fortification if they choose to do so. If organic food manufacturers are not allowed to fortify their products, they will not be able to compete fairly with conventional products, and this will harm the industry.

Our support for adding choline and inositol to the National List is based on the following:

- 1. **Infant Formula**: Both choline and inositol are extremely important for the proper growth and development of infants. These two nutrients are mandated for addition to non-milk based infant formulas, and they are always added to milk based formulas to ensure that the cow's milk based formulas contain levels of choline and inositol that are comparable to human milk and meet adequate intake levels
- 2. **Foods for Other Age Groups**: Toddlers and young children are especially vulnerable to inadequate intakes of nutrients because their brain and other organ

systems are still developing. Foods fortified with choline and inositol will help ensure that these young children receive the adequate nutrition that they need. There is evidence that individuals in various age groups do not consume the adequate intake recommendations for choline as determined by the Food and Nutrition Board of the Institute of Medicine.

- Safety: Inositol and the two choline salts, choline chloride and choline bitartrate, are classified as GRAS or generally recognized as safe for direct addition to food for human consumption. These are codified in 21 CFR Sections 184.1370, 182.8250, and 182.8252.
- 4. **Meets all criteria for addition to the national list**: Choline and inositol meet all of the criteria for allowed substances as delineated in 7 CFR 205.600. They are essential for the handling of organically produced agricultural products, and there are no organic substitutes. These nutrients are GRAS and their manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling.

In conclusion, we urge the members of the National Organic Standards Board to vote yes to adding choline and inositol to 205.605 (b) for <u>all</u> products labeled organic or made with organic. We thank the Board members for all of their hard work and for considering our comments.

Sincerely,

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