

May 3, 2012

Ms. Ann Michelle Arsenault
Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re: AMS-NOP-12-0017; NOP-12-06:
Notice of Meeting of the National
Organic Standards Board

Dear Ms. Arsenault,

The International Formula Council (IFC) appreciates the opportunity to comment on the Agricultural Marketing Service's April 9, 2012 Notice of Meeting of the National Organic Standards Board (NOSB), including a number of the substances to be considered by the NOSB for continued listing on the National List of Allowed and Prohibited Substances (National List). We are also commenting on two separate matters regarding other substances. The IFC is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are based predominantly in North America.

The IFC supports the continued use of all substances currently allowed as ingredients in or on processed products labeled as "organic" or "made with organic." These ingredients are deemed safe and suitable by the U.S. Food and Drug Administration for inclusion in infant formula. They have also been evaluated previously by the NOSB and the National Organic Program and deemed appropriate for inclusion in organic products.

In particular, we are commenting on two NOSB Handling Committee proposals regarding choline and inositol, the Handling Committee's Sunset 2013 Proposal on 205.605a regarding carrageenan, and a recent NOSB recommendation regarding hexane extraction and arachidonic acid (ARA).

Choline and Inositol

The IFC strongly supports the Handling Committee's recommendations to add choline and inositol to the National List 205.605(b) for use in infant formula labeled organic or made with organic (specified ingredients or food group(s)).

Organic infant formula manufacturers' use of these substances is a result of science-based advances in nutrition and expert evaluation of resulting data, which has determined they are safe and suitable for use by infants. Manufacturers who make both organic and non-organic infant formulas use all of the petitioned substances in all of their routine infant formula products, because the science justifies such use.

* IFC members are: Abbott Nutrition; Mead Johnson Nutrition; Nestlé Infant Nutrition; PBM Products, LLC, A Perrigo Company; and Pfizer Nutrition. This submission also includes the views of the Hain Celestial Group, Inc., which is a marketer of organic infant formula but is not an IFC member company.

Therefore, if choline and/or inositol were to be denied for use in organic formulas, such products would have a major competitive disadvantage because they would be nutritionally inferior to conventional infant formula. In addition, regulations mandate the addition of choline and inositol to non-milk based infant formulas. Therefore, non-milk based organic infant formula without choline and inositol cannot be sold in the United States. Further, the disallowance of choline or inositol from organic infant formula could lead to a disruption in the marketplace and potentially force manufacturers to reconsider their presence in the organic infant formula market.

Carrageenan

The IFC strongly supports the Handling Committee's recommendation to keep carrageenan on the National List. The FDA has deemed carrageenan is safe for consumption by infants and it has a long history of safe use in infant formulas and other foods. Carrageenan is a unique thickening substance which infant formula manufacturers use to ensure their liquid products remain in suspension so that nutrients are delivered appropriately during feeding. Removing carrageenan from the National List would result in a disruption in the availability of liquid organic infant formula and would force manufacturers to reconsider their presence in the market.

Arachidonic Acid

We would also like to comment on a recommendation made by the NOSB at its October 2011 meeting. The recommendation to prohibit the use of substances that are derived using hexane extraction may have a significant impact on organic infant formulas and manufacturers' desire to remain in the market. Arachidonic acid (ARA) is always added to infant formula in a specific ratio with docosahexaenoic acid (DHA) to ensure metabolic similarity with human milk. Both fatty acids are provided in U.S. commercial infant formulas and are viewed as very important constituents of infant formula. However, there is currently no source of ARA that has been permitted by the FDA for use in infant formula that does not use hexane extraction.

If the NOSB's recommendation is carried out and current forms of ARA are no longer allowed for use in organic infant formulas, an alternative form of ARA will need to be petitioned and allowed for use. Infant formulas are a unique food and are often a sole-source of nutrition for a very vulnerable segment of the population. Therefore, infant formula manufacturers would need appropriate time to ensure any new substance is Generally Recognized as Safe for infant formula use, reformulate, develop shelf life data and prepare and submit an Infant Formula Notification to FDA as required by the U.S. Infant Formula Act, a process that could result in the elimination of organic infant formula from the market.

Therefore, we strongly urge the NOSB to reconsider its October 2011 recommendation to prohibit the use of substances that are derived using hexane extraction.

In closing IFC strongly supports the listing of choline and inositol in the Code of Federal Regulations, Title 7, Part 205, under Sections 205.605(b), and the relisting of carrageenan on 205.605(a). These ingredients should be approved for products labeled "organic" and "made with organic." We also urge the NOSB to reconsider its October 2011 recommendation regarding the use of hexane extraction.

Thank you for the opportunity to comment, and please contact me with questions.

Sincerely,



Mardi K. Mountford, MPH
Executive Vice President