

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,



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Executive Vice President