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May 2, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

RE: Docket: AMS-NOP-12-0017
Handling Committee Choline Recommendation

Dear National Organic Standards Board Members:

Nestle Nutrition/GERBER Products Company (Gerber) is the leading manufacturer of foods specifically marketed and designed for infants and toddlers in the United States. We are also a leader in marketing organic foods to young children – launching our first organic line of organic baby foods in 1997 and working to support organic farmers across the U.S.

On April 18, 2011, Gerber requested choline be added to Section 205.605 of the National Organic Program's National List of Allowed and Prohibited Substances. On April 9, 2012, we received the Handling Committee proposal in response to our petition as well as another petition submitted by Balchem Corp.

Gerber supports the recommendation by the Handling Committee to permit the addition of choline to organic infant formulas. However, we were disappointed that the Committee recommendation did not also include the addition of choline to organic foods for adults and did not address the addition to foods specifically marketed and designed for infants and young children as requested in our petition.

Choline: an essential nutrient

Choline is an essential nutrient. In 1998, the Food and Nutrition Board of the Institute of Medicine (IOM) recognized choline as an essential nutrient and set Adequate Intake (AI) recommendations (IOM, 1997; Zeisel, 1991). While, the issuance of an AI is an indication that more research is needed to determine the mean and distribution of requirements, it in no way lessens that fact that the nutrient is necessary to support an adequate nutritional state, such as growth or development.

Other nutrients with adequate intake levels established by the IOM include:

Nutrient	Population Groups with AI
Calcium	Infants 0-12 months
Folate	Infants 0-12 months
Niacin	Infants 0-12 months
Pantothenic Acid	All population groups
Biotin	All population groups
Potassium	All populations groups

Choline is critical during pregnancy and early development

Choline is important for cell function and for muscle and memory function. Choline during pregnancy is important for optimal fetal development. Emerging research also suggests that adequate choline intake may be associated with lower risk of neural tube defects (Sanders and Zeisel, 2007). Because brain development continues for several years after birth, infant and toddler diets should also contain adequate levels of choline.

Choline Intakes are below Adequate Intakes

Prior to 2005, little data were available on choline intakes of the US population. Starting in 2005, the NHANES surveys have estimated choline intakes in the US population.

The most recent NHANES data reported by USDA, 2007-2008, show mean adult intakes of choline to be below the AI for both women and men. For women choline intakes are about 40% less than the AI (Chester et.al. 2011). This lack of choline in the diet of women is especially disturbing given the importance of choline during pregnancy.

Choline AI compared to Mean Intakes form NHANES 2007-8

Population group	AI	Mean Intake
Men 19 and older	550 mg/day	396 mg /day
Women 19 and older	425 mg/day	260 mg/day
Pregnancy	450 mg/day	

The Nestle Feeding Infants and Toddlers Study (FITS 2008) is the most comprehensive survey of the dietary intakes of infants and young children, with a sample size of over 3,000 children between the ages of 0 and 48 months (Briefel et. al. 2010). Data from FITS shows intakes of choline for infants less than 12 months of age are below the current AI established by the IOM – with over 50% of children between 0 and 12 months below the adequate intake level. Over 76% of children, 7-12 months of age, have choline intakes below the adequate intake level (FITS 2008, unpublished data).

Choline AI compared to Mean Intakes from FITS 2008

Age	Choline AI	Mean Intakes	Percent below AI
0-6 months	125 mg/day	108 mg/day	54%
7-12 months	150 mg/day	130 mg /day	76%
12-24 months	200 mg/day	185 mg/day	66%

Sources of Choline in the Diet

NHANES reports the major contributors of dietary choline include meat, poultry, and fish, grain based-mixed dishes, dairy and eggs (Chester et.al. 2011). From FITS 2008, the top food sources of choline for infants (7-12 months) include infant formula or breastmilk and infant cereal contributing 62% of total choline intake. All other food sources contribute less than 3% of choline intake. While eggs have choline, only 4% of children this age are consuming eggs on a given day (FITS 2008, unpublished data).

While we appreciate the Committee's suggestion that organic consumers should obtain their choline from dietary sources such as eggs and liver, this is not realistic. It is unlikely that consumers will change their dietary patterns without education or guidance. Guidance for consumers who are also vegan can be even more complicated since most major sources of choline (meat, poultry, eggs, and milk) are all animal derived.

The Committee also suggests that soy lecithin can be a source of choline in the diet. To achieve a meaningful amount of choline for an infant 7-12 months (10% of the 150 AI), about 5% soy lecithin would need to be added to a 100 g serving of pureed baby food or almost 30% would need to be added to a 15 g serving of infant cereal (typical level in infant cereal is 1%). Clearly these levels are not consistent with the level of soy lecithin typically added to foods nor are they practical from a food processing view.

Vitamins & Minerals: 21 CFR 101.9

In January 2012, the NOP proposed to revise the National List to read "Vitamins and minerals. For food – vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula – vitamins and minerals as required by 21 CFR 107.100 or 107.10". This proposal would narrow the number of potential nutrients or dietary ingredients that could be added to organic foods.

Choline is not currently listed in 21 CFR 101.9. With some exceptions, the nutrients listed in this section are based on the 1968 Recommended Dietary Allowances. In 1995, FDA established Reference Daily Intakes for vitamin K, selenium, manganese, chromium, molybdenum, and chloride based on the 1989 Recommended Dietary Allowances. While the 1989 Recommended Dietary Allowances did discuss choline, at that time, choline had not been determined to be essential for humans.

To a large extent nutrients listed in 21 CFR 101.9 are based on science that is more than 40 years old; even the nutrients added by FDA in 1995 are now based on a scientific review that is over 20 years old.

Through the National List, the NOSB has the ability to reflect scientific advances in nutrition knowledge and allow organic foods to provide these to consumers.

In 2008, FDA published an Advanced Notice of Proposed Rulemaking requesting comments on revisions to the RDIs and DRIs in light of the updated IOM reports on Dietary Reference Intakes. FDA is in the process of evaluating comments and no proposal rule has been issued. We would recommend that the NOSB request FDA's opinion on timing for the proposed rule and whether they intend to propose a RDI for choline.

Choline should not be a Compromise

The recommendation of the Handling Committee to allow choline only for "made with" organic foods forces the organic consumer to compromise their desire for organic foods if they want the additional insurance of adequate choline intakes that fortified foods provide. Consumers of organic products should have the option to be able to choose foods with this important nutrient. This is especially important in light of the potential benefits of choline during pregnancy and early development and the low intakes reported by both NHANES and FITS.

We urge the NOSB to carefully consider the request to include choline in the National List as an essential nutrient appropriate for addition to all organic foods consistent with the development of a fortification rationale (21 CFR 104.20).

Thank you for the opportunity to comment.

Regards,

Cheryl A. Callen
Director Regulatory Affairs
Nestlé Infant Nutrition

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Chester DN, Goldman JD, Ahuja JK, Moshfegh AJ. *Dietary Intakes of Choline: What We Eat in America, NHANES 2007-2008*. Food Surveys Research Group Dietary Data Brief No 9. October 2011. Available at: http://ars.usda.gov/Services/docs.htm?docid=19476

Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Thiamine, Riboflavin, Niacin, Vitamin B6, Folate, Pantothenic Acid, Biotin, and Choline. *National Academy Press*, Washington, DC 1997; 390-422

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Zeisel SH, daCosta Ka, Franklin PD, Alexander EA, Lamont JT, Sheard NF, Beiser A. 1991. Choline, an essential nutrient for humans. *FASEB J* 5:2093-2098.