Richard C Theuer

April 24, 2012

National Organic Standards Board
c/o USDA–AMS–NOP
Washington, DC 20250–0268

Re: Materials Committee Recommendation on the Petitioned Substance Choline

NOSB Members:

The recommended annotation that the Handling Committee is bringing to the full Board is:

1. to add Choline to the National List 205.605(b) for use in infant formula labeled organic or made with organic (specified ingredients or food group(s)).
2. to add Choline to the National List 205.605(b) for use only in agricultural products other than infant formula labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".

This recommendation of the Handling Committee apparently is based on the conclusion in their document "Petitioned Material Proposal Choline," dated March 20, 2012, that "The substance is deemed essential in infant formula by regulating authorities but the NOSB committee does not feel it is essential to supplement it for adults."

The Handling Committee document misleadingly states that "Choline has been petitioned for addition to adult food items." However, at least one of the choline petitions deals with choline addition to infant foods other than infant formula. Moreover, scientific information published by the USDA documents the need for supplementary choline by children other than infants. The Handling Committee's proposed annotation is far from a surgical strike at restricting choline addition to organic foods for adults; it's a shotgun blast that blows away the possibility of choline fortification of organic foods for pre-school and school-age children. If implemented, this food policy would have an adverse effect on the nutritional health of children seeking processed foods labeled as "organic" to satisfy their nutritional needs.

I am stimulated to enter this comment after reading a recent editorial by Dr. Roger Clemens, the President of the Institute of Food Technologists, in the April 2012 issue of the journal Food Technology (page 11), entitled "Advancing the Well-being of Children and Adults." The relevant passage of his article reads as follows:

> *"As you are well aware, policymakers recently revamped the National School Lunch and School Breakfast Programs to limit or eliminate certain foods such as potatoes and whole milk from children's mealtime choices. While this strategy may be well intended, it may have unintended consequences that we as food professionals need to be aware of as we respond to policy decisions. For example, potatoes have dietary fiber and more potassium than bananas. The primary sources of choline and vitamin D in the diet are eggs and milk – which are high in saturated fat and cholesterol – and under the guidelines should be limited. If children skip or limit eggs and milk to avoid saturated fat, they could end up with deficient levels of choline and vitamin D. In fact,* ***the National***

> ***Health and Nutrition Examination Survey (NHANES) data indicate intake of these nutrients is inadequate within this high-risk population.****"*(emphasis added)

In October 2011, the Agricultural Research Service of USDA published a report entitled "Dietary Intakes of Choline: What We Eat in America, NHANES 2007-2008." A pdf copy is attached. Figure 3 of this report shows the **mean** daily choline intake of children and adults, by sex, age, race and ethnicity. Mean intakes for boys 6 to 11 years hover around 250 mg/day; those for girls hover around 200 mg/day. The mean intakes of girls 12 to 19 years of age are just a little over 200 mg/day.

In 2000, the Institute of Medicine of the National Academies established Advisable Intakes (AI[1]) for choline[2] of 250 mg/day for boys and girls 4 to 8 years of age and 375 mg for boys and girls 9 to 13 years of age. Given that the mean intake of boys 6 to 11 years of age is about 250 mg/day, maybe about half of them are getting the AI. The situation is even worse for young girls 6 to 11, with a mean intake around 200 mg/day and an AI of either 250 mg/day or 375 mg/day at these ages. Girls 14 to 18 years of age have an AI of 400 mg/day, against a mean intake a little over 200 mg/day for girls 12 to 19, about 50% of the AI. A fair summary of these data is that many American children are receiving far less than the advisable intake of choline!

It is relevant that the periodic NHANES assessment of the nation's nutritional status is a USDA activity. It also is relevant that the Agricultural Research Service that published these choline intake data is a USDA entity. If the NOSB adopts the recommended annotation of the Handling Committee, the Secretary is in an unenviable position, given the Department's laudatory effort to make the public aware of the tenuous choline nutritional status of America's children. Implementing the Handling Committee's recommendation would permit continued marketing of organic infant formulas for the betterment of infants, but it would deprive children of the opportunity to partake of foods labeled as "organic" that are fortified with choline.

Finally, I question the Handling Committee's scientific expertise when I read in the March 20 document that ". . . the NOSB committee does not feel it is essential to supplement it (choline) for adults."

The ARS document notes, on page 1, "For individuals 20 years of age and older, estimated mean daily intake of choline was 396 mg for males and 260 mg for females." The Dietary Reference Intakes for choline established by the Institute of Medicine of the National Academies states (page 404): "The AI for choline in all forms for men in all age groups is 550 mg and for women is 425 mg." Thus adult American men consume on average only 72% of their Advisable Intake and adult American women consume on average only 61% of their Advisable Intake.

The Federal Register of Thursday, January 12, 2012, [77FR1982] has the following statement: "The NOSB Handling Committee recommended that the listing (for nutrient vitamins and

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[1] An Advisable Intake is "a recommended daily intake value based on observed or experimentally determined approximations of nutrient intake by a group or groups of healthy people that are assumed to adequate (when a Recommended Dietary Allowance cannot be determined)."

[2] Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline http://www.nap.edu/catalog/6015.html . Chapter 12, pages 390 ff. Pdf file attached.

minerals) be renewed as follows: § 205.605(b): Nutrient Vitamins and Minerals, restricted to materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods including infant formula, and ***materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies***." Thus, three months ago, the Federal Register reported that the Handling Committee acknowledged the authority of the IOM, which, in the case of choline, used as its "primary criterion . . . to estimate the Adequate Intake (AI) for choline . . . the prevention of liver damage as assessed by measuring serum alanine aminotransferase levels." What science justifies why "the NOSB (Handling) committee does not feel it is essential to supplement it (choline) for adults"? Absent some science, there is no reason for the recommended annotation that restricts the addition of choline in non-infant formula products labeled as "organic."

I hope that these comments are useful for the Board.

Sincerely,

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NOSB Member; Chair, Processing, Handling and Labeling Committee 1992-1995
Member, American Society for Nutrition, 1971-current
Member, Technical Advisory Group, Committee on Nutrition, American Academy of Pediatrics 1984-1995
Member, Institute of Food Technologists, 1994 - current