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May 1, 2012

National Organic Standards Board
Spring 2012 Meeting
Albuquerque, NM

**Re. Comments on Handling Materials**

Dear Board Members:

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

## I. Petitioned Materials

Comments on curry leaves and Kaffir lime (*Citrus hystrix*) leaves will be submitted separately.

### A. Choline

#### 1. Is there a need?

The Handling Committee has divided its recommendation into separate listing motions for infant formula and agricultural products other than infant formula. Regarding infant formula, the Committee appears to base its determination of essentiality on the FDA requirement establishing minimum levels of choline in non-milk infant formulas. Does this requirement actually necessitate supplementation with a synthetic form of choline? The Technical Evaluation Report (TR) states (lines 125-127), "Lecithin (a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol) is a direct food substance affirmed as GRAS by FDA with no limitation other than good manufacturing practice (21 CFR 184.1400)." Lecithin is available in both organic and nonorganic forms for supplementing foods. In addition, we question whether all non-milk infant formulas need supplementing with any form of choline. An online nutritional analysis of unfortified soymilk[1] states that a 131 calorie portion contains 57.3 mg choline, which works out to 43.7 mg per 100 calories, and the minimum FDA requires, according to the TR, is 7 mg/100 calories (kcal). We therefore request that the committee take a closer look at the need for supplementation and the availability of natural choline if supplementation should prove to be necessary.

[1] http://nutritiondata.self.com/facts/legumes-and-legume-products/4387/2

Furthermore, there is no explanation in the Handling Committee's recommendation regarding why the FDA's requirement for choline in non-milk infant formula should also justify its allowance in milk-based infant formulas labeled as "organic" or "made with…"

The Handling Committee further states 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." Despite this determination that choline is not essential for the petitioned uses in agricultural products other than infant formula, the Committee recommends allowing it in the "made with organic…" category. This is an unnecessary addition of a synthetic material and is not justified, given the TR statement (60), "Choline compounds are widely distributed in common foods…"

### 2. What are the human health and ecological impacts?

The TR does not identify any recognizable, adverse human health impacts for natural choline, but there are several materials and processes involved in the production of choline that would raise concerns about the cradle to grave impacts of using the material. For example, the TR states (439-443):

> The organic compound 1,4-dioxane has been classified as 'possibly carcinogenic to humans' by the World Health Organization's International Agency for Research on Cancer (IARC, 1999). It may be present in choline salts due to the use of ethylene oxide in the manufacturing process (The Sapphire Group, 2007).

1,4-dioxane is on the Proposition 65 list of chemicals known to the state of California to cause cancer or reproductive toxicity and is the subject of a consumer movement to remove it from consumer products, including Tide detergent.[2]

The TR states (475-476), "The manufacture of choline salts may result in the release of trimethylamine and/or ethylene oxide to the environment (HSDB, 2009a)." Both trimethylamine and ethylene oxide are recognized as hazardous air pollutants with potentially serious health effects, particularly to workers who might be exposed to higher concentrations.[3]

In addition, choline bitartrate, which is used in preference to choline chloride in powdered infant formulas, is associated with "harmful effects in laboratory rats associated ingesting the chemical manufactured using the synthetic form of tartaric acid (DL-tartaric acid)." (445-446) "It was believed that the kidney and bladder stones were caused by either the synthetic tartaric acid itself or by a toxic contaminant present at trace levels in the choline bitartrate that had

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[2] Andrew Martin, 2012. Mothers Challenge a Trace Contaminant in Tide, N.Y. Times, April 23, 2012. http://green.blogs.nytimes.com/2012/04/23/mothers-challenge-trace-ingredient-in-detergent/

[3] EPA Air Toxics website. http://www.epa.gov/ttn/atw/hlthef/ethylene.html and http://www.epa.gov/ttn/atw/hlthef/tri-lami.html .

been introduced into the product at some step in the process, possibly during the synthesis of DL-tartaric acid (Klurfeld, 2002)." (451-454)

We also have concerns about the addition of materials to the petitioned substance that would result in a formulated product containing "other ingredients." The Balchem petition says (p. 9):

> The choline salts are first chemically synthesized in water (or other solvent) using pure chemical feedstocks, including amine-based compounds, and acids. The resultant solutions are then filtered to remove extraneous matter. This step is followed by removal of solvent, and a final drying step, yielding a powder-granular product. A conditioning aid may be added to facilitate powder flow. Material then goes through quality checks, is packaged, and released for shipment.

### 3. Is it consistent with principles or organic production and handling?

When asked if the substance is compatible with organic handling (25.600b.2), the Handling Committee responds "no." When asked if the substance is consistent with organic farming and handling based on the OFPA, the Handling Committee again answers "no." There is no documentation provided or statement in the narrative description of its decision to explain why a substance that is not compatible with organic handling should be allowed.

The addition of an unnecessary synthetic ingredient to organic food is not compatible with consumer expectations of organic food.

### 4. Conclusion

The Handling Committee has not shown a need for synthetic choline to be added to the National List. The manufacture requires nonrenewable feedstocks, may release toxic air pollutants, and may result in a formulated product containing toxic chemical residues in the synthetic choline. Therefore, we urge the board to reject the recommendation to list synthetic choline for use in infant formulas.

## B. Inositol

### 1. Is there a need?

The Handling Committee has divided its recommendation into separate listing motions for infant formula and agricultural products other than infant formula. Regarding infant formula, the Committee appears to base its determination of essentiality on the FDA requirement establishing minimum levels of inositol in non-milk infant formulas. According to the Technical Evaluation Report (102-106),

> Non-milk-based infant formulas for sale in the U.S. must contain at least 4 mg inositol per 100 kilocalories to use a nutrient content claim (21 CFR 107.100(a)); however there is no maximum level prescribed in this regulation. The formula label must list the

amount of inositol in milligrams per 100 kilocalories of formula, except when it is not added to milk-based formulas (21 CFR 107.10).

Supplementation is only necessary if the formula does not contain adequate inositol without supplementation. Has the committee determined that the non-milk formulas would be deficient in inositol without supplementation. As stated in the TR for choline (lines 125-127), "Lecithin (a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol) is a direct food substance affirmed as GRAS by FDA with no limitation other than good manufacturing practice (21 CFR 184.1400)." Lecithin is available in both organic and nonorganic forms for supplementing foods. Thus, even if the formula does require supplementation, a natural form is available.

There is no explanation in the Handling Committee's recommendation why the FDA's requirement for inositol in non-milk infant formula should also justify its allowance in milk-based infant formulas labeled as "organic" or "made with…" The Handling Committee also recommends without justification allowing it in the "made with organic…" category for use in agricultural products other than infant formula.

**2. What are the human health and ecological impacts?**

Although the TR does not point out any hazards to human health or the environment from the manufacture of synthetic inositol, the three commercially practical procedures for isolating inositol from corn or rice steep liquor involve hazardous materials including sulfurous acid, hydrochloric acid, sulfuric acid, ammonium salts, and barium. (TR lines 268-311) While there is a yeast-based process that still results in a synthetic inositol, the TR states that there do not appear to be any sources of inositol produced this way.

**3. Is it consistent with principles of organic production and handling?**

Addition of an unnecessary synthetic ingredient to organic food is not compatible with consumer expectations of organic food.

**4. Conclusion**

The Handling Committee has not shown a need for synthetic inositol to be added to the National List. Therefore, we urge the board to reject the recommendation to list synthetic inositol for use in infant formulas.

## C. Gibberellic Acid

**1. Is there a need?**

The Technical Evaluation Report (TR) for gibberellic acid (GA) does not establish a need for GA in bananas or any other fruit. In fact, we note that the question, "Is there another practice that would make the substance unnecessary?," was not addressed in the TR, as required for review.