

March 29, 2017

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

Re. HS: L-Methionine petitioned for organic pediatric enteral formula

These comments to the National Organic Standards Board (NOSB) on its Spring 2017 agenda are submitted on behalf of 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, Beyond Pesticides 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 the world.

L-methionine has been petitioned for addition to organic pediatric enteral soy formulas. There are two issues raised by this petition:

- The use of synthetic macronutrients (e.g., protein—amino acids) in organic food;
- The construction of "organic pediatric enteral formula" from synthetic materials, including isolated soy protein;

Synthetic macronutrients (for example, amino acids, which are building blocks of protein) should not be added to organic foods.

Organic food produces high quality nutrition through building healthy soils that support healthy plants and animals. Food in which major nutrients like protein are supplied by nonorganic or synthetic sources does not satisfy the expectations of consumers regarding the authenticity and integrity of organic products. For this reason, amino acids petitioned for addition to organic pediatric enteral formula do not meet the criterion of being compatible with organic principles.

The construction of "organic" soy pediatric enteral formula from largely synthetic materials, including isolated soy protein, is incompatible with organic principles.

There was a time when soy formula was made from whole soybeans. According to the American Academy of Pediatrics Committee on Nutrition,

Before the 1960s, soy protein-based formulas used soy flour, which imparted a tan color and nutty odor to the formula, and infants consuming it often had diarrhea and excessive intestinal gas. These features and symptoms were attributed to residual indigestible carbohydrates in the soy. Since the mid-1960s, a soy protein isolate has been used, reducing these concerns and greatly increasing acceptance of the product.

Formulas based on isolated soy protein lack some of the amino acids found in human milk and cow's milk, as well as some of the other nutrients removed in the extraction process. Insofar as the NOSB has acted on isolated soy protein, it has proceeded on the assumption — based on the unanimous opinion of three TAP reviewers— that isolated soy protein is synthetic.

The NOSB considered a petition to list isolated soy protein for use as a crop input in the spring of 2004. The TAP reviewers found the material to be synthetic. The Crops Committee voted that soy protein isolate is synthetic, and therefore not permissible as a fertilizer. At the NOSB meeting in April 2004, the board decided to reject the TAP review and defer consideration of soy protein isolate because the TAP review focused on food use and did not deal with the use in the soil, and also did not address its manufacture adequately.

The NOSB apparently has not resolved the status of isolated soy protein since that meeting. Until the NOSB can resolve issues surrounding isolated soy protein, we believe it would be improper to base other materials decisions on the need to supplement a formula — truly a chemical formula — based on a material that is at least highly refined, possibly extracted with hexane or other volatile synthetic extractants, and probably falling under the NOSB's definition of synthetic.

Thus, we believe that infant and pediatric enteral formulas (and the synthetic and nonorganic additives that make them possible) do not meet the compatibility criterion for listing materials on the National List for use in products labeled "organic" or "100% organic." For those cases in which such a formula is necessary, we do support high quality formula labeled "made with organic soy."

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D. Board of Directors

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¹ AAP, 1998. Soy-Protein-Based Formulas: Recommendations for Use in Infant Feeding, *Pediatrics* 101 (1): 148-153. Updated version is: AAP, 2008. Use of Soy-Based Formulas in Infant Feeding, *Pediatrics* 121(5): 1062-1068. http://pediatrics.aappublications.org/content/121/5/1062.full.html.