



BEYOND PESTICIDES

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National Organic Standards Board
Fall 2012 Meeting
Providence, RI

Re. HS: Materials petitioned for organic infant formula

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.

The following synthetic substances were petitioned for listing on §205.605(b) for addition to organic infant formula:

Petitioned material	Milk/soy formula	Recommended by HS?	Preservative?	Required?
Ascorbyl palmitate	Both	No (0-6-1)	Yes	No
Beta carotene	Both	No (0-5-2)	Yes	No
Lutein	Both	No (3-4-0)	No	No
Lycopene	Both	No (0-5-2)	No	No
L-carnitine	Soy	No (2-3-1)	No	No
L-methionine	Soy	Yes (6-0-1)	No	Protein quality
Nucleotides	Both	Yes (4-3-0)	No	No
Taurine	Both	No (0-4-3)	No	No

We oppose the addition of any of these synthetic substances to organic infant formula. There are five cross-cutting issues raised by these petitions:

1. The use of synthetic macronutrients (eg, protein—amino acids) in organic food, specifically organic infant formula;
2. The use of synthetic antioxidants as preservatives in organic food, specifically organic infant formula;
3. The construction of “organic infant formula” from synthetic materials, including isolated soy protein;

4. Over fortification of infant formula must be avoided; and
5. We should all be concerned about whether the label “organic” attached to infant formula might encourage some mothers not to breastfeed or to breastfeed less than they might otherwise.

1. 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, the amino acids petitioned for addition to organic infant formula do not meet the criterion of being compatible with organic principles.

2. Synthetic antioxidants must not be used as preservatives in organic foods.

§205.600(b)(4) establishes as a criterion for addition of a synthetic material in processing, “The substance’s primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law.” The petitioned use of ascorbyl palmitate and beta carotene is as an antioxidant to preserve the quality of polyunsaturated fatty acids, and therefore these materials do not meet the criteria for listing.

3. The construction of “organic” soy infant formula from largely synthetic materials, including isolated soy protein, is totally incompatible with organic principles.

There was a time when soy infant formula was made from whole soybeans. According to the American Academy of Pediatrics Committee on Nutrition,¹

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.^{4,5} 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. The Handling Subcommittee’s recommendation on L-Methionine states, “If L-Methionine is not added to soy formula there would be no organic soy based formula.”

The larger problem, however, is that 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

¹ AAP, 1998. Soy-Protein-Based Formulas: Recommendations for Use in Infant Feeding, *Pediatrics* 101 (1): 148-153.

soy protein isolate is synthetic, and therefore not permissible as a fertilizer. However, 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 the manufacture adequately.

The NOSB apparently has not addressed the status of isolated soy protein since that meeting. Apparently, some certifiers have found isolated soy protein from organic soybeans to be not only nonsynthetic, but also organic, and we wonder what their justification is, given this history.

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, probably extracted with hexane or other volatile synthetic extractants, and probably fitting the NOSB's definition of synthetic.

4. Avoid over-fortification of infant formulas.

While it may seem harmless to add more nutrients to infant formula based on reputed benefits, infants do not have the ability to process excess nutrients through excretion as well as adults. An International Expert Group of the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) warns,

The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on metabolic and other physiologic functions of the infant. Those components taken in the diet, which are not utilized or stored by the body, have to be excreted, often as solutes in the urine. Since water available to form urine is limited and the infant's ability to concentrate urine is not fully developed during the first months of life, the need to excrete any additional solutes will reduce the margin of safety, especially under conditions of stress, such as fever, diarrhea or during weight loss.²

Therefore, we urge you not to permit fortification of organic infant formulas with synthetic or nonorganic nutrients that are not required by law.

5. Support breastfeeding.

According to Stuebe and Schwartz, writing in the *Journal of Perinatology*,³

Health outcomes differ substantially for mothers and infants who formula-feed, compared with those who breast-feed, even in wealthy countries such as the United States. Unfortunately, rates of breast-feeding in the United States continue to fall short of the World Health Organization's recommendations that children are breast-fed for their first 2 years of life. The American Academy of Pediatrics and the American Academy of Family Physicians recommend exclusive breast-feeding for the first 6

² Koletzko B, Baker S, Cleghorn G, et al. Global standard for the composition of infant formula. Recommendations of an ESPGHAN coordinated International Expert Group. *JPGN* 2005.

³ AM Stuebe and EB Schwartz, 2010. The risks and benefits of infant feeding practices for women and their children, *Journal of Perinatology* 2010 Mar;30(3):155-62.

months of life, continuing at least through the infant's first birthday, and as long thereafter as is mutually desired. In the United States, in 2005, only 74% of the United States infants were breast-fed at least once after delivery, only 32% were exclusively breast-fed at 3 months of age, and just 12% were exclusively breast-fed at 6 months of age.

The American Academy of Pediatrics stated in the 2012 update to its policy on breastfeeding:⁴ Research and practice in the 5 years since publication of the last AAP policy statement have reinforced the conclusion that breastfeeding and the use of human milk confer unique nutritional and nonnutritional benefits to the infant and the mother and, in turn, optimize infant, child, and adult health as well as child growth and development. Recently, published evidence-based studies have confirmed and quantitated the risks of not breastfeeding. Thus, infant feeding should not be considered as a lifestyle choice but rather as a basic health issue.

The policy paper also states, "Medical contraindications to breastfeeding are rare." Both of the above papers stress the fact that feeding infant formula instead of breastfeeding causes adverse health effects for both mother and child. Thus, we believe that infant formula (and the synthetic and nonorganic additives that make it possible) do not meet the health effects criterion for listing materials on the National List for use in products labeled "organic" or "100% organic." For those rare cases in which it is necessary to have an alternative to breast milk, we do support high quality formula labeled "made with organic milk."

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

⁴ AAP Section on Breastfeeding, 2012. Policy Statement: Breastfeeding and the Use of Human Milk, Pediatrics 129 (3): e827-e841. <http://pediatrics.aappublications.org/content/129/3/e827>