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: Nutrient Vitamins and Minerals Discussion Document  

These comments to the National Organic Standards Board (NOSB) on its Spring 2016 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.

We appreciate the efforts of the Handling Subcommittee (HS) in untangling the mess that has come from mistaken implementation of past NOSB recommendations. We agree –for the most part– with option 1. However, we believe that although nonsynthetic vitamins and minerals required by law should be allowed in food, those described in annotation #3 (for food, those identified as essential in 21 CFR 101.9; for infant formula, as required by 21 CFR 107.100 or § 107.10) should be allowed only in products labeled “made with organic.”

Option 1 is complicated.  
We would like to clarify what we understand is the sum of the annotations #1, 2, and 3 of Option 1. Taken altogether, we understand that Option 1 allows the following:  

**In food labeled "organic":** Synthetic vitamins, minerals, and other isolated nutrients only when their use is required by law or to meet an FDA standard of identity in which they are incorporated. Nonsynthetic minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9.

**In food labeled "made with organic":** Synthetic or nonsynthetic vitamins, minerals, and other isolated nutrients when their use is required by law or to meet an FDA standard of identity in which they are incorporated, or identified as essential in 21 CFR 101.9.  

**In infant formula labeled "organic":** No synthetic vitamins, minerals, or other isolated nutrients may be added. Nonsynthetic vitamins and minerals as required by 21 CFR
In infant formula labeled "made with organic": Synthetic or nonsynthetic vitamins and minerals as required by 21 CFR 107.100 or § 107.10.

Option 2 would allow everything allowed in Option 1 for made with organic, for both organic and made with organic.

We Support an Amended Option 1
We suggest that the following be allowed:

**In food labeled "organic":** Synthetic and nonsynthetic vitamins, minerals, and other isolated nutrients only when their use is required by law or to meet an FDA standard of identity in which they are incorporated.

**In food labeled "made with organic":** Synthetic and nonsynthetic vitamins, minerals, and other isolated nutrients when their use is required by law or to meet an FDA standard of identity in which they are incorporated, or identified as essential in 21 CFR 101.9. [Unchanged.]

**In infant formula labeled "organic":** No synthetic or nonsynthetic vitamins, minerals, or other isolated nutrients may be added.

**In infant formula labeled "made with organic":** Synthetic and nonsynthetic vitamins and minerals as required by 21 CFR 107.100 or § 107.10. [Unchanged.]

Vitamins and Minerals in Food
Our reasoning mostly echoes that of the HS. Proposed Annotation #1. To allow in food labeled “organic” synthetic or nonsynthetic minerals (including trace elements), vitamins and similar isolated ingredients only when their use is required by law or to meet an FDA standard of identity in which they are incorporated best meets the expectations of organic consumers and original NOSB intent. The Technical Review that spells out legal requirements is essential to the understanding of the proposal.

We agree with those members of the HS who say that the allowance of supplementation with other vitamins and minerals viewed as “essential” is an appropriate use of the “made with organic” label. Organic consumers expect that their food contains a full complement of vitamins and minerals based on organic agricultural production practices, not supplementation. Applying the same rule to added synthetic and nonsynthetic vitamins would also simplify the ACA’s determination of whether the formulation is appropriate to the label.

Vitamins and Minerals in Infant Formula
It appears that Option 1 would probably not allow any infant formula to be labeled “organic,” given the requirements of 21 CFR 107.100 and the difficulty of sourcing nonsynthetic forms of
some vitamins and minerals.\textsuperscript{1} Thus, adding a further restriction that allows nonsynthetic forms only in foods and formulas labeled “made with organic” would not have a greater impact on organic infant formula.

Unlike other foods, infant formula is known to be an imitation product. Making formulas for infant feeding has required attempts to make cow’s milk more like breast milk and adding nutrients that are not optimal or sufficient. So it is a very complex problem and difficult to reconcile with organic principles. Although formula manufacturers have generally been responsible in improving formulas, they have promoted formula feeding, often in a not responsible fashion, which has caused consistent tension between them and the pediatric community and other advocates of breastfeeding who stress that “breast is best.” This is compounded and conflicted by the enormous monies contributed by formula manufacturers to the American Academy of Pediatric academic institutions and other pediatric groups by the formula manufacturers.

Therefore, the principle that we cite above of consistency with consumer expectations that organic food will derive its nutrients from organic agricultural processes does not necessarily apply in the case of infant formula. An argument can be made for allowing supplementation by vitamins and minerals required by 21 CFR 107.100 because infant formula is by its nature artificial. On the other hand, it does not seem right to allow substances in organic infant formula that are not allowed in other organic foods.

The result of either option 1 or option 1 combined with the restriction on nonsynthetic vitamins and minerals required by 21 CFR 107.100 or § 107.10 would be that the top-of-the-line infant formula would be labeled “made with organic” rather than “organic.” This is actually a positive result because it would remove or reduce an incentive against breastfeeding.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

\textsuperscript{1} 2015 TR, lines 442-459.