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September 19, 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: Nutrient Vitamins and Minerals Annotation Change

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

After producing a discussion document with different options for public comment in Spring 2016, the Handling Subcommittee (HS) has apparently let drop the issue of changing the annotation for nutrient vitamins and minerals. As stated by the HS, "It has been acknowledged that it [the annotation] needs to change since the Federal Rule first came out." Lacking a specific proposal, we resubmit our comments of Spring 2016 and urge the HS to complete work on this important issue.

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 the nonsynthetic vitamins and minerals described in annotation #3 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 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. Nonsynthetic minerals (including trace elements) and vitamins 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 107.100 or § 107.10.

In infant formula labeled "made with organic": vitamins and minerals as required by 21 CFR 107.100 or § 107.10. 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.

Vitamins and Minerals in Food

Our reasoning mostly echoes that of the HS. Proposed Annotation #1 (§205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed 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 other uses of synthetic vitamins and minerals viewed as essential is an appropriate use of the “made with organic” label. However, we would also apply that reasoning to nonsynthetic vitamins and minerals. 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 Accredited Certifiers Association’s (ACA) 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.¹ Thus, only allowing nonsynthetic forms in foods and formulas labeled “made with organic” would not have a greater impact on organic infant formula.

¹ 2015 TR, lines 442-459.

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 question and difficult to reconcile with "organic" principles. Though formula manufacturers have generally been responsible in improving formulas, they have promoted formula feeding, often in an irresponsible fashion, which has caused consistent tension between them and the pediatric community and other advocates of breast feeding who stress that "breast is best." This is compounded and conflicted by the enormous monies contributed by formula manufacturers to the American Academy of Pediatrics, academic institutions, and other pediatric groups by the formula manufacturers.

Therefore, the principle, which 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 is inconsistent to allow substances in organic infant formula that are not allowed in other organic foods.

The effect of adopting option 1 or option 1 combined with the restriction that allows nonsynthetic vitamins and minerals required by 21 CFR 107.100 or § 107.10 will be infant formula labeled as "made with organic" rather than "organic." This is actually a positive result because it may remove or reduce an incentive against breastfeeding.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors