



April 14, 2016

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-15-0085

RE: Handling Subcommittee – Nutrient Vitamins and Minerals Annotation Change (Discussion)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Discussion Document on changing the annotation on the listing for Nutrient Vitamins and Minerals.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Handling Subcommittee is requesting feedback on two options for revising the current annotation on the listing of Nutrient Vitamins and Minerals:

Option #1:

- Allow vitamins and minerals for food only when they are required by law to meet an FDA standard of identity;
- Allow vitamins and minerals for food as essential in 21 CFR 101.9 and for infant formula as required by 21 CFR 107.100 or 107.10 ONLY in products labeled "MADE WITH ORGANIC;" and
- Add a listing to the non-synthetic section of the National List (205.605(a)) as follows: Vitamins and minerals, non-synthetic. For food as essential in 21 CFR 101.9 and for infant formula as required by 21 CFR 107.100 or 107.10 for use in agricultural products labeled as organic.

Option #2

- Allow vitamins and minerals for food as essential in 21 CFR 101.9 and for infant formula as required by 21 CFR 107.100 or 107.10 in "ORGANIC" and "MADE WITH ORGANIC" products.

Summary of OTA's Position

OTA agrees that the current annotation on the listing of nutrient vitamins and minerals ("when used in accordance with 21 CFR 104.20") is problematic because it is difficult to navigate and does not include several of the nutrient vitamins and minerals that were reviewed and approved by NOSB in 1995. It also does not contain several of the essential vitamins and minerals required in food products today. Based on extensive research and dialogue with 1995 NOSB members, OTA believes the option that most accurately captures the intent of the 1995 Recommendation is Option #2.

First and foremost, OTA would like to see the National Organic Program (NOP) complete rulemaking on this exact topic because considerable time and stakeholder energy went into a two-year process that led to a 2012 proposed rule that has yet to be finalized. The proposed rule was largely based on NOSB discussions and feedback received from the public on the Handling Subcommittee's March 2011 recommendation. We recognize that NOSB opted to remove proposing a subsequent recommendation for an annotation change from its fall 2011 meeting agenda since NOP would be taking action to amend the listing through a proposed rule. Unfortunately, that process has not been completed, and businesses are left in a place of uncertainty. Revisiting the annotation at the NOSB level appears to be a duplicative effort when NOP's resources are best spent on finalizing a rule. We hope NOSB's decision to revisit this topic will effectively provide NOP with additional comments allowing the agency to move forward.

With respect to an annotation change, OTA **continues** to support a listing for Nutrient Vitamins and Minerals that is certifiable, enforceable and captures the intent of the 1995 NOSB recommendation. Consistent with OTA's comments to NOSB in 2011 and to NOP in 2012, we suggest the following annotation, which is essentially a shorter (more concise) version of the annotation presented in Option #2 of the Discussion Document:

Vitamins and minerals identified as essential in 21 CFR 101.9, or as required for infant formula by 21 CFR § 107.100 or 107.10

The allowance of vitamins and minerals, with this revised annotation, should continue to be listed under the National List (7 CFR 205.605) heading for "nonagricultural substances that are allowed in or on products labeled as 'organic' or 'made with organic.'"

OTA's preferred annotation is concise, supports consumer preference, and references three distinct lists of essential nutrients found in the FDA Code of Federal Regulations. Together, the references comprise a complete and updated list of the vitamins and minerals FDA considers essential in food and infant formula and reflects the vitamins and minerals enumerated in NOSB's 1995 review. Any other nutrient allowed in NOP certified products would need to be petitioned to the National List. OTA supports this approach because it's consistent with the intent of NOSB's 1995 recommendation on nutrient supplementation of organic foods, and it will delineate the exact vitamins and minerals that may be allowed in NOP certified products. This will result in a more certifiable and enforceable regulation.

We offer the following more detailed comments:

OTA has spent a considerable amount of time reviewing the 1995 recommendation on "The Use of Nutrient Supplementation in Organic Foods," the 1995 Austin, Texas, Meeting Transcripts, the 1995 Technical Advisory Panel (TAP) reviews on vitamins and minerals, and the various Code of Federal Regulations governing nutrients allowed in foods, the most recent 2013 Technical Reports and NOP's

Proposed Rule of 2012. We have also engaged in extensive dialogue with our members, including the OTA Vitamin and Mineral Task Force, and with several 1995 NOSB members to understand the intentions of their recommendation. We believe we have good understanding of the history and offer an annotation that supports past NOSB decisions, consumer preference and the organic trade.

The research that we have done on this topic consistently leads us to our suggested annotation and the following key points central to our comments. OTA supports:

- The continued allowance of vitamins and minerals in NOP certified foods and the rational and safe addition of nutrients to foods to preserve a balance of nutrients in the consumer diet.
- The fortification of organic foods and the maximum freedom of choice for organic consumers.
- Organic products that are nutritionally equal to their conventional counterparts.
- The statutory authority of NOSB to review materials and develop the proposed National List. OTA understands that in 1995, NOSB endorsed the use of vitamins, minerals and accessory nutrients. However, prior to its final recommendation, NOSB had only conducted TAP reviews on vitamins and minerals. NOSB intended for any vitamin, mineral, or accessory nutrient not enumerated in the two TAP Reviews to be subject to the National List process.
- A listing and annotation that is certifiable and enforceable, specifically an annotation that supports the use of the vitamins and minerals allowed under 21 CFR 101.9 and 107.100.

The Intent of the 1995 Recommendation

At the NOSB meeting in October-November 1995, NOSB voted on two items related to this issue. It made a Final Board Recommendation for the National List regarding the Use of Nutrient Supplementation in Organic Foods (31 October 1995 minutes: Page 5, lines 160-169). The Board also voted to add the synthetic substances Nutrient Vitamins and Minerals to the Proposed National List with a specific annotation (an “exemption” within the meaning of the Act) (31 October 1995 minutes: Page 15, lines 488-493).

In its Final Board Recommendation on the Use of Nutrient Supplementation in Organic Foods, NOSB provided a definition of the term “Accessory Nutrients” to make it clear exactly to what it was referring. The NOSB definition is as follows: The term “accessory nutrients” means nutrients not specifically classified as a vitamin or mineral but found to promote optimal health. NOSB cited five examples of nutrients or nutrient groups that met the definition at that point (omega-3 fatty acids, inositol, choline, carnitine, and taurine).

Later that same day (October 31, 1995), NOSB voted to include on the National List Nutrient Vitamins and Minerals, two classes of synthetic substances—specifically enumerated Nutrient Vitamins and specifically enumerated Nutrients Minerals—that had been subjected to the National List process. NOSB included the following Annotation for Nutrient Vitamins and Minerals:

Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.

Instead of accepting the NOSB recommended annotation, the Program decided that the most appropriate reference was the FDA Nutritional Quality Guidelines for Foods found at 21 CFR 104.20.

Thus our listing in the current NOP regulations is:

Nutrient Vitamins and Minerals – when used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.

In our discussions with past NOSB members, and as expressed in the recorded minutes of the NOSB meeting, two central messages emerged:

1. NOSB was opposed to the helter-skelter addition of nutrients to organic foods but was determined to permit fortification in those instances where an independent professional organization deemed fortification was appropriate;
2. The will of NOSB was that vitamins and minerals, including accessory nutrients, not specifically enumerated in the two TAP Reviews are NOT exempt from the National List Process.

An Annotation that is Certifiable and Enforceable

OTA firmly believes that we need an annotation that includes CFR references that connect to a clear list of specific vitamins and minerals. Anything beyond the vitamins and minerals included in those lists must be petitioned individually. The annotation we suggest be adopted is consistent with the intent of NOSB and the vitamins and minerals that were specifically reviewed at that time. It definitively states which vitamins and minerals may be added to NOP certified food and infant formula. This should eliminate misinterpretation and uncertainty, and also provide Accredited Certifying Agents (ACAs) and NOP with language that is clear, certifiable and enforceable.

An annotation that references 21 CFR 101.9, 21 CFR 107.100 and 107.10 provides stakeholders with information that is easy to look up, easy to present, and is ultimately transparent to anyone who wants this information. This will allow organic operations to make confident business decisions and NOP to make consistent compliance decisions that, in turn, should allow consumers to feel confident about the organic products they are purchasing.

Advocating for use of Natural (Non-synthetic) Vitamins and Minerals

OTA does not believe that a listing for synthetic vitamins and minerals precludes the use of non-synthetic vitamins or minerals when they are available and compliant with the regulations. OTA continues to favor and advocate for the use of natural and organic alternatives over the use of synthetic. In the case of vitamins, and in support of the information contained in the Technical Review, there are some cases where the only form available of a non-synthetic vitamin is one that is produced through fermentation using a genetically modified organism. The certification process ensures that certified operators are only using **non-GMO** vitamins and minerals; therefore, the only non-GMO compliant option may be the synthetic form. From this perspective, certified operators would need to choose the synthetic version to be in compliance with the regulations. In any case, OTA would like to see operators using organic and/or natural vitamins if they are commercially available and compliant. We believe the most definitive and enforceable mechanism in place to make this happen is the petition process. Companies that offer organic vitamins or natural (organic compliant) vitamins have an opportunity to petition the National List!

Fortification of Organic Foods: Consumer attitudes and preference

A fact-based understanding of consumer preference, expectations, and trends is necessary to accurately answer the question of consumer acceptance and desire for fortified organic foods and their compatibility with organic handling systems. Fortification of organic products is widespread 20 years after the original NOSB Recommendation and 15 years after the 2000 NOP Proposed Rule. Fortified organic product categories include but are not limited to: cereals/bars; infant formula; baby and toddler food; fluid milk/dairy products/plant-based beverages; dietary and herbal supplements; and pet food.

In 2010, when NOP issued its memo to NOSB clarifying the meaning of the FDA guidance at 21 CFR 104.20, OTA collaborated with *KIWI Magazine*¹ on a national research study to gauge attitudes, preferences and behavior of families concerning fortification and organic product. The research project was managed and executed by a third-party, RMI Research and Consulting LLC. The study was fielded among U.S. households during early April, 2011.² Unfortunately, OTA was unable to conduct an updated survey in the given time allotted for this comment period time. However, we are providing the highlights of the 2011 survey, and would be willing to conduct an additional survey as needed.

Key Survey Highlights:

Survey respondents were fairly evenly split among *Newly Organic* consumers (31%) who first purchased organic products within the past 2 years, *Experienced Organics* (21%) who began purchasing organic products between 2 and 5 years ago, and *Seasoned Organics* (35%) with more than 5 years of organic buying experience. Non-Buyers represented 4% of the respondent population.

- For nine in ten respondents (89%), choosing organic foods when grocery shopping was either “very important” or “somewhat important”.
- For nearly eight in ten (78%) respondents, choosing fortified foods when grocery shopping for their family was either “very important” or “somewhat important.”

With respect to foods such as “cereals, nutrition bars, milk and other dairy products, infant formula and/or baby and toddler foods:”

¹ <http://www.kiwimagonline.com/>

² The target audience consisted of *KIWI Magazine*’s Parents’ Advisory Board (PAB), online panel, Moms Meet panel and Moms Meet Facebook community.

- The *KIWI* PAB, an opt-in, online panel of parents interested in natural and organic living, provides an important sample of self-identified ‘organic believers’ enabling the research to drill down into organic purchasing behaviors.
- Panelists were invited to participate in a web survey via e-mail.
- All respondents were screened to be 18 and over with at least one child under the age of 18 in the household and to have sole or shared responsibility for household grocery store purchases.
- Data collection took place between Monday, April 4, 2011, and Thursday, April 7, 2011.
- A total of 1,071 usable surveys were completed.
- The total sample of 1,071 reflects the target population of U.S. households self-identified as ‘organic believers.’

- For almost nine in ten respondents (87%), an organic version of these foods fortified with nutrients, vitamins, and minerals would make them “more likely to buy” an organic version of these foods or would “make no difference” in their likelihood to buy.
 - One in ten (12%) reported they would be “less likely to buy” these organic foods if they were fortified.

With respect to fortification with nutrients, vitamins and minerals:

- Respondents indicated specific nutrients would have a largely positive impact on their decision, including “healthy fats such as Omega-3 (69%),” “calcium (67%),” “antioxidants (64%),” “vitamin D (63%),” and “probiotics (63%).” On average, over six in ten say they would be “more likely to buy” an organic food fortified with any of these nutrients, vitamins, and minerals.

Choice in the marketplace:

Consumer preference can also be demonstrated by syndicated retail scan data. OTA collected data in 2011 in partnership with SPINSScan. The growth rate at that time was two and one-half times the growth rate for all organic foods for the same time period.³ Again, we did not have the time to repeat this data collection but we can expect the numbers would remain consistent with the general growth rate of organic food and beverage sales from 2011-2015. The numbers⁴ presented below speak to a strong indication of consumers’ preference and future trends in consumer expectations for organic. **Nothing demonstrates more clearly consumer’s preference about something than cash register scan figures.**

	Current Dollars	Year Ago Dollars	% Change Dollars
Current 52 Weeks Ending 2010-Oct-02			
ALL CHANNEL excluding Whole Foods and Walmart			
Total Organic Food & Bev (org=70%+)	\$6,549,517,115	\$6,094,291,161	7.5%
Fortified Organic Food & Bev (org=70%+)	\$97,664,453	\$83,334,572	17.2%

Conclusion

OTA supports the allowance of vitamins and minerals in NOP certified foods and the rational and safe addition of nutrients to foods to preserve a balance of nutrients in the consumer diet. We also support the maximum freedom of choice for organic consumers, and believe that organic products should be nutritionally equal to their conventional counterparts.

³ SPINSScan Conventional (powered by Nielsen Scantrack) 52 Weeks Ending 10/02/10.

⁴ The figures included in the chart above do not include unreported scans (Wal-Mart and Whole Foods Market and select unreported private label sales) as well as ingredient commodity sales to fortified products based on a standard assumption of the ratio of farm-gate fluid milk sales to retail scan sales. OTA member feedback suggests an estimated dollar figure that would more accurately represent total sales of organic fortified products is over 2 billion dollars.



OTA emphasizes that the organic sector has been fortifying organic products for many years. The 1995 NOSB endorsed the fortification of organic foods with vitamins, minerals and accessory nutrients, but determined permitting fortification only in those instances where their use was appropriate and the nutrients had undergone complete NOSB review via the National List Process. Such process was designed to allow for the discriminate use of inputs and ingredients that are essential and compatible with organic principles, but unavailable in organic or natural forms. We would like to see the organic sector continue to support this intent and see NOP move forward with an annotation that is transparent, certifiable and enforceable.

As stated at the beginning of our comments, we believe it is a priority for NOP to complete the rulemaking it started in 2012. NOP proposed an annotation similar to our preferred annotation and to the annotation suggested by NOSB in Option 2 (Annotation #4). We hope NOSB's request for information will provide NOP with additional information to help move the process forward, and encourage NOSB and other organic stakeholders to communicate to NOP the importance of moving to a final rule.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Gwendolyn V. Wyard".

Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association