



April 4, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-18-0071

RE: Nutrient Vitamins and Minerals (Sunset 2021)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Sunset Review of nutrient vitamins and minerals listed on 205.605(b) (non-agricultural, synthetic) of the National List.

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 over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. 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 Organic Trade Association supports the continued listing of nutrient vitamins and minerals on the National List at 205.605(b) (non-agricultural, synthetic) and we strongly support the review of nutrient vitamins and minerals by the National Organic Standards Board (NOSB). Please reference the results of our Sunset Survey 2021 in our separate comments.

NOSB is asking the following questions in this first round of its Sunset Review:

1. Is the current listing meeting the needs of the organic community, certifiers and industry – if not, how should it be revised?
2. How are certifiers currently dealing with non-synthetic nutrient vitamins and minerals?
3. It is speculated that the 2012 rulemaking was stopped due to the impact this change would have on the currently established organic infant formula market which has both established manufacturers and consumers. How should NOSB move this topic forward in light of this issue?
4. Given that added vitamins and minerals need to be listed on ingredient panels, are consumers enabled to make educated purchasing decisions on fortified foods? If not, please explain?

The Organic Trade Association is in a position to address #1 and #3 and provide some thoughts on #2.

Overall, we encourage NOSB and other organic stakeholders to take this Sunset Review opportunity to support the renewal of nutrient vitamins and minerals, as listed, and to urge NOP to continue with its rulemaking process and publish an annotation that is transparent, certifiable and enforceable.

OTA continues to support a listing for Nutrient Vitamins and Minerals that is certifiable, enforceable and captures the intent of the 1995 NOSB recommendation. The organic sector has been fortifying organic

products for many years, and has been doing so in compliance with the NOP regulations and in response to consumer demand. The 1995 NOSB endorsed the fortification of organic foods and put in place a process that was designed to allow for the discriminate use of vitamins, minerals and nutrients that are essential and compatible with organic principles, but unavailable in organic or natural forms. The Organic Trade Association would like to see the organic sector continue to support this intent. However, 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.

Considerable time and energy went into a two-year process that led to a 2012 NOP proposed rule that has yet to be finalized. The 2012 proposed rule was largely based on NOSB discussions and feedback received from the public on the Handling Subcommittee’s March 2011 recommendation (in response to a memo from NOP to NOSB in April 2010), and we believe it most accurately captures the intent of the original 1995 NOSB recommendation:

Vitamins and minerals identified as essential in 21 CFR 101.9, or as required for infant formula by 21 CFR § 107.100 or 107.1

There is a long and important history that led to the January 2012 NOP Proposed Rule, and the Organic Trade Association would like to see NOP continue with its rulemaking, including all the nutrients petitioned and passed by the NOSB, and publish an annotation that is transparent, certifiable and enforceable.

IMPORTANT BACKGROUND

In 1995, the National Organic Standards Board (NOSB) voted to permit the use of synthetic vitamins, minerals and accessory nutrients in organic foods provided their use was appropriate and the nutrients had undergone complete NOSB review via the National List Process. The Board also conducted technical reviews of specific vitamins and minerals [\[1\]](#) and passed the following recommendation:

Nutrient vitamins and minerals – Determined to be synthetic. NOSB’s decision is to allow this material for use in organic food processing. *Annotation:* Accepted for use in organic foods for enrichment when required by regulations or recommended by an independent organization.

USDA’s National Organic Program (NOP) Final Rule published on December 21, 2000, did not include the NOSB annotations “when required by regulation” or “recommended by an independent organization.” Instead, NOP decided that the most appropriate reference was the FDA Nutritional Quality Guidelines for Foods found at 21 CFR 104.20.

§ 205.605(b) *Synthetics Allowed:* Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

In 2006, NOP received a complaint that substances such as DHA, ARA and taurine were being added to organic infant formula. **In 2007**, NOP clarified that DHA and ARA and other nutrients are allowed in organic foods because 21 CFR 104.20 allows a wide variety of nutrients beyond the vitamin and minerals allowed under § 104.20 and the ones that were reviewed by the 1995 Board.

In 2010, after meeting with FDA, NOP released a memo recognizing that its interpretation of FDA's fortification policy was incorrect. The memo clarified the real meaning of § 104.20 and explained that the policy does not include nutrients beyond the ones listed under § 104.20. NOP also recognized that certifiers and certified operations made decisions based on NOP's incorrect interpretation and explained it would be moving forward with draft guidance that would include adequate time for businesses to transition products to comply with the FDA regulations as written.

In 2012, NOP issued a proposed rule requesting comments on the following proposed annotation:

§ 205.605(b) Synthetics Allowed: "Vitamins and minerals. For food— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10."

The proposal clarified that the "nutrients" that were not on these CFR sections had to be petitioned.

In 2011-2013, many nutrients were petitioned to the National List. A few were recommended to be listed by the NOSB (i.e. Choline and Inositol - for use in infant formula and medical nutritional enteral products, DHA and ARA - not hexane extracted; other ingredients that are agricultural must be organic), but several were not (i.e. lutein, taurine, L-carnitine, lycopene, nucleotides, ascorbyl palmitate, and beta-carotene). It should also be noted that in the last couple years, choline¹ was added to 21 CFR 101.9.

NOP did not finalize the proposed rule, but on **September 27, 2012**, published an Interim Rule, which renewed without change the original listing (21 CFR 104.20).

Upon release of the interim rule, NOP announced "that vitamins and minerals may continue to be added to organic products while the Department continues to clarify which additional nutrients may be added to organic products."

No further NOP rulemaking has occurred to date.

[1] Vitamin A, C, D, E, K, B6, B12, Thiamin, Riboflavin, Niacin, Folate, Biotin, Pantothenic acid, Choline, Inositol, Phosphorous, Magnesium, Zinc, Iodine, Copper, Manganese, Chloride, Sulfur

OTA Supports an Annotation that is Certifiable and Enforceable

The Organic Trade Association believes that we need an annotation that includes CFR references that connect to a clear list of specific vitamins and minerals that are essential. We also believe that revisiting the annotation at the NOSB level is a duplicative effort. USDA's resources are best spent on completing its rulemaking. This includes addressing the nutrients that were petitioned and reviewed by NOSB from 2011 - 2013.

¹ NOSB passed recommendations to add Choline and Inositol at the May 2012 meeting. **Choline chloride** (CAS # 67-48-1) and **Choline bitartrate** (CAS # 87-67-2) for use in infant formula and medical nutritional enteral products. **Inositol** CAS # 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) for use in infant formula and medical nutritional enteral products.

The annotation in the 2012 proposed rule, coupled with nutrients petitioned and passed by the NOSB, offer NOP a concise path forward that reflects consumer preferences, and references distinct lists of essential nutrients found in the FDA Code of Federal Regulations. OTA supports this NOP action because it's consistent with the intent of NOSB's 1995 recommendation on nutrient supplementation of organic foods and will result in a more certifiable and enforceable regulation.

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

The Organic Trade Association 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, 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!

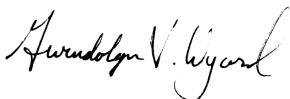
Conclusion

The Organic Trade Association 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.

As stated at the beginning of our comments, we believe it is important for NOP to complete the rulemaking it started in 2012 and respond to the petitions that were received from 2011 - 2013. We encourage NOSB and other organic stakeholders to take this Sunset Review opportunity to support the renewal of nutrient vitamins and minerals, as listed, and to urge NOP to continue with its rulemaking and publish an annotation that is transparent, certifiable and enforceable.

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

Respectfully submitted,



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cc: Laura Batcha
Executive Director/CEO
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