

OTA BACKGROUND AND FACT SHEET

VITAMINS AND MINERALS ALLOWED IN USDA NOP CERTIFIED PRODUCTS

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 minerals¹ and passed the following recommendation:

Nutrient vitamins and minerals – Determined to be synthetic. The 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operations made decisions based on NOP’s incorrect interpretation and explained it would be moving forward with draft guidance that would include adequate time for businesses to transition products to comply with the FDA regulations as written.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. DHA and ARA) but most were not (i.e. lutein, taurine, L-carnitine, lycopene, nucleotides, ascorbyl palmitate, and beta-carotene).

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 POSITION

OTA supports the rational and safe fortification of organic foods. We also support the maximum freedom of choice for organic consumers, and believe that organic products should be nutritionally equal to their conventional counterparts.

Consistent with our comments to NOSB in 2011 and 2016 and to NOP in 2012, OTA **continues** to support a listing for vitamins and minerals that is certifiable, enforceable and captures the intent of the 1995 NOSB recommendation. Specifically we support the following annotation that reflects an updated list of the vitamins and minerals FDA considers essential in food and infant formula as well as the vitamins and minerals enumerated in NOSB's 1995 review:

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

OTA supports this approach because it is 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 in addition to any others that are successfully petitioned to the National List. This will result in a more certifiable and enforceable regulation.

OTA emphasizes that 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.

OTA would like to see the organic sector continue to support this intent. We urge NOP to complete its rulemaking and publish an annotation that is transparent, certifiable and enforceable. We also urge NOP to prioritize the petitions that were submitted to NOSB and upon release of any final rule, provide certified operations with sufficient time to re-label and/or reformulate affected products that are currently certified and sold in the marketplace.

HELPFUL RESOURCES

NOSB and NOP Documents:

- Memo From NOP to NOSB (April 26, 2010): [Scope of Nutrient Vitamins and Minerals in Organic Food](#)
- NOP [Proposed Rule](#) (January 2012)
- NOP [Questions and Answers \(pdf\)](#) on the Proposed Rule
- [Interim Rule with request for comments](#) (2012)
- [NOP Announcement on Continued Allowance of Vitamins and Minerals](#)
- NOSB Spring 2016 Recommendation

OTA Comments:

- [OTA comments on NOSB's April 2011 Recommendation](#)
- [OTA comments on NOP's 2012 Proposed Rule](#)
- [OTA comments on NOP's 2012 Interim Rule](#)
- [OTA comments on NOSB's 2016 Spring Discussion Document](#)

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