

FACT SHEET

VITAMINS AND MINERALS ALLOWED IN USDA NOP CERTIFIED PRODUCTS

OTA POSITION

The Organic Trade Association (OTA) supports the rational and safe fortification of organic foods. The allowance of non-organic vitamins, minerals and other essential nutrients in less than 5% of a product formulation is an appropriate application of the National List of allowed substances in organic products. Fortification of organic products in accordance with the regulations allows organic products, on the shelf, to be nutritionally comparable to other fortified conventional products and provides a choice for consumers in the marketplace.

OTA continues to support review of these, and all nonorganic allowed substances in an organic product formulation, by the industry and public advisory committee the National Organic Standards Board.

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.

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

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

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.