



## Proposed Rule for Vitamins and Minerals in USDA Organic Products

### What does the rule propose?

The proposed rule published by USDA's National Organic Program (NOP) clarifies what specific vitamins and minerals are allowed in organic food products, including infant formula.

Once finalized, the rule will establish clear, enforceable parameters for the use of vitamins and minerals in organic products. Specifically, it corrects regulatory references in the USDA organic standards to state that only essential vitamins and minerals, as defined by the Food and Drug Administration (FDA), are permitted in organic foods (for fortification purposes). Additionally, it specifically identifies FDA-required vitamins and minerals that may be added to organic infant formula.

**Fortification of organic food.** The Food and Drug Administration allows the following essential vitamins and minerals for fortification of food: Vitamins A, C, K, D, E, thiamin, riboflavin, niacin, B<sub>6</sub>, B<sub>12</sub>, biotin, folate, pantothenic acid, calcium, iron, phosphorus, magnesium, zinc, iodine, copper, potassium, selenium, manganese, chromium, molybdenum, and chloride. The proposed rule would allow these essential vitamins and minerals in organic food products.

**Fortification of infant formula.** Since infants have different nutritional needs than adults, the list of essential vitamins and minerals for infant formula is similar but has some key differences. Under a separate regulatory reference, the FDA requires infant formula to contain the following essential vitamins and minerals: Vitamins A, C, K, D, E, thiamin, riboflavin, niacin, B<sub>6</sub>, B<sub>12</sub>, folic acid, pantothenic acid, calcium, iron, phosphorus, magnesium, zinc, iodine, copper, sodium, potassium, selenium, manganese, and chloride. Non-dairy infant formulas must also include biotin, choline, and inositol. The proposed rule would allow for organic infant formula.

### Why is the action necessary?

Section 205.605 of the National List of Allowed and Prohibited Substances includes the listing of: Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods. These nutritional guidelines in 21 CFR 104.20 are developed and overseen by the FDA.

In 2007, the NOP incorrectly interpreted the FDA's nutritional guidelines (21 CFR 104.20) and allowed the addition of nutrients to organic food products that are outside the scope of FDA's listing of nutrient vitamins and minerals. As a result of NOP's incorrect interpretation, sectors of the organic industry have added nutrients to certain types of organic products, such as infant formula or pet food, that are not covered by the current regulatory reference. Examples include certain forms of docosahexanoic acid (DHA) and arachidonic acid (ARA) in fluid milk and dairy products, and taurine in pet food. Additionally, organic infant formulas contain vitamins and minerals that are not permitted by the current regulatory reference.

The NOP is proposing the regulatory change in this rule to establish clear, transparent parameters for using vitamins and minerals in organic products that align with FDA regulatory provisions.

### Who determines what substances are included on the National List?

The Organic Foods Production Act (OFPA) allows the use of natural substances in organic crop and livestock production unless they are specifically prohibited and prohibits the allowance of synthetic substances unless they are specifically allowed. The National List of Allowed and Prohibited Substances is the portion of the USDA organic standards that specifically identifies which synthetic substances are allowed and which non-synthetic (natural) substances are prohibited in organic crop and livestock production. The National List also specifies which non-organic ingredients and processing aids can be used in processed organic products.

OFPA states that the National Organic Standards Board (NOSB) must recommend approval of any substance added to the National List of Allowed and Prohibited Substances. The NOSB is an independent federal advisory board composed of organic industry and stakeholder representatives. Members represent a diversity of interests, including organic farmers and handlers, environmentalists, consumer representatives, a scientist, certifier, and retailer.

When reviewing materials that are petitioned for inclusion on the National List, the NOSB considers public comments, technical reports, and other information to determine if the substance should be allowed or prohibited in organic production and handling. Each substance must meet several criteria, including compatibility with sustainable agriculture, low impact on the environment and human health, and essentiality in organic production and handling. The advisory board also considers natural alternatives to each National List substance before recommending whether the substance should be added to the National List.

After the NOSB makes their final recommendations, the NOP reviews the recommendations and determines whether to move forward with amending the National List. NOSB recommendations are not in effect unless the NOP amends the National List after public comment and the publication of proposed and final rules.

### How long before organic products in the marketplace reflect this change?

To provide adequate time for companies to change their formulations (as necessary), the NOP is proposing a two-year implementation period after the publication of a Final Rule. The two-year implementation period would also provide time for additional substances to be petitioned for potential addition to the National List of Allowed and Prohibited Substances.

### What about DHA algal oil and ARA fungal oil?

The proposed rule defines exactly which vitamins and minerals are permitted in organic products. It does not include nutrients that are not specifically referenced under FDA policy. A number of substances, including the fatty acid nutrients DHA algal oil and ARA fungal oil, were previously permitted by the NOP due to the incorrect interpretation of the FDA fortification policy. These substances will need to be petitioned separately to be considered by the NOSB for inclusion on the National List.

In early December 2011, the NOSB examined DHA algal oil and ARA fungal oil in response to petitions requesting to allow them in organic food products and infant formula. [A webcast](#) of the NOSB discussion is available on the NOP website. The NOSB voted 10-4 to allow DHA algal oil and ARA fungal oil in organic food products with the following restrictions: all agricultural ingredients must be organic and DHA algal oil and ARA

fungal oil must not be hexane extracted. The NOP will review the NOSB final recommendations and plans to issue a proposed rule in a separate Federal Register publication.

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