



1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

April 26, 2010

ACTION MEMORANDUM FOR THE CHAIRMAN OF THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles McEvoy
Deputy Administrator
National Organic Program

A handwritten signature in black ink, appearing to read "Miles McEvoy", written over a large, empty oval shape.

SUBJECT: Scope of Nutrient Vitamins and Minerals in Organic Food

ISSUE:

The National Organic Program (NOP) requests that the National Organic Standards Board (NOSB) reevaluate their recommendation for nutrient vitamins and minerals, currently codified in 7 CFR §205.605(b), in the sunset 2012 process and define the scope of permitted vitamins, minerals and nutrients. This evaluation is requested due to a clarification of scope of the current annotation for nutrient vitamins and minerals which references the Food and Drug Administration (FDA) fortification policy in 21 CFR §104.20.

DISCUSSION:

In November 1995, the NOSB voted to permit nutrient vitamins and minerals in organic food. Two technical advisory panel (TAP) reviews were conducted prior to the meeting. The TAP review for "nutrient minerals" covered calcium, phosphorus, magnesium, sulfur, copper, iodine, iron, manganese and zinc; the TAP review for "nutrient vitamins" included vitamins A, D, E, K, C, B6, B12, folic acid, thiamin (B1), riboflavin (B2) and biotin. There was not a TAP review of substances identified as "accessory nutrients."

According to the record of the NOSB October 31 – November 4, 1995 meeting, the Board adopted a final recommendation titled *The Use of Nutrient Supplementation in Organic Foods*.¹

This addendum includes reference to accessory nutrients, stating:

In the recommendation listed below, the term accessory nutrients means nutrients not specifically classified as a vitamin or mineral but found to promote optimal health. Examples include omega-3 fatty acids, inositol, choline, carnitine, [sic] and taurine. Without this inclusion, we believe we may be limiting ourselves given future nutritional discoveries. It is also a term used frequently throughout the food and supplement industries.

¹ Final Recommendation Addendum Number 13 available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5058973>

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NOSB Recommendation:

Upon implementation of the National Organic Program, the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.

Following the adoption of the above addendum, the NOSB vote on the listing of nutrient vitamins and minerals was recorded as follows:

Nutrient Vitamins and Minerals - Determined to be synthetic; Vote - Unanimous. The NOSB's decision is to allow this material for use in organic food processing; Vote: 10 aye / 4 opposed. Annotation: Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.²

The recommendation voted upon for nutrient vitamins and minerals did not include the term "accessory nutrients." The NOP proposed rule, published on March 13, 2000 (65 FR 13512), did not include the NOSB annotations "when required by regulation" or "when recommended by an independent professional organization." The NOP final rule, as published on December 21, 2000 (65 FR 80548), retained the reference to 21 CFR §104.20, and did not incorporate the term "accessory nutrients:"

§205.605(b) *Synthetics allowed:*

Nutrient vitamins and minerals, in accordance with 21 CFR §104.20, Nutritional Quality Guidelines for Food. ■

In 2006 the NOP received a complaint that substances such as arachidonic acid (ARA), docosahexaenoic acid (DHA), sterols, and taurine³ were being added to infant formula and other organically labeled products. In a 2007 letter, the NOP clarified that DHA, ARA and other nutrients are allowed in organic foods because "[n]utrients allowed under section 205.605(b) are not limited to the nutrients listed in section 104.20(d)(3), because section 104.20(f) provided that nutrients may be added to foods as permitted or required by applicable regulations established elsewhere by FDA. Thus, for example, ARA and DHA are covered under section 205.605(b) of the National List because the FDA permits their use as nutrients that are GRAS."⁴

² FINAL MINUTES OF THE NATIONAL ORGANIC STANDARDS BOARD FULL BOARD MEETING
AUSTIN, TEXAS, OCTOBER 31 - NOVEMBER 4, 1995

³ ARA and DHA are omega-6 and omega-3 fatty acids, respectively; phytosterols are a type of organic compound naturally occurring in plants; taurine is an organic acid.

⁴ Letter from USDA AMS Compliance to complainant, April 3, 2007.

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FDA Clarification

The FDA fortification policy is established in 21 CFR §104.20. Section 104.20(d)(3) permits the following nutrients for fortification in accordance with its policy: protein, calcium, iron, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, magnesium, zinc, iodine, copper, potassium, and vitamins A, C, D, E, B₆, and B₁₂.

The NOP met with FDA staff from the Office of Nutrition, Labeling and Dietary Supplements for clarification of the scope of 21 CFR §104.20. The FDA explained that “nutrients” as referenced in 21 CFR §104.20(f) are intended to pertain only to those nutrients listed in §104.20(d)(3) and as specified in the standards of identity (21 CFR Parts 130-169) for a food or class of foods. The standards of identity for enriched cereal-flours and related products, for example, require fortification at specified levels with thiamin, riboflavin, niacin, iron and folic acid (21 CFR §137). The FDA noted that some foods have separate requirements and are not subject to 21 CFR §104.20, such as infant formula which is subject to comply with the nutrition requirements at 21 CFR §107.100.

In summary, 21 CFR §104.20(f) does not apply to the use of substances such as ARA, DHA, taurine, or sterols that have been added to products such as infant formula, milk, pet food, or energy bars as nutrients.

NOSB CONSIDERATION:

The NOP is requesting that the NOSB reevaluate their recommendation for nutrient vitamins and minerals during the 2012 sunset process, and provide specific recommendations regarding the scope of permitted vitamins, mineral and nutrients in organic food products.

The NOP requests that NOSB consider the following:

- Are the “nutrient vitamins and minerals” specified within 21 CFR §104.20 aligned with the 1995 NOSB recommendation? If not, are there substances that should be prohibited or additional substances that should be allowed?

SUMMARY

In conclusion, the NOP acknowledges that its previous interpretation of 21 CFR 104.20 was incorrect. The NOP recognizes that many certifiers and certified operations have made decisions based on the NOP’s incorrect interpretation of the FDA guidelines.

In the future, the NOP will not be making policy decisions in letters. All policy decisions will be made through the federal register and in compliance with Executive Order 12866. Transparency is a core principle for the NOP, AMS and the USDA administration. We are committed to an open public process. All NOP guidance will be published through the federal register with public comment.

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In regards to nutrient vitamins and minerals, the NOP plans to publish draft guidance later this year that will align with the FDA interpretation of 21 CFR 104.20. The draft guidance will provide a transition time for businesses to reformulate products to comply with the regulations as per the FDA guidelines. There will be a 60 day comment period for the draft guidance. Final guidance will be published after consideration of the comments received.

The NOP also notes that companies or interest groups may petition to add substances to the National List during this transition period. Specifically the pet food industry may want to consider petitioning to add substances to the National List in order to meet the nutritional requirements for pets.