

**National Organic Standards Board
Handling Committee
Proposed Recommendation
The Use of Nutrient Supplementation in Organic Foods**

March 7, 2011

In 1995 the NOSB made a recommendation to the Secretary of the USDA on “The Use of Nutrient Supplementation in Organic Foods.”

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.

The recommendation said, “the term ‘accessory nutrients’ means nutrients not specifically classified as a vitamin or a mineral but found to promote optimum health.” The purpose of the “accessory nutrient” reference was given: “without this inclusion, we believe we may be limiting ourselves given future nutritional discoveries.”

The recommendation thus authorized a category or class of approved materials on the National List comprised of vitamins, minerals and/or accessory nutrients. Consistent with the direction from Congress that the National List be updated and refreshed by new information, the recommendation proposed that the boundaries of the category be maintained by the state of current scientific literature and expert opinion. The reliance on current scientific literature and expert opinion properly limited the class of materials to those having received independent assessment and recognition as supplementing the human diet or providing support for optimal health.

When the National List was finally proposed by the Secretary, an annotation appeared that was not part of the authorizing NOSB recommendation.

National List §205.605(b): Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods

The text of this listing failed to track the Recommendation. We believe the Recommendation expressly distinguished nutrients from vitamins for the purpose of including micronutrients that may be essential or that have been generally accepted as promoting optimal health. Based on the foregoing, the committee believes that the National List should be clarified by changing the listing to read: “Nutrients, Vitamins and Minerals.”¹

¹ The Committee recognizes that amendment of the actual listing, as distinguished from the annotation, will require a separate action. To that end, a separate proposal from the Handling Committee will be presented at the NOSB Spring 2011 meeting that recommends the relisting of the material with an amended annotation. Amendment of the listing itself will be the subject of a Petition that the Handling Committee intends to produce before the Fall 2011 meeting.

Also, the addition of the reference to 21 CFR §104.20 through an annotation altered the scope and meaning of the authorization intended by the 1995 recommendation and created significant confusion and conflict. Fortunately, the annotation was interpreted by the NOP in subsequent years in a manner that circumvented its more confusing and inappropriately restrictive aspects. Organic certifiers and businesses relied in good faith on these interpretations. Over the years innovative products have been developed that include the nutrient materials authorized by the NOP's determinations, and that are highly valued by organic consumers. Based on these facts, the record demonstrates that support for retaining the current annotation has completely dissolved and strong support for clarifying the authorization for this class of material has emerged.

The Handling Committee believes that the National List authorization intended by the 1995 NOSB Recommendation--a category of vitamin, mineral and nutrient materials for fortifying multi-ingredient organic foods in a manner consistent with existing applicable federal regulation and current scientific understanding--aligns neatly with the existing, updated record, and the demonstrated needs of the organic food industry and its consumers' expectations. Accordingly, the committee recommends that the existing National List authorization for §205.605(b) should be clarified in the following manner.

Proposed Amended Annotation: "Materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods, including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies."

This approach, changing both the text of the listing and the annotation, comports with the OFPA and would achieve four key purposes:

- First, it would honor and implement the authorization proposed by the NOSB in 1995 by restoring the meaning of the listing and eliminating the annotation erroneously added during rulemaking.
- Second, it would annotate the listing during the sunset process in a manner that recognizes and embraces both the development of the organic marketplace since the time of the adoption of the original National List and the NOP rulings and Guidance issued since the inception of the National List by the NOP.
- Third, it would harmonize the rules on fortification, supplementation and enrichment of organic food products with the rules governing other foods in a manner that avoids unnecessary conflict with other statutes and governmental agencies.
- Lastly, it ensures the maximum freedom of choice for organic consumers.

For the purpose of the 2012 Sunset consideration to relist Nutrient Vitamins and Minerals to National List §205.605(b), the NOSB is authorized to recommend annotation changes for the purpose of limiting or clarifying the annotation. We believe amending the annotation as proposed above clarifies the listing and the annotation.

NOP Guidance

The committee sees great value in the FDA's expenditure of resources implementing its role in regulating the safety and efficacy of nutrients, vitamins and minerals and little value in a separate nutrient supplementation regime for food products that contain organic agricultural ingredients.

We respectfully request that the NOP delay publishing any Guidance regarding this listing, or materials currently in use pursuant to this listing, until after the publication of the proposed amended annotation in the Federal Register and receipt by the NOP and NOSB of comments by the public and any references or comments from the FDA and/or the Institute of Medicine.

Committee Vote

Motion by: Tracy Miedema

Second: Joe Dickson

Yes: 4

No: 3

Absent: 0

Abstain: 0

Recuse: 0