



April 10th, 2011

Ms. Patricia Atkins
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2646-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-11-0014

RE: 2012 Sunset Proposed Recommendation & The Use of Nutrient Supplementation in Organic Foods

Dear Ms. Atkins:

Thank you very much for this opportunity to provide comment on the Handling Committee's recommendation on Nutrient Vitamins and Minerals.

Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members, and its mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy (<http://www.ota.com/>).

OTA supports the use of nutrient in organic foods and we support the renewal of Nutrient Vitamins and Minerals on the National List.

While we support the general direction of the Handling Committee's recommended annotation change, we would like instead to see an annotation that is more specific. We are suggesting the following language as an alternative:

¹Vitamins and minerals identified as essential in 21 CFR 101.9, or as required for infant formula by 21 CFR § 107.100 or 107.10

The outcome we do NOT support is the retention of the current annotation ("when used in accordance with 21 CFR 104.20") whereas fortification of certified products would be limited to the vitamins and minerals listed in 21 CFR 104.20(d)(3). That list DOES NOT include several of the

¹ The annotation we are supporting is the annotation suggested by the National Organic Program to the NOSB Handling Committee in an e-mail on Feb. 25th, 2011. The NOP openly shared the e-mail with OTA for review and consideration.

nutrients reviewed in the 1995 NOSB TAP reviews and it does not contain several of the essential vitamins and minerals required in food products today.

For the purpose of the Sunset Recommendation, our comments focus on retaining nutrient vitamins and minerals as currently listed with the clarifying annotation presented above. **We are however fully in support of the use and allowance of “Accessory Nutrients” in NOP certified products provided they have gone through the National List process.**

OTA has spent a considerable amount of time reviewing the 1995 Recommendation on “The Use of Nutrient Supplementation in Organic Foods”, the 1995 Austin, Texas Meeting Transcripts, the 1995 Technical Advisory Panel (TAP) reviews on vitamins and minerals, and the various Code of Federal Regulations governing nutrients allowed in foods. We have also engaged in extensive dialogue with our members, including the OTA Accessory Nutrient Task Force, and with several 1995 Board members to understand the intentions of their Recommendation. We believe we have good understanding of the history and a reasonable recommendation for moving forwards.

The research that we have done on this topic has led us to support the following key points central to our comments. OTA supports:

- The continued allowance of vitamins and minerals in NOP certified foods and the rational and safe addition of nutrients to foods in order to preserve a balance of nutrients in the consumer diet.
- The fortification of organic foods and the maximum freedom of choice for organic consumers.
- Organic products that are nutritionally equal to their conventional counterparts.
- The statutory authority of the NOSB to review materials and develop the proposed National List. OTA understands that in 1995 the NOSB endorsed the use of vitamins, minerals and accessory nutrients, however prior to their final recommendation they had only conducted TAP reviews on vitamins and minerals. They intended for any vitamin, mineral, or accessory nutrient that was not enumerated in the two TAP Reviews be subject to the National List process.
- A categorical review of “accessory nutrients” for inclusion on the National List to be conducted at the Fall 2011 meeting – See “Step Two” of our comments.
- A listing and annotation that is certifiable and enforceable, specifically an annotation that supports the use of the vitamins and minerals allowed under 21 CFR 101.9 and 107.100.
- National List implementation that honors the authorization proposed by the NOSB according to 7 U.S.C. 6517(d)².

² “(1) IN GENERAL: The National List proposed by the Secretary shall be based upon a proposed National List or proposed amendments to the National List developed by the National Organic Standards Board. (2) NO ADDITIONS: The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.”

OTA respectfully submits the following more specific comments:

Fortification of Organic Foods: Consumer attitudes and preference

Nutrient Vitamins and Minerals are currently listed under § 205.605(b)³ of the National List and accordingly allowed in the 5% or 30% of products labeled as “organic” or “made with (specified organic ingredients or food group(s)), respectively. Fortification of organic products is widespread 15 years after the original NOSB Recommendation and 10 years after the NOP Proposed Rule. Fortified organic product categories include but are not limited to: Cereals/Bars; Infant Formula; Baby and Toddler Food; Fluid Milk/Dairy Products/Plant Based Beverages; Dietary and Herbal Supplements; and Pet Food.

A fact-based understanding of consumer preference, expectations, and trends is necessary to accurately answer the question of consumer acceptance and desire for fortified organic foods and their compatibility with organic handling systems.

OTA collaborated with *KIWI Magazine*⁴ on a national research study to gauge attitudes, preferences and behavior of families concerning fortification and organic product. The research project was managed and executed by a third-party, RMI Research and Consulting, LLC. The study was fielded among U.S. households during early April, 2011.⁵

Survey respondents are fairly evenly split among *Newly Organic* consumers (31%) who first purchased organic products within the past 2 years, *Experienced Organics* (21%) who began purchasing organic products between 2 and 5 years ago, and *Seasoned Organics* (35%) with more than 5 years of organic buying experience. Non-Buyers represent 4% of the respondent population.

³ § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetics Allowed

⁴ <http://www.kiwimagonline.com/>

⁵ The target audience consisted of *KIWI Magazine*’s Parents’ Advisory Board (PAB), online panel, Moms Meet panel and Moms Meet Facebook community.

- The *KIWI* PAB, an opt-in, online panel of parents interested in natural and organic living, provides an important sample of self-identified ‘organic believers’ enabling the research to drill down into organic purchasing behaviors.
- Panelists were invited to participate in a web survey via e-mail.
- All respondents were screened to be 18 and over with at least one child under the age of 18 in the household and to have sole or shared responsibility for household grocery store purchases.
- Data collection took place between Monday, April 4, 2011, and Thursday, April 7, 2011.
- A total of 1,071 usable surveys were completed.
- The total sample of 1,071 reflects the target population of U.S. households self-identified as ‘organic believers’.

Key Survey Highlights:

- For nine in ten respondents (89%), choosing organic foods when grocery shopping is either “very important” or “somewhat important”.
- For nearly eight in ten (78%) respondents, choosing fortified foods when grocery shopping for their family is either “very important” or “somewhat important”.

With respect to foods such as “cereals, nutrition bars, milk and other dairy products, infant formula and/or baby and toddler foods:”

- For almost nine in ten respondents (87%), an organic version of these foods fortified with nutrients, vitamins, and minerals would make them “more likely to buy” an organic version of these foods or would “make no difference” in their likelihood to buy.
 - One in ten (12%) report they would be “less likely to buy” these organic foods if they were fortified.

With respect to fortification with nutrients, vitamins and minerals:

- Respondents indicated specific nutrients would have a largely positive impact on their decision, including “healthy fats such as Omega-3 (69%),” “calcium (67%),” “antioxidants (64%),” “vitamin D (63%),” and “probiotics (63%).” On average, over six in ten say they would be “more likely to buy” an organic food fortified with any of these nutrients, vitamins, and minerals.

Choice in the marketplace:

- The growth rate for fortified organic foods, as demonstrated by syndicated retail scan data, is two and one-half times the growth rate for all organic foods for the same time period.⁶ This is a strong indication of consumers’ preference and future trends in consumer expectations for organic. **Nothing demonstrates more clearly consumers preference about something than cash register scan figures.**

	Current Dollars	Year Ago Dollars	% Change Dollars
Current 52 Weeks Ending 2010-Oct-02			
ALL CHANNEL excluding Whole Foods and Wal-mart			
Total Organic Food & Bev (org=70%+)	\$6,549,517,115	\$6,094,291,161	7.5%
Fortified Organic Food & Bev (org=70%+)	\$97,664,453	\$83,334,572	17.2%

⁶ SPINSScan Conventional (powered by Nielsen Scantrack) 52 Weeks Ending 10/02/10.

Background - Timeline

Original NOSB Recommendation – October 31, 1995 (see section on Intent below)

NOP proposed rule: The National Organic Program (NOP) offered its first proposed rule in 1997, proposing the allowance of “nutrient supplements.” The listing was changed in the 2000 proposed rule to “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods,”⁷ although NOP did not comment on the change in the preamble.

NOSB comment on the proposed rule: On June 12, 2000, NOSB’s comment on the proposed rule was simple; “The NOSB recommends that 21 CFR 104.20 not be the reference for the allowance of nutrient vitamins and minerals for the organic industry.”⁸

NOP final rule: However, the listing in the final rule remained the same as in the 2000 Proposed Rule, “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.”

NOP Action Memorandum: On April 26, 2010, the National Organic Program requested that NOSB reevaluate its recommendation on nutrient vitamins and minerals in the sunset 2012 process due to a clarification of scope of the current annotation which references the Food and Drug Administration (FDA) fortification policy in 21 CFR 104.20. *“NOP requests that NOSB consider the following: Are the “nutrients and vitamins” specified within 21 CFR §104.20 aligned with the 1995 recommendation? If not, are there substances which should be prohibited or additional substances that should be allowed?”*

The Intent of the 1995 Recommendation

At the NOSB meeting in October-November 1995 the NOSB voted on two items related to this issue. The Board made a Final Board Recommendation for the National List regarding the Use of Nutrient Supplementation in Organic Foods (31 October 1995 minutes: page 5, lines 160-169). The Board also voted to add the synthetic substances Nutrient Vitamins and Minerals to the Proposed National List with a specific annotation (an “exemption” within the meaning of the Act) (31 October 1995 minutes: page 15, lines 488-493).

In its Final Board Recommendation on the Use of Nutrient Supplementation in Organic Foods, the NOSB provided therein a definition of the term “Accessory Nutrients” to make it clear exactly what it was referring to. The NOSB definition is as follows: The term “accessory nutrients means nutrients not specifically classified as a vitamin or mineral but found to promote optimal health.” The NOSB cited five examples of nutrients or nutrient groups that met their definition at that point in time (omega-3 fatty acids, inositol, choline, carnitine, and taurine).

⁷ See 21 CFR 104.20 at: <http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&sid=d34b49182d11080e5d7852963b9a65f9&rgn=div8&view=text&node=21:2.0.1.1.4.2.1.1&idno=21>

⁸ NOSB Chairman letter to NOP program manager RE comments to proposed rule, Docket Number TMD00-02-PR2.

Later that same day, 31 October 1995, the NOSB voted to include on the National List Nutrient Vitamins and Minerals, two classes of synthetic substances – specifically enumerated Nutrient Vitamins and specifically enumerated Nutrients Minerals – that had been subjected to the National List process. The NOSB included the following Annotation for Nutrient Vitamins and Minerals:

Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.

Instead of accepting the NOSB recommended annotation, the Program decided that the most appropriate reference was the FDA Nutritional Quality Guidelines for Foods found at 21 CFR 104.20.

Thus our listing in the current NOP regulations is:

Nutrient Vitamins and Minerals – when used in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.

In our discussions with past NOSB members, and as expressed in the recorded minutes of the NOSB meeting, two central messages emerged:

1. The NOSB was opposed to the helter-skelter addition of nutrients to organic foods but was determined to permit fortification in those instances where an independent professional organization deemed fortification was appropriate;
2. The will of the NOSB was that vitamins and minerals, including accessory nutrients, not specifically enumerated in the two TAP Reviews are NOT exempt from the National List Process.

An Annotation that is Certifiable and Enforceable

OTA supports the general the direction that was taken by the Handling Committee to capture the spirit of the 1995 Recommendation. We see the proposed Committee annotation as a commendable attempt to capture the universe of nutrients that COULD be allowed, consistent with the intent of the 1995 Committee to permit fortification when it's deemed appropriate.

OTA believes however that with respect allowable vitamins and minerals an annotation that includes specific CFR references will be certifiable and enforceable. We want to emphasize that the revision of an annotation as it relates to vitamins and minerals is only the first step to capturing the intent of the 1995 Recommendation. We request a second step that will focus on nutrients take place at the Fall meeting.

Step One (Spring 2011 Meeting): The first step is to designate the vitamins and minerals that should be permitted in organic food and infant formula based on the current regulation and the Recommendation of 1995. The first step can be accomplished through an annotation change voted on during the Sunset review of “nutrient vitamins and minerals.

OTA supports the annotation that was presented to us by the National Organic Program, and presented to the Handling Committee as an alternative to the current listing at 205.605(b):

Vitamins and minerals identified as essential in 21 CFR 101.9, or as required for infant formula by 21 CFR § 107.100 or 107.10⁹:

Below is a chart that includes a side-by-side comparison of 21 CFR 104.20, the CFRs included in the suggested annotation, and the vitamins and minerals that were reviewed in 1995. The allowance of the nutrients listed 21 CFR 101.9(c)(8)(iv) and 21 CFR 107.100 will align with the materials reviewed in 1995 and encompass the materials that are currently allowed under the § 205.605(b) listing.

Nutrient	§104.20(d)(3) Fortification Policy	§101.9(c)(8)(iv) Food Labeling	Infant Formula Citations 21 CFR 107.100	NOSB TAP for Vitamins and Minerals
*Protein	listed		listed	
Vitamin A	listed	listed	listed	listed
Vitamin C	listed	listed	listed	listed
Calcium	listed	listed	listed	listed
Iron	listed	listed	listed	listed
Vitamin D	listed	listed	listed	listed
Vitamin E	listed	listed	listed	listed
Vitamin K		listed	listed	listed
Thiamin	listed	listed	listed	listed
Riboflavin	listed	listed	listed	listed
Niacin	listed	listed	listed	listed
Vitamin B6	listed	listed	listed	listed
Folate	listed	listed	listed	listed
Vitamin B12	listed	listed	listed	listed
Biotin	listed	listed	listed	listed
Pantothenic acid	listed	listed	listed	listed
Choline			listed	listed
Inositol			listed	listed

⁹ 21 CFR 107.10 provides a provision for additional nutrients (e.g. selenium) for which the National Academy of Sciences (NAS) Institute of Medicine (IOM) has recommended inclusion, and all formula manufacturers need to have in their formulation, but for which the FDA has yet to codify at 21 CFR 107.100. To address this issue 107.10 is included.

Phosphorus	listed	listed	listed	listed
Magnesium	listed	listed	listed	listed
Zinc	listed	listed	listed	listed
Iodine	listed	listed	listed	listed
Copper	listed	Listed (101.9(c)(9))	listed	listed
Potassium	listed	listed	listed	
Selenium		listed		
Manganese		listed	listed	listed
Chromium		listed		
Molybdenum		listed		
Chloride		listed	listed	listed
Sulfur				listed
L-Tryptophan				
Boron				
DHA				
EPA				
Vanadium				
Fluoride				
Sodium				
L-Carnitine				
5' Nucleotides				
Taurine				

Step Two (Fall Meeting): The second step would take place at the NOSB Fall meeting and generally follow the thought process expressed in the Committee’s Recommendation titled “The Use of Supplementation in Organic Foods”. The NOSB could write a recommendation that would capture the 1995 NOSB’s endorsement of “Accessory Nutrients” and the definition provided in that 1995 Recommendation. Accessory Nutrients could be reviewed for listing on the National List and include subcategories for the specific materials that are reviewed. As stated by the committee in the Recommendation:

The text of this listing failed to track the 1995 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." Footnoted:

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.

Conclusion

OTA supports the continued allowance of vitamins and minerals in NOP certified foods and the rational and safe addition of nutrients to foods in order to preserve a balance of nutrients in the consumer diet. We also support the maximum freedom of choice for organic consumers and we believe that organic products should be nutritionally equal to their conventional counterparts. The 1995 Board endorsed the fortification of organic foods with vitamins, minerals and accessory nutrients as deemed appropriate and we would like to see the organic sector continue to support this intent.

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. As the organic sector moves through the transition of Rule Change and/or the National List Process in response to the National Organic Program announcement of April 26th, 2010 we request that adequate time is provided for companies to bring their products into compliance.

Again, OTA thanks the National Organic Standards Board for the opportunity to comment and for carefully considering our comments.

Respectfully submitted,



Gwendolyn Wyard
Associate Director of Organic Standards and Industry Outreach
Organic Trade Association (OTA)

CC: Laura Batcha
Chief of Policy and External Relations
Organic Trade Association

Attachments:

OTA Task Force White Paper & Consumer Survey
Additional Nutrient Charts with Certified Product Categories

