December 23, 2012

Toni Strother, Agricultural Marketing Specialist
National Organic Program, USDA–AMS–NOP
1400 Independence Ave., S.W.
Room 2646–So., Ag Stop 0268
Washington, DC 20250–0268

RE: National Organic Program: Sunset Review (2012) for Nutrient Vitamins and Minerals

Comment on Docket number AMS-NOP–10–0083; NOP–10–09IR

Dear Ms. Strother:

Thank you for the opportunity to comment on the interim rule to continue the listing of nutrient vitamins and minerals on the National List for five years beyond Oct. 12, 2012.

The 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 represents hundreds of certified operations that will be affected by a final rule on Nutrient Vitamins and Minerals.

This interim rule continues the allowance for nutrient vitamins and minerals at section 205.605(b) and enables the organic sector to continue with the status quo until additional public comments are received and considered and a final rule is published.

The January 12, 2012, proposed rule would amend paragraph (b) of § 205.605 of the National List regulations that currently reads ''Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods'' to be revised as follows:

> ''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.''

Summary

OTA supports moving forward with a final rule that will continue the allowance of nutrient vitamins and minerals that have been reviewed and approved by the National Organic Standards Board (NOSB). Consistent with our March 2012 comments on the proposed rule, OTA continues to support the amended annotation in order to clarify what specific vitamins and minerals are allowed in National Organic Program (NOP) certified products.

However, OTA ***does not*** believe that the proposed two-year implementation period, applied across the

board to all products, will give certified operators a sufficient amount of time to reformulate or re-label affected products that are currently certified and sold in the marketplace. OTA strongly believes that the status of each petitioned nutrient needs to be taken into consideration. NOP's incorrect interpretation of U.S. Food and Drug Administration's (FDA's) fortification policy resulted in the use of a number of accessory nutrients that were petitioned to the National List, and a final ruling on a number of those petitioned nutrients is pending. Therefore, the outcome is uncertain, and does not provide operators with adequate information to help direct formulation changes.

Due to the number of unpredictable factors in the NOSB petition process and the unknown outcome of the NOP rulemaking process, OTA strongly requests that for nutrients that will no longer be allowed as a result of the final rule, the full process for adding each of these nutrients to the National List should be allowed to run. Once a final rule is issued for each successful nutrient, a two-year implementation period should then follow.

In other words, for products certified under NOP's incorrect interpretation of FDA's fortification policy, a compliance date with a two-year implementation period be set from:

1) The date of a final rule for a successfully petitioned substance affected by the proposed rule (i.e., final rule for the addition of L-methionine to the National List); OR

2) The date of a final rule or NOP action memorandum for substances that have been petitioned but not yet reviewed by NOSB (i.e., amino acids for pet food); OR

3) The date the January 12, 2012, proposed rule becomes final. This would apply to products containing nutrients that were rejected in the NOSB petition process and are **not** listed at 21 CFR 104.20, 101.9 or 107.100 (i.e. lutein, taurine, L-carnitine, lycopene, nucleotides, ascorbyl palmitate, and beta-carotene).

Any nutrient affected by this proposed rule that is not petitioned and in queue for NOSB review prior to the date the January 12, 2012, proposed rule becomes final would fall under the two-year implementation period set from that final rule date.

OTA offers the following more detailed comments.

Proposed Annotation

OTA continues to support the following annotation as written in the January 12, 2012, proposed rule:

> ''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 proposed annotation references three distinct lists of essential nutrients found in the FDA Code of Federal Regulations. Together they comprise a complete and updated list of the vitamins and minerals FDA considers essential in food and infant formula. Any other nutrient allowed in NOP certified products would need to be petitioned to the National List. OTA supports this approach because it's consistent with the intent of NOSB's 1995 recommendation on nutrient supplementation of organic foods, and it will delineate the exact vitamins and minerals that may be allowed in NOP certified products. This will result in a more certifiable and enforceable regulation.

The 1995 NOSB recommendation endorsed the fortification of organic foods with vitamins, minerals and accessory nutrients, but determined permitting fortification only in those instances where their use was appropriate and the nutrients had undergone complete NOSB review via the National List process. Such process was designed to allow for the discriminate use of inputs and ingredients that are essential and compatible with organic principles, but unavailable in organic or natural forms. OTA believes the proposed rule is clear and consistent with the intent of NOSB, and it should eliminate misinterpretation and uncertainty. As stated in the proposed rule, this will allow organic operations to make confident business decisions, and NOP to make consistent compliance decisions that, in turn, should allow consumers to feel confident about the organic products they are purchasing.

Implementation Period

AMS expects that a proposed two-year implementation period from the date the proposed rule becomes final will provide time for NOSB to complete its consideration of the petitions for substances affected by this action, and for AMS to conclude rulemaking to add substances to the National List. AMS believes that the implementation phase would also provide affected entities time to explore reformulation or relabeling of affected products. OTA disagrees with this assessment due to the fact that a final ruling for a number of nutrients will be released independently from the proposed rule under review.

The interim rule includes a table of nutrients that are used in organic products and would be prohibited from use under the proposed action, along with the status of the petitions. OTA appreciates the addition of this table and, to the best of our knowledge, believes it closely reflects the majority, if not all, of the ingredients that will be affected by the proposed rule. Since the time the interim rule was released, NOSB has voted on all but the amino acids petitioned for pet food. Therefore, while NOSB has mostly completed its process, we do not have a final ruling on a number of nutrients, and the vote on amino acids for pets is scheduled for the spring 2013 meeting.

Until a final rule is issued on a petitioned substance or until the petitioned substance is rejected at the NOSB level, certified operators cannot positively determine the reformulation or relabeling that would need to occur. At a minimum, reformulating a product will include sourcing and testing alternative ingredients, establishing product specifications, researching and developing the reformulated product, NOP certification review and approval, quality and cost analysis, consumer product trials, market analysis, and product launch. Relabeling includes label design, nutritional analysis and food nutrition facts development, regulatory compliance review and approval. This entire process usually takes 2 years at a minimum.

Without a final ruling on the petitioned substance(s) in question, operators are left guessing at the possible scenarios that might occur, and they would be prompted to invest time and resources on unknown outcomes. This is costly and quite frankly a waste of time when operators have, in good faith, developed, marketed and grown business in compliance with the regulations.

OTA strongly requests that for products certified under NOP's incorrect interpretation of FDA's fortification policy, a compliance date with a two-year implementation period be set from:

1) The date of the final rule for a successfully petitioned substance affected by the proposed rule (i.e., final rule for the addition of L-methionine to the National List); OR

2) The date of a final rule for substances that have been petitioned but not yet reviewed by NOSB (i.e., amino acids for pet food). If the petition is rejected by NOSB the date would be set from the release date of a NOP final action memorandum in response to NOSB; OR

3) The date the January 12, 2012, proposed rule becomes final. This would apply to products containing nutrients that were rejected in the NOSB petition process and are not listed at 21 CFR 104.20, 101.9 or 107.100 (i.e., lutein, taurine, L-carnitine, lycopene, nucleotides, ascorbyl palmitate, beta-carotene).

According to our request, the implementation would follow accordingly:

- Should the NOSB recommend the addition of the petitioned substance to the National List, such as the case with L-methionine, the implementation period would be set two years from the date a corresponding final rule for that nutrient is published.

- Should one or more of the ingredients fail the NOSB review process, such as lutein, the implementation period for bringing products containing any of those nutrients into compliance would be set two years from the date the final rule (as per the January 12, 2012, proposed rule) is published.

- Any nutrient affected by this proposed rule that is not petitioned and in queue for NOSB review prior to the date the January 12, 2012, proposed rule becomes final would fall under the two-year implementation period set from that final rule date.

This approach will provide certified operators with the time needed to reformulate and/or re-label products according to a definite outcome.

As pointed out in the proposed rule, the petition process does not provide a guarantee that a substance will be added to the National List. We also know that the petition process does not guarantee that the petitioned substance will be accepted in the form in which it was petitioned. NOSB may vote to include restrictions on the processing methods that may be used to manufacture the petitioned substance. This, in turn, may require the petitioner to reformulate the petitioned substance, and/or require another company to develop a compliant form that would be acceptable. The possibility and timeframe of this prospect are unknown, and the investment to do so hinges on multiple factors such as the desire of the petitioner or other manufacturer to develop an alternative, NOP acceptance of the NOSB recommendation, and the issuance of a final rule that may or may not be consistent with the NOSB recommendation and proposed rule.

Finally, OTA believes that a two-year implementation period may be adequate. However, we understand that there may be unforeseen circumstances and considerations. Therefore, we ask that special attention and careful consideration be given to the comments received on the time needed to reformulate and re-label affected products.

Consumer Preferences

In the proposed rule, AMS explains several factors that are expected to mitigate the potential impact the rule might have on sales of organic products. AMS makes the assumption that if some products are discontinued as a result of this proposed rule, some consumers will purchase, as an alternative, an organic product within the same category rather than a non-organic product. AMS also believes it is accurate to infer that some portion of purchases are motivated by perceived benefits of the organic certification rather than the nutrients added, which would decrease the estimated sales impact.

OTA points out that in some cases, an organic product within the same category does not exist.

Moreover, we believe that organic products should be nutritionally equal to their conventional counterparts, and that consumers should have the maximum freedom of choice. In order to accurately answer the question of consumer acceptance and desire for fortified organic foods and their compatibility with organic handling systems, a fact-based understanding of consumer preferences, expectations, and trends is necessary.

In 2011, OTA collaborated with *KIWI Magazine*[1] 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.[2]

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

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.

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[1] http://www.kiwimagonline.com/

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

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- 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.'

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.[3] 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%**

American shoppers are increasingly choosing fortified foods, and this includes organic shoppers as well. In addition to believing that consumers should have maximum freedom of choice when they are choosing organic foods, OTA does not want organic foods to be viewed by shoppers as "nutritionally inferior" to non-organic foods.

Cost of the Rule

As referenced in the proposed rule, OTA reported that the estimated economic impact of fortified organic product sales is approximately one-half billion dollars annually ($489,054,107). The estimate included retails sales of fortified products across all distribution channels as demonstrated by syndicated retail scan data and industry standard assumptions regarding unreported scan figures (Wal-Mart and Whole Foods Market and select unreported private label sales), as well as ingredient commodity sales to fortified products based on a standard assumption of the ratio of farm-gate fluid milk sales to retail scan sales. This figure is based on specific proprietary data/ UPC codes supplied and all products specifically not identified during the work of the task force. **Thus, as pointed out in the proposed rule, it should be considered a very conservative estimate**. The ability to more precisely identify the entire universe affected would reveal a much larger annual figure. OTA member feedback suggests an estimated economic impact of well over 1 billion dollars.

OTA stresses that the economic impact is not limited to handlers and processors alone. Disruption in availability of organic products on retail shelves has a direct impact on domestic and international

[3] SPINS scan Conventional (powered by Nielsen Scantrack) 52 Weeks Ending 10/02/10.

agricultural markets. To not supply consumers with this choice will limit the growth of the organic sector, domestic agricultural production, environmental stewardship, and farmer livelihoods.

Conclusion

In summary, OTA supports the continued allowance of NOSB approved 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 believe that organic products should be nutritionally equal to their conventional counterparts.

OTA believes that the amended annotation in the proposed rule will not only convey the intent of the codified listing by coherently and accurately stating which synthetic nutrient substances may be added to organic food and organic infant formula, but it will also improve the market for organic products by allowing consumers to choose organic foods that contain the essential vitamins and minerals necessary to ensure they are meeting their individual nutritional requirements throughout all phases of life. We urge NOP to complete the rulemaking process.

In regards to an adequate implementation period, 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. Considering the products and markets that have been developed over the past ten years, OTA believes that the implementation phase proposed in our comments will be absolutely necessary to adequately minimize disruption to the organic industry.

As stated earlier, in addition to the time needed for NOSB to consider petitions for substances that are affected by this proposed rule and for AMS to conclude rulemaking to add substances to the National List, operators ultimately need a ***final*** ruling on the ingredients that would be prohibited by the proposed rule so they can conduct product research and development, and reformulate and/or re-label ingredients and products according to a definite outcome.

Again, on behalf of our members across the supply chain and the country, OTA thanks NOP for the opportunity to comment.

Respectfully submitted,

Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association

cc: Laura Batcha
Executive Vice President
Organic Trade Association