

**National Organic Standards Board  
Handling Subcommittee  
Nutrient Vitamins and Minerals §205.605(b) Annotation Change - Discussion Document  
February 23, 2016**

## **Introduction**

The Handling Subcommittee would like to change the annotation for the listing for Nutrient Vitamins and Minerals. It has been acknowledged that it needs to change since the Federal Rule first came out, but there have been mixed opinions on how to change it. This Discussion Document covers the background on the issue and presents several options for changes to the annotation. Members of the Handling Subcommittee are not unanimous on any of these options but wish to explain them and solicit public input on the pros and cons of them.

## **Background and Relevant Areas of the Rule**

**Reference:** §205.605(b) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

**Technical Report:** [1995 TAP - Minerals](#); [1995 TAP - Vitamins](#); [Technical Report \(2015\) \(PDF\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2011 Handling Subcommittee Proposal](#); [04/2011 sunset recommendation](#), [10/2015 sunset review](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)), Proposed Rule published 01/12 2012 ([77 FR 1980](#)), Sunset Review 2012, Interim rule published 09/27/2012 ([77 FR 59287](#)).

**Sunset Date:** 10/21/2017

## Brief History of this issue

- In 1995 the NOSB added nutrient vitamins and minerals to the National List with the following annotation, “Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.”<sup>1</sup> A second recommendation was also passed entitled “Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.” This stated, “Upon implementation of the National Organic Program (NOP), 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 final rule that was published in 2000 (65 FR 13512) came out with the current annotation. It was recognized soon after that the cross reference to the FDA’s fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing is necessary.<sup>2</sup>

The existing annotation is not what the original NOSB recommended in 1995. In 2011, the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to

<sup>1</sup> NOSB, 1995. Final Minutes of the National Organic Standards Board Full Board Meeting Austin, Texas, October 31–November 4, 1995, available at:

<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

<sup>2</sup> 77 FR 1980 – NOP proposed rule from 2012.

the April 2011 NOSB meeting and the NOSB supported relisting with existing annotation for the 2012 sunset review.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamin and minerals. In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a [memo to the NOSB in April 2010](#) explaining this clarification.
- On January 12, 2012 a proposed rule was published in the Federal Register ([77 FR 1980](#)) to change the annotation to:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”  
(b) *Synthetics allowed*  
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.<sup>3</sup>
- This clarified that the "nutrients" that were not on these CFR sections had to be petitioned individually for the National List because this listing did not cover them.
- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule ([77 FR 59287](#)), which renewed without change the original listing, as per the NOSB April 2011 recommendation.
- In 2011 through 2013 many such items were petitioned. A few were recommended to be listed by the NOSB and most were not. No rulemaking has happened to add the recommended substances or clarify the current reference, so the prohibited ones are still in use and the recommended ones have not been added to the National List.
- In 2014 the Handling Subcommittee commissioned a new Technical Report in preparation for Sunset 2017 reviews. This was completed in February 2015. It clarifies a lot about which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.
- Both the TR and the proposed rule are required reading to understand this issue.

## **Discussion**

All members of the Handling Subcommittee agree that the proposed language in the 2012 proposed rule would change the title of the listing from "Nutrient Vitamins and Minerals" to " Vitamins and minerals. For food" is a preferred choice. Some believe in limiting the category further than what was proposed and some do not. In addition, the Handling Subcommittee believes that the past decisions of the NOSB regarding petitioned nutrients for infant formula needs to be acted upon by the NOP as soon as possible.

### **Option 1 for discussion:**

Some members of the Handling Subcommittee believe that the original intent of the NOSB is what should form the backbone of the listing and annotation for Vitamins of Minerals and, to achieve this, they have proposed three related annotations.

**Proposed Annotation #1: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed only when**

<sup>3</sup> 77 FR 1980 – NOP proposed rule from 2012.

**their use is required by law or to meet an FDA standard of identity in which they are incorporated.**

This has a lot of advantages:

- It is in alignment with all other international organic standards (and what we have now is not).
- (from the proposed rule 2012): 1. The authority citation for 7 CFR part 205 continues to read as follows: Authority: 7 U.S.C. 6501–6522. 2. Section 205.605(b) is amended by: A. Removing the listing for “Nutrient vitamins and minerals”. B. Adding a listing for “Vitamins and minerals”.
- With new information from the FDA and the Technical Report we can now spell out which exact fortifications and enrichments are required by law. They are:

**Standards of Identity in Title 21 CFR that require Nutrient Fortification <sup>4</sup>**

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.100 21 CFR 107.10	All nutrients known to be essential and listed therein
Margarine	21 CFR 166.110	Vitamin A
Milk	21 CFR Part 131	Vitamins A & D (required by some states)

**Examples of other specific regulations include the following:**

Food class	Regulation	Specific vitamins or minerals
Milk for Women, Infant and Children (WIC) program	7 CFR 246.10	Vitamins A & D
Soy-based beverage (milk alternative) for WIC	7 CFR 246.10	Vitamins A & D, calcium, magnesium, phosphorus, riboflavin, vitamin B12
Fruit juice for WIC	7 CFR 246.10	Vitamin C
Infant cereals (WIC)	7 CFR 246.10	Iron
Adult cereals (WIC)	7 CFR 246.10	Iron

There are many products out there that are currently fortified with synthetic vitamins and minerals that are not required to be. Consumers have repeatedly stated that they do not want synthetic ingredients in their organic food and that they should have the right to make informed decisions about their food choices. Nutrient supplementation is one of those choices that some consumers may choose but others would like to avoid. Therefore we propose a second annotation:

**Proposed Annotation #2: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic” (except as noted in annotation #1).**

- Some Handling Subcommittee members' hold the opinion that this is exactly why the "Made with organic" category was written into the rule. It enables products to be made with organic agricultural ingredients, but still have desirable synthetic ingredients added to them.

<sup>4</sup> Excerpted from [2015 TR, Nutrient Vitamins and Minerals](#)

- This lessens the economic burden for companies who would not have to re-formulate entirely, but only have to change their label to a Made with Organic claim.
- Consumers can easily understand this, contrary to some industry claims.

These two annotations would set the course straight for limiting synthetic vitamins and minerals in organic foods but there is one loose end from these changes. The recent TR points out that many of the Vitamins in use are made from fermentation processes and could be determined to be nonsynthetic. It also points out that biotechnology is being increasingly used in the production of some vitamins. See Evaluation Question #1 from the 2015 TR (lines 425- 459). Since we believe that the public's concern is primarily with synthetic vitamins and minerals, we suggest that the nonsynthetic forms should continue to be allowed, but this means placing them on §205.605(a). ACA's would have to determine which forms meet a nonsynthetic allowance, but the TR refers primarily to Vitamins D2, B2, B12, E, F, K, and C.

**Proposed Annotation #3: §205.605 (a) Vitamins and minerals, non-synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled Organic.**

#### **Option 2 for discussion:**

Some members of the Handling Subcommittee believe that the language in the 2012 proposed rule should be adopted for both the Organic and Made with Organic Categories of products.

**Proposed Annotation #4: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and “made with organic (specified ingredients or food group(s))”.**

- This removes the old incorrect 21 CFR citation and substitutes the correct ones for both adult food and infant formula.
- This has the least impact on companies with products that are already supplemented with vitamins and minerals.
- Consumers still have a choice to not purchase products with synthetic ingredients because they are listed on the label.

#### **Questions for Public Comment:**

1. Which of these options do you prefer, and why?
2. Is there another option that should be considered instead of these?
3. Are there mandatory international fortification requirements that should be taken into consideration for products being exported and, if so, how should the annotation be revised?

#### **Subcommittee Vote**

Motion to adopt the discussion document on Nutrient Vitamins and Minerals

Motion by: Zea Sonnabend

Second: Harold Austin

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0