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October 12th, 2010

The National Organic Standards Board
c/o Lisa Ahramjian, Executive Director
1400 Independence Avenue, SW
Room 2646 – So., Ag Stop 0268
Washington D.C. 20250-0268

RE: AMS-NOP-10-0068; NOP-10-08

Nutrient Vitamin & Minerals

Dear NOSB Handling Committee members:

Oregon Tilth supports the committees' efforts to seek more historical, scientific, and legal information on the supplementation of NOP certified foods. It's our understanding, as expressed in the 1995 NOSB Recommendation and corresponding meeting minutes, that the allowance of vitamins and minerals in certified foods was never intended to be a blanket allowance for supplementation, but rather *an allowance for vitamins, minerals and other nutrients as required by law or as recommended for enrichment and fortification by independent professional associations*.

It's also our understanding that the program in consultation with the FDA decided to reference 21 CFR 104.20 rather than the NOSB's recommended annotation because the NOSB's reference to "as recommended for enrichment and fortification by independent professional associations" was too vague.

Preamble at 90615

"The NOP, in consultation with FDA, considers 21 CFR 104.20 to be the most appropriate reference regarding nutritional supplementation for organic foods."

We believe that in many respects the reference to § 104.20 aligns with the thinking behind the 1995 Recommendation. As per the preamble to 21 CFR 104.20 Federal Register Vol. 45, No. 18 / Friday, January 25, 1980:

The fundamental premise underlying those guidelines is that food fortification should provide consumers with a reasonable benefit without contributing to nutritional imbalances in the diet and without misleading consumers into believing that the consumption of the fortified food per se will ensure a complete or nutritionally sound diet. In the absence of a unifying set of principles or guidelines, random and arbitrary fortification of some foods is likely to occur. This may result in the overfortification of the food supply with some nutrients such as vitamin c, which are inexpensive and technologically simple to add, and the

underfortification with others such as some of the trace minerals. A balance of the essential nutrients is biologically for proper nutrition; therefore a reasonable balance of essential nutrients in the food supply is desirable. In addition, overfortification of the food supply by random addition, and/or the addition of high levels, of some nutrients, such as vitamin D and the trace minerals, is undesirable because of the potential for toxicity.

Our concern is that somewhere between the intent of the Board and their recommended annotation (that wasn't accepted), the program's decision to reference 21 CFR 104.20 (containing a nutrient listing that hasn't been amended since January 1993), and the FDA clarification on the interpretation of 21 CFR 104.20, we have or will lose the ability to use certain vitamins, minerals, proteins or accessory nutrients that may be essential or at very least reasonably desirable.

The Handling Committee asked for input on six questions. We trust that our industry experts will provide the Board with answers to the questions on scientific and legal developments in the field of human nutrition, and we will hear from consumers on their preference for or against the fortification of foods certified under the NOP. One part of the regulatory question Oregon Tilth would like to address, in case it hasn't yet been brought to the Board's attention, is the discrepancy we see between 21 CFR 104.20(d)(3), the listing under 21 CFR 101.9(c), and the NOSB TAP for Vitamins and Minerals.

As mentioned earlier, the nutrient listing in **§ 104.20(d)(3) has not been amended since January 1993**. It differs from the nutrient listing in FDA's current nutritional labeling regulations (21 CFR Part 101) for adults and children 4 or more years of age. **21 CFR Part 101 was last amended in 2005**.

Statement of Purpose under 21 CFR 104.20:

To preserve a balance of nutrients in the diet, manufactures who elect to fortify foods are urged to utilize these principles when adding nutrients to food. **It is reasonable to anticipate that the U.S. RDA's as delineated in 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific U.S. RDA's as improved knowledge about human nutrient requirements and allowances develops.** The policy set forth in this section is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

21 CFR 101.9(c) establishes the declaration of nutrition information on the label and 101.9(c)(8)(iv) sets the RDIs and nomenclature established for the vitamins and minerals ***which are essential in human nutrition***.

The following nutrient vitamins and minerals are either allowed under 104.20(d)(3), or 101.9 (c), and/or they were named in the NOSB TAP for vitamins or minerals. The highlighted nutrients are not allowed in NOP certified products because they are not specifically listed under 104.20(d)(3).

Nutrient	§104.20(d)(3) Fortification Policy	§101.9(c)(8)(iv) Food Labeling	NOSB TAP for Vitamins and Minerals
*Protein	listed		
Vitamin A	listed	listed	listed
Vitamin C	listed	listed	listed
Calcium	listed	listed	listed
Iron	listed	listed	listed
Vitamin D	listed	listed	listed
Vitamin E	listed	listed	listed

Vitamin K		listed	listed
Thiamin	listed	listed	listed
Riboflavin	listed	listed	listed
Niacin	listed	listed	listed
Vitamin B6	listed	listed	listed
Folate	listed	listed	listed (folic acid)
Vitamin B12	listed	listed	listed
Biotin	listed	listed	listed
Pantothenic acid	listed	listed	listed
Choline			listed
Inositol			listed
Phosphorus	listed	listed	listed
Magnesium	listed	listed	listed
Zinc	listed	listed	listed
Iodine	listed	listed	listed
Copper	listed	listed	listed
Potassium	listed	listed	
Selenium		listed	
Manganese		listed	listed
Chromium		listed	
Molybdenum		listed	
Chloride		listed	listed
Sulfur			listed

Vitamin K, Manganese, and Chloride are listed under §101.9 (essential in human nutrition) *AND* were named in the NOSB TAP. **Molybdenum, Chromium, and Selenium** are listed under 101.9. **Choline, Inositol, and Sulfur** were recognized in the NOSB TAP on vitamins or minerals. None of the highlighted are listed under 21 CFR 104.20(d)(3).

***Protein** is listed under §104.20 and under §101.9(c)(7), however since protein is not listed under § 205.605(b) it is not allowed.

We are hoping that this information will fulfill at least part of the questions regarding history and legal developments in the federal regulatory system, and suggest that the NOSB *should* revisit its 1995 Recommendation.

Thank you for carefully considering Oregon Tilth's comments.

Respectfully submitted,

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Oregon Tilth, Inc.

Oregon Tilth, Inc. is a non-profit 501(c)(3) organization that supports and promotes biologically sound and socially equitable agriculture. Oregon Tilth offers educational events throughout the state of Oregon, and provides organic certification services to organic growers, processors, and handlers internationally. An NOP accredited certifier since 2002, Oregon Tilth currently certifies over 650 farms and ranches and over 600 handlers in more than 35 states affording us a broad perspective of current practices and challenges faced by organic producers and handlers. This perspective also extends to the anticipated successes and challenges that this discussion topic will affect upon them.

