National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Vitamins in aquatic plant production (B1, B12, and H)

[+]February 18, 2014

Summary of Proposed Action:

Synthetic vitamins B1, B12 and H are proposed to be added to the National List at 205.609 for use in production of aquatic plants. Section 205.609 of the National List will contain a list of synthetic substances for use in the production of aquatic plants.

Healthy plant growth in water and on land depends on the level of nutrients available in plant environment. Synthetic vitamins (B1, C and E) are presently on the National List at 205.601(j)(8) as plant or soil amendments. Vitamins B1 (Thiamine), Vitamin B12 (Choline), and Vitamin H are the only vitamins being petitioned and for use in organic aquatic plant production, and only for use in closed systems.

The manufacture of vitamins can be by chemical processes, fermentation or extraction depending on the specific vitamin. Fermentation can be synthetic or non-synthetic. Vitamins should not be considered persistent in marine environments. Adverse effects due to persistence are more likely to be seen in closed systems.

Synthetic vitamins are not specifically manufactured for use in aquatic plant production. However, the vitamins proposed for use in aquatic plants production are produced from the same type of processes and manufacturers of vitamins for organic livestock.

In reviewing whether vitamins are compatible with organic farming the subcommittee took into consideration the Organic Food Production Act (OFPA) which limits the use of synthetics to various categories, one of which is “pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins, and minerals.” Vitamins are listed in the OFPA at 6517(c)(1)(B)(i).

The NOP received the petition for the use of synthetic vitamins in aquatic plants on August 3, 2012. The Crops subcommittee deemed the petition sufficient on June 16, 2013; no technical review (TR) was requested. In October, 2013, the aquatic petitions were transferred to the Livestock Subcommittee to be considered as a group. The crops subcommittee did not request a TR because vitamins are already allowed at §205.603(d)(3) for livestock feed, and specific ones (B1, C, and E) are allowed for crops at §205.601(j)(8).TR references in this Checklist are from the TR dated April 29, 2013 requested by the livestock subcommittee for vitamin use in production of aquatic animals.

The NOSB seeks public input on the essentiality of the use of vitamins in aquatic plant production.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic or animal production and this proposal is based on NOSB Recommendations of Standards voted in 2007, 2008, and 2009.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x☐ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x☐ Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:** N/A

Subcommittee Action & Vote.

Classification Motion: Motion to classify vitamins (B1, B12, and H), as petitioned, as synthetic:

Motion by: Jean Richardson
Seconded by: Colehour Bondera
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list vitamins (B1, B12 and H) at §205.609 of the National List

Motion by: C. Reuben Walker
Seconded by: Jean Richardson
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation: None proposed

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation Notes:

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 18, 2014

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 1. Adverse impacts on humans or the environment? Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		Vitamins are dissolved in growing media for aquatic plants in very dilute solutions ranging from 0.4-0.02 ppm. Media and plant cultures are in containers, such as on-shore tanks and ponds. The petitioner does NOT seek allowance for synthetic vitamins for production of aquatic plants in public waters. (Petition page 2). It is unlikely that vitamin use or misuse will result in environmental impairment due to their short half lives in aquatic systems. (TR 972-973 and 807-829). Large amounts of vitamins released into open waters may result in promotion of algal blooms and red-tides (TR 986-987) and perhaps eutrophication (TR 1075-1079). Overall, accidental release of small amounts of vitamins into the environment is not assumed to pose any significant risk (TR 982-983).
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See 1 above. Industrial production of synthetic vitamins includes use of reagents and fermentation waste which can have negative environmental impacts, but no specific examples of such contamination are cited in TR (TR 945-987).
3. Are there any adverse impacts on biodiversity? (§205.200)		X		See 1 above.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		No (TR 541-548).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Overall vitamins should not be considered persistent in marine environments as these compounds readily decompose in oxic (oxygen rich) environments (TR 827-829).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		See 5 above and 7 below.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		See 5 above. The vitamins petitioned , Thiamine, Choline and Biotin are water soluble. The potential for toxicity is generally dependent on the vitamin's solubility properties. Water soluble vitamins (thiamine, riboflavin, pyridoxine, pantothenic acid, niacin, biotin, folic acid, choline, inositol, and ascorbic acid) are rapidly depleted and these vitamins do not bioaccumulate in animal fatty tissue. Lipid-soluble vitamins A, D, E, and K bioaccumulate in fatty tissue (TR 847-876). Literature on bioaccumulation or persistence of vitamins in aquatic environments is limited. In general lipid soluble vitamins are more likely to bioaccumulate in fatty tissues (TR 830-836). Adverse effects due to persistence will be more severe in closed systems (TR 805-806).
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See 1, 5, and 7 above. Limited information is available regarding potential for environmental or human health toxicity at the small levels used (TR 1045-1050).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		It is unlikely that vitamins used in closed containers during aquatic plant production would enter a terrestrial agro-ecosystem. No studies have been found indicating toxic effects of vitamins in soil dwelling organisms (TR 1030-1033). Overloading aquatic ecosystems with nutrients could potentially reduce BOD , but with good regulations in place negative impacts are unlikely from use in closed systems as petitioned.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See 1, 7, and 9 above. No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms (TR 1033).

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 2. Is the Substance Essential for Organic Production?: Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			There are 3 vitamins petitioned. Production methods vary. All three can be produced by fermentation, but are typically commercially produced by chemical processes (TR 553-554). Fermentation can be considered synthetic or non-synthetic (TR 785-786).
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X	X		See 2 above. Extraction from natural sources is widely considered inefficient and low yielding (TR 574-773).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		There are no known natural alternatives (Petition page 7) Vitamin B1 can be produced from many plant sources. Vitamin B7 can be produced from both plant and animal sources, including fish meal and fish solubles. Vitamin B 12 can be produced from animal and fish by-products.
6. Is there an organic substitute? [§205.600(b)(1)]		X		None.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X	X		See 5 above .
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		Little information was provided to be able to answer this question

NOSB Evaluation Criteria for Substances Added To the National List: Crops

Category 3. Is the substance compatible with organic production practices? Vitamins for aquatic plants

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Vitamins B1, C and E are presently on the National List at 205.601(j)(8) as plant or soil amendments. Vitamins are listed in the OFPA at 6517 (c) (1)(B)(i)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See 1 above.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds	X	X		Thiamine and biotin are sulfur containing. (TR 537-539).
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

Minority Opinion - Vitamins In aquatic plant production
February 21, 2014

A minority of the subcommittee suggested that the subcommittee adopt an annotation motion for plant vitamins use in aquaculture that set a 5-year expiration date on the listing, with a justification explaining that the specific time frame for an expiration date allows the Board to

monitor the use of the material, update its scientific and essentiality review, incentivize alternatives and continuous improvement, and vote on the continuation of use pending the receipt of a petition requesting that use be extended.

Support for the annotation is based on the following justification: Since this petition is being considered in the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time. Therefore, the NOSB needs to reconsider the approval in five years at the least. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to those in water receiving discharges or open water systems; alternatives derived from natural source; and compatibility with organic and sustainable agriculture. In particular, although the petitioner has stated that the vitamins would be used in closed systems and needed only for growth of starter cultures, there is nothing in the proposed listing from the subcommittee to restrict the use to starter cultures in closed systems. The review in 5 years provides an opportunity for the Board to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

In addition, the minority makes the following comments and additions to the majority checklist, which it believes does not provide a full assessment of environmental and health standards review required under the Organic Foods Production Act (OFPA): The petitioner has told the subcommittee that the vitamins will be used only in closed systems for starting cultures. The minority believes that this should be part of the annotation.

With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:

- Vitamin B1: Commercial production involves a six-step synthetic procedure beginning with ethyl 3-ethoxypropionate as the feedstock and reactants including ethyl formate, acetamidine hydrochloride, phosphorus(V) oxychloride, alcoholic ammonia, hydrobromic acid, and 4-methyl 5-hydroxyethyl thiazole. TR lines 594-600.
- A search of the patent literature revealed two methods for vitamin B1 (thiamine) production by fermentative methods that appear to use genetically engineered bacteria. TR lines 601-606.
- Vitamin B7 (H, biotin): The synthesis begins with fumaric acid as the starting material and involves 15 linear synthetic steps, including vicinal bromination of fumaric acid, benzylamine, oxalyl chloride, acetic anhydride, zinc, acetic anhydride, acetic acid, dihydrogen sulfide, potassium hydrosulfide, zinc/acetic acid, an appropriate Grignard reagent, hydrogen over palladium, hydrobromic acid, silver d-camphorsulfonate, sodium diethyl malonate, and hydrobromic acid. TR lines 660-672.
- Microbial fermentation methods have been developed to produce only the biologically active isomer of biotin. As an example, a microorganism of the genus Kurthia (bacteria) was developed with resistance through exposure to a mutagen, selecting lines capable of producing d-biotin under aerobic conditions (Hoshino, 2002). TR lines 673-679.
- MSDSs for several feedstock chemicals and other chemical reagents used in the synthesis of biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. TR lines 946-946.
- Vitamin B12. Microorganism fermentation is the exclusive commercial method of synthesizing vitamin B12. Some strains are genetically engineered. TR lines 770-773.
- All: The fermentative production of vitamins presents a slight risk of product contamination from genetic material in the fermentation broth and any chemicals used during processing. TR lines 918-920.
- If released to the water, most of the water-soluble vitamins are not expected to adsorb to suspended solids and sediment. TR lines 930-931.

- Many of the feedstock chemicals and reagents used in vitamin synthetic procedures are considered petrochemicals or may be obtained from genetically modified organisms (GMOs). Acetone, for example, is a commonly used chemical reagent derived from petroleum as well as from GMOs such as corn. TR lines 955-958
- Waste streams resulting from the fermentative production of vitamins may also pose risks to the environment. In general, the EPA assumes "no control features for the fermentor offgases, and no inactivation of the fermentation broth for the liquid and solid waste releases," suggesting that environmental exposure to these waste streams is likely. Some potential risks to the environment include the transfer of novel genes into crops, poisoned wildlife, and the creation of new and more potent viruses, in addition to a host of unknown risks. TR lines 959-966.
- Release of large amounts of vitamins into the environment may result in eco-toxic events, such as the promotion of algal blooms and red tides. TR lines 985-987.
- Unicellular photosynthetic algae require nutritional intake of vitamin B1 (thiamine), B7 (biotin), and B12 (cobalamin) (NAS, 1969). These vitamins, as well as other macro- and micronutrients, can be a limiting growth factor for environmentally beneficial and deleterious algae. TR lines 976-979
- Excessive vitamin loadings can lead to synergistic and/or antagonistic effects for the absorption and bioavailability of minerals and other trace nutrients. TR lines 1011-1012.
- Overloading aquatic ecosystems with nutrients, such as vitamins, could potentially lead to depletion of the dissolved oxygen content and eutrophication. This is commonly manifested through occurrences of algal blooms and red tides, fish kills, and overall loss of biodiversity from the aquatic system. TR lines 1075-1077.

With regard to checklist Category 2, Essentiality, the minority believes the following need to be considered:

- Vitamins B1, B7, and B12 may all be produced through fermentation. Vitamins B1 and B7 may also be produced through chemical reactions of synthetic chemicals. (See Category 1, question 2.)
- Natural forms are produced by plants, animals, and microorganisms.
- Natural sources of the three vitamins include:
    - **Vitamin B1:** Dried brewers yeast, wheat middlings, wheat mill run, rice bran, rice polishings, dried torula yeast, groundnut (peanut) meal, wheat bran, barley, dried fish solubles, cottonseed meal, soybean meal, linseed meal, dried distillers solubles, broad beans, lima beans, dried delactose whey, glandular meals (liver/kidney), green leafy crops, outer coat or germ of cereals.
    - **Vitamin B7:** Dried brewers yeast, dried torula yeast, dried distillers solubles, rapeseed meal, safflower seed meal, sunflower seed meal, whole hens eggs, rice polishings, dried brewers grains, liver and lung meal, rice bran, dried delactose whey, cottonseed meal, groundnut meal, soybean meal, dried skim milk, alfalfa meal, oats, sorghum, dried blood meal, dried fish solubles, fish meal, wheat bran, wheat mill run, legumes, green vegetables.
    - **Vitamin B12:** Animal by-products, liver, kidney, heart, muscle meats, fish meals, shellfish, meat and bone meal, condensed fish solubles, and poultry by-product meal. TR lines 1189-1192; 1207-1211; 1237-1238.

Under Category 3, Compatibility, the minority points out the following:

- Compatibility depends on how they are used—on routine basis, or occasionally, when needed.
- Synthetic vitamins are permitted for animals only when natural vitamins are not available in EEC, UK, Japan, and IFOAM standards. TR lines 495-525.
- It is not sustainable to depend on external synthetic inputs.