

**National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Vitamins in aquatic animal production**

June 17 2013

Reviewed January 21, 2014 - Minor formatting revisions only

Summary of Proposed Action:

Synthetic vitamins are proposed to be added to the National List at 205.611 for use in production of aquatic animals. Synthetic vitamins are presently approved at 205.603(d) (3) for use in organic, soil based, livestock production as "Vitamins for enrichment or fortification when FDA approved." Vitamins are listed in the OFPA at 6517 (c) (1) (B)(i).

Vitamins are essential for production of animals, and although feed consisting of fish meal, or ingredients such as soy, corn, or vegetable oils could be used to supply vitamins. Currently, synthetic vitamin forms provide a more readily available and consistent source of vitamins to ensure good health for organic livestock. In the case of nutrient requirements for fish and shrimp, the National Research Council (NRC) defines essential vitamin compounds as "required", and it is this group of 15 synthetic vitamins which are proposed for addition to the National List: Vitamin A; B1 (Thiamine); B2 (Riboflavin); B3 (Niacin); B5 (Pantothenic Acid); B6 (Pyridoxine); B7 (Biotin); B8 Choline; B9 (Folic Acid); B12 (Cobalamin); Inositol; Vitamin C; Vitamin D3; Vitamin E Tocopherols; and Vitamin K.

Manufacture of vitamins can be by chemical processes, fermentation or extraction depending on the specific vitamin. Fermentation can be synthetic or non-synthetic. Typically chemical processes are used to achieve consistent and balanced feed pre-mixes. While large spills during manufacture may result in algal blooms, the typical feeding of vitamins for fish production is not considered to pose environmental harm. Vitamins should not be considered persistent in marine environments. Adverse effects due to persistence are more likely to be seen in closed systems.

In considering alternative sources for the 15 vitamins petitioned, Vitamin E can be extracted from vegetable oils and a diet comprised of forage and fish oils is the most natural means of providing vitamins to carnivorous and omnivorous fish. However, the aquaculture industry is working to mitigate use of and possible depletion of wild fish if it continues to be used in large amounts as a feed source in aquaculture. Extraction from natural sources is widely considered inefficient and low yielding.

In reviewing whether vitamins are compatible with organic agriculture 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.

It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant 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 <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	x <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	x <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

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

Subcommittee Action & Vote,

Classification Motion: Motion to classify vitamins, as petitioned, as synthetic: Vitamin A, CAS #127-47-9; B1 (Thiamine), CAS # 59-43-8; B2 (Riboflavin), CAS # 83-88-5; B3 (Niacin), CAS # 59 67-6; B5 (Pantothenic Acid), CAS #137-08-6; B6 (Pyridoxine), CAS # 58-56-0; B7 (Biotin), CAS # 58-85-5; B8 (Inositol), CAS # 87-89-8; B9 (Folic Acid), CAS # 59-30-3; B12, (Cobalamin), CAS # 68-19-9; Choline, CAS # 67-48-1; Vitamin C, CAS # 50-81-7; Vitamin D, CAS # 67-97-0; Vitamin E, Tocopherols CAS # 59-02-9; and Vitamin K, CAS # 130-37-0.

Motion by: C. Reuben Walker
 Seconded by: Jean Richardson
 Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list vitamins as listed above at §205.611 of the National List

Motion by: C. Reuben Walker
 Seconded by: Jean Richardson
 Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation: None

Minority Opinion: see end of document

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 21, 2014

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

Category 1. Adverse impacts on humans or the environment? Vitamins (aquatic animals)

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		Vitamin pre-mixes are incorporated into feed at a rate of approximately 0.5%-1.5% (Petition page 3) and releases are assumed to pose no risk (TR 982-983). 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). It is unlikely that vitamins use or misuse will result in environmental impairment due to their short half lives in aquatic systems. (TR 972-973 and 807-829). 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). No direct interactions of vitamins and other aquatic animal feed additives have been identified (TR 991).
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 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 aquatic animal feed would enter a terrestrial agro-ecosystem (TR 1027-1028). No studies have been found indicating toxic effects of vitamins in soil dwelling organisms (TR 1030-1033). Vitamin D3 is used in a rodenticide (TR1071-1072). Overloading aquatic ecosystems with nutrients could potentially reduce BOD but this would negatively impact fish production and thus with good management can be avoided (TR1075-1079).
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).

Category 2. Is the Substance Essential for Organic Production? Vitamins (aquatic animals)

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	X		There are 15 Vitamins petitioned and the production methods vary. Some can be produced by fermentation or extraction from natural sources, 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 1 above. Of the 15 synthetic vitamins petitioned Vitamins A, D, E, and K are lipid (TR 852-853). Vitamin E, tocopherols is typically extracted from natural materials, i.e. vegetable oils (TR 779).

				Extraction from natural sources in widely considered inefficient and low yielding (TR 574-773).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See 1 above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		See 1 and 3 above and 9 below.
6. Is there an organic substitute? [§205.600(b)(1)]	X	X		Vegetable oil for Vitamin E, but not for the others petitioned.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		For some of the vitamins vegetable oils or fish oils can be used.
8. Are there any alternative substances? [§6518(m)(6)]	X	X		See 1 and 8 above and 9 below.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		When possible a diet comprised of forage fish is the most natural means of incorporating proteins and vitamins into diets of carnivorous and omnivorous fish (TR 1247-1249) but the fish industry is working to mitigate demand for wild fish as fish feed (TR 1277-1285).

Category 3. Is the substance compatible with organic production practices? Vitamins (aquatic animals)

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 are presently on the National List at 205.603(d) (3). 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			Vitamins enrich and fortify feed.
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		

This is a **proposal** by a Subcommittee of the National Organic Standards Board (NOSB). Proposals are posted for public comment and then may be voted upon by the full Board. They are not final Board recommendations or NOP policy.

<p>6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);</p> <p>copper and sulfur compounds</p>	X	X		Thiamine and biotin and vitamin K are sulfur containing. The other vitamins listed do not contain sulfur (TR 537-539).
<p>toxins derived from bacteria</p>		X		
<p>pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals</p>	X			
<p>livestock parasiticides and medicines</p>		X		
<p>production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers</p>		X		