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

August 22, 2013
***Reviewed and revised January 21, 2014**

Summary of Proposed Action:
Synthetic Tocopherols are proposed to be added to the National List at 205.611 for use in aquatic animal production as an anti-oxidant added to feed. Section 205.611 of the National List will contain the list of synthetic substances allowed in organic aquatic animal production.

Tocopherols were petitioned in 2012 by the Aquaculture Working Group for use in aquaculture livestock production. Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term "tocopherols" refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from plant products are often referred to as "mixed tocopherols" because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41). Tocopherols are mixed with fish oil, fishmeal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish (Hardy and Roley, 2000). Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E. Finally, oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000). Tocopherols are considered essential for the health of aquatic animals

Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" when rosemary extracts are not a suitable alternative (7 CFR 205.605[b])(TR lines 26-32).

Tocopherols are also affirmed as GRAS by the FDA when used as chemical preservatives (21 CFR 582.3890) and nutrients and/or dietary supplements (21 CFR 582.5890) in animal feeds in accordance with good manufacturing or feeding practice. No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. TR lines 464-466. "Tocopherols are currently permitted by Canadian, European, and Japanese Organic Standards, IFOAM and CODEX, although they may not specifically be permitted as antioxidants in livestock feed production.

In reviewing whether use of synthetic tocopherols is compatible with or essential to organic agriculture the subcommittee took into consideration the Organic Foods Production Act (OFP) which limits use of synthetics. Tocopherols are in the vitamin group listed at section 6517(c)(1)(B)(i).

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 the NOSB Recommendations of standards voted in 2007, 2008, and 2009. Therefore the livestock subcommittee recommends reassessment of this material when regulations for open and closed systems are in place.

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:**

Subcommittee Action & Vote

Classification Motion: Motion to classify tocopherols, as petitioned, as synthetic.
Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list tocopherols at §205.611 of the National List for use in aquatic livestock production as an antioxidant added to aquatic animal feed with the following annotation: Tocopherols derived from vegetable oils are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative.

Motion by: Jean Richardson
Seconded by: Mac Stone
Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): Tocopherols derived from vegetable oils are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative.

Basis for annotation: x☐ 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 January 21, 2014

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

Category 1. Adverse impacts on humans or the environment? Tocopherols (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		If solvents used in the manufacturing are released into the environment through waste streams, environmental contamination could occur. However, no sources were identified that discussed environmental contamination resulting from the manufacturing of tocopherols. (TR lines 498-501)
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		The extraction of tocopherols from vegetable oil byproducts may include one or more of the following chemical processes: esterification, saponification, solvent extraction, and/or crystallization using a solvent (TR 281-314). Physical separation methods may also be used during the extraction of tocopherols, and these include various distillation steps. Solvents used include: hexane, ethanol, isopropanol, acetone, isopentane, isohexane, and trichloroethylene (TR lines 282-284). Can also be made from a byproduct of vegetable oil refining (oils of soybean, canola, sunflower, corn, and cottonseed, some of which may be genetically engineered) (TR lines 289-292).
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		TR lines 451-450.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X			Excessive intake of tocopherols above the vitamin E requirement of fish could result in hypervitaminosis E, a condition of high storage levels of the vitamin in the fish which could result in toxic symptoms such as poor growth, toxic liver reaction, and death (De Silva et al., 2012; Halver, 2002) (TR lines 480-483).

6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Tocopherols exert their antioxidant properties by reacting with free radicals, so they are unlikely to persist. Oxidized tocopherols can be recycled in the presence of other antioxidants, however, and some of the metabolites of tocopherols can be toxic.[1]
7. 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 TR lines 393-439. The tocopherol level found in the flesh of a fish is related to the fish's total dietary intake of tocopherols (Sargent et al., 2002). The use of tocopherols as an antioxidant or vitamin supplement in aquatic animal feed will possibly increase tocopherol levels in those fish that consume the feed, with unknown effects on the human consumer (TR lines 522-524). No sources were identified that discuss adverse effects upon human health from the use of tocopherols as an antioxidant in aquatic or terrestrial animal feed. It is unlikely that the use of tocopherols as an antioxidant in aquatic animal feed would be harmful to human health. (TR lines 509-511)
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. (TR lines 464-466.)
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]			X	

Category 2. Is the Substance Essential for Organic Production? Tocopherols (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			TR lines 276-369. The 1995 Technical Advisory Panel (TAP) Report for Tocopherols, which

[1] Aalt Bast and Guido R.M.M. Haenen, 2002. The toxicity of antioxidants and their metabolites. Environmental Toxicology and Pharmacology 11 (2002) 251–258.

				reviewed the use of tocopherols as a food antioxidant, states that tocopherols are made via vacuum steam distillation of edible vegetable oil products (NOSB, 1995). (TR lines 285-287)
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			(TR lines 276-369.) Synthetics are added in extraction process. All of the methods found in the literature involve chemical processes. At the end of the process used to extract and purify tocopherols, the compounds remain in the same form as in the naturally occurring source materials. (TR lines 320-322) The petitioner provided a material safety data sheet (MSDS) for a product called Naturox® IPO Liquid (Kemin Industries, Inc.) which lists organic sunflower oil, lecithin, and rosemary extract as components of the mixed tocopherols formulation (Kemin Industries, Inc., 2008). The Joint Expert Committee on Food Additives (JECFA) specification for the food additive "mixed tocopherols concentrate" states that it may contain an edible vegetable oil added to adjust the required amount of total tocopherols (JECFA, 2006). Powdered forms of mixed tocopherols contain a carrier such as tapioca starch, gum acacia, and/or maltodextrin (Organic Technologies, 2009; NOSB, 1995). No additional sources were found that discuss possible additives to commercially-produced tocopherols for use as antioxidants in food or feed, including aquaculture feed products. (TR lines 55-63)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X	X		Naturally occurring tocopherols exist. But the petition is for synthetic tocopherols.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term "tocopherols" refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from

				plant products are often referred to as "mixed tocopherols" because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41)
6. Is there an organic substitute? [§205.600(b)(1)]	X			Organic Rosemary oil may work in some applications.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Rosemary extract, lecithin, vitamin C, natural sources of vitamin E (eg, wheat germ oil), and others (TR lines 531-583).
8. Are there any alternative substances? [§6518(m)(6)]	X			See 7 above.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			No sources were identified that discussed alternative practices that would make the use of an antioxidant unnecessary in aquatic animal feed (TR 595-597).

Category 3. Is the substance compatible with organic production practices? Tocopherols (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			Synthetic tocopherols are currently permitted for specific uses in organic livestock production and organic handling. Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" when rosemary extracts are not a suitable alternative (7 CFR 205.605[b])(TR lines 26-32).
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			Tocopherols are mixed with fish oil, fish meal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and

				thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish (Hardy and Roley, 2000). (TR lines 99-105) Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E.
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]	X			Oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000). (TR lines 107-109) Tocopherols are used to stabilize fishmeal and are required under law if fishmeal is to be transported.
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		See comments at Item 3 above.
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		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			Tocopherols are in the vitamin group
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 - Tocopherols in aquatic animal production
February 21, 2014

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, so the NOSB needs to reconsider the approval in five (5) years. The minority believes that there should be a five-year expiration date as an annotation. Current consideration of the material has raised issues relating to health or environmental impacts, especially relating to those relating to extractants, as well as alterative natural materials. The review in five (5) years provides an opportunity for the Board to monitor the use of the material, update its scientific and essentiality review, incentivize alternatives and continuous improvement, and vote on continued or modified use of the material under the same standard of review that is used to approve the material during its petition review, pending the receipt of a petition requesting the use be extended.

The minority also has concerns about the unnecessary presence of volatile synthetic solvents in tocopherols. The Livestock Subcommittee received a letter from Oh Oh Organics supporting the consistent availability of natural tocopherols extracted without synthetic solvents. The letter states,

> I have sold Non-GMO, non-solvent extracted tocopherol since 2005. Both BASF, an international ingredient manufacturer out of Germany and BTSA, a company specializing in non-GMO Tocopherols supply this material. It is consistently available and is broadly used in the food, cosmetic and household cleaning business. Additionally I have seen ISO certified documents for a supplier in China...so, I believe it available around the world.

The minority believes that the use of synthetic tocopherols is incompatible with organic agriculture because:

- It is inconsistent with use of vitamins in terrestrial animals, where they are restricted to use for, “enrichment or fortification when FDA approved.”
- It is a synthetic preservative.