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

National Organic Standards Board Livestock Subcommittee Petitioned Material Proposal Vitamins in Organic Aquatic Animals Production

June 17, 2013

Summary of Proposed Action:

The use of synthetic vitamins in organic aquatic animal production was petitioned by the Aquaculture Working Group (AWG). The National Organic Program (NOP) allows the use of vitamins in organic livestock production as feed additives, under §205.603(d)(3) as "Vitamins, used for enrichment or fortification when FDA approved."

Vitamins are essential for animals raised on land or in water. Natural vitamins are found in sources that include fish, fish oils, green leafy vegetables, soybean, and many livestock by-products. The commercial availability is a major impediment and concern. Synthetic vitamins can be processed via chemical and fermentation methods.

The use of synthetic vitamins should help reduce the harvesting of our fish populations worldwide. As our fish population declines, its can have a negative impact on individuals of various communities, countries, and cultures.

Most of the major standards for organic aquaculture allow the use of synthetic vitamins. These included the Canadian General Standards Board, European Economic Community Council (EEC), United Kingdom Soil Association Standards, Codex Alimentarius, International Federation of Organic Agricultural Movements (IFOAM). In the United States, synthetic vitamins are NOP approved for use in land-based livestock production. For consistency, the allowance for synthetic vitamins is fair and balance approach for meeting the essential nutrient demand of vitamins in aquatic animal diets, until viable non-synthetic vitamins sources are in the market place.

The Livestock Subcommittee has received a petition for the use of synthetic vitamins in aquatic animals feed on January 6, 2012. A Technical Report (TR) was requested by the subcommittee. The TR provided new and helpful information for the LSC and full NOSB to consider in the evaluation of synthetic vitamins in aquatic animals diets.

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

| | | Criteria | a Satisfie | ed? |
|----|-----------------------------------|----------|--------------|-------|
| 1. | Impact on Humans and Environment | X Yes | □ No | □ N/A |
| 2. | Essential & Availability Criteria | X Yes | \square No | □ N/A |
| 3. | Compatibility & Consistency | X Yes | \square No | □ N/A |

Substance Fails Criteria Category: None Comments: No criteria category failed.

Subcommittee Action & Vote

Classification Motion: Move to classify vitamins as petitioned for aquatic animals as synthetic

Motion by: Jean Richardson Seconded by: C. Reuben Walker

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Move to list vitamins as petitioned for aquatic animals on section 205.611 of the National

l ist

Motion by: C. Reuben Walker Seconded by: Mac Stone

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): None

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB June 17, 2013

NOSB Evaluation Criteria for Substances Added To the National List Livestock

Category 1. Adverse impacts on humans or the environment? Substance: Vitamins for 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)] | Х | X | | Environmental contamination could possibly occur; however, the risks are low when manufacturers exercise good standard operating procedures for vitamins production, use, and disposal. [See 2013 Vitamins for Aquatic Animals TR, pgs. 19-24] |
| 2. | Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)] | X | X | | The environmental risks are low when manufacturers exercise good standard operating procedures. [See 2013 Vitamins for Aquatic Animals TR, pgs. 19-24] |
| 3. | Does the substance contain inerts classified by EPA as "inerts of toxicological concern?" [§6517 (c)(1)(B)(ii)] | | Х | | According to the 2013 Vitamins for Aquatic Animals TR, pg. 24) it is unlikely that any of the petitioned vitamins would cause bioaccumulation in aquatic life. Practicing good aquatic animal husbandry practices for feeding intervals and volumes are approaches to mitigate potential harm to the environment and biodiversity. [See 2013 Vitamins for Aquatic Animals TR, pg. 24] |
| 4. | Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)] | | х | | Most of the chemical interactions of vitamins occur inside the aquatic animal body. The proper incorporation of the various vitamins in aquatic animals feed should bring about good health and negate or minimize any detrimental chemical interactions with other materials used. [See 2013 Vitamins for Aquatic Animals TR, pgs. 22-23] |
| 5. | Is there a toxic or other adverse action of | | | | ,, , |
| | the material or its breakdown products? [§6518(m)(2)] | X | Х | | See #3 |
| 6. | Is there persistence or concentration of | Χ | Χ | | |

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

| | Question | Yes | No | N/A | Comments/Documentation (TAP; petition; regulatory agency; other) |
|----|---|-----|----|-----|--|
| | the material or breakdown products in the environment? [§6518(m)(2)] | | | | See #3 |
| 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 | | No harmful effect is expected to result from the petitioned used (i.e. aquatic vitamin feed supplement). [See 2013 Vitamins for Aquatic Animals TR, pgs. 24-25] |
| 8. | Are there adverse biological and chemical interactions in the agroecosystem, including biodiversity? [§6518(m)(5)] | | X | | It is unlikely that adverse biological and chemical interactions in the agroecosystem environment would occur. [See 2013 Vitamins for Aquatic Animals TR, pg. 23] |
| 9. | Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)] | | Х | | See #8 |

NOSB Evaluation Criteria for Substances Added To the National List Livestock

Category 2. Is the Substance Essential for Organic Production? Substance: Vitamins for Aquatic Animals

| | Question | Yes | No | N/A | Comments/Documentation (TAP; petition; regulatory agency; other) |
|----|---|-----|----|-----|---|
| 1. | Is the substance agricultural? [§6502(1)] | | Χ | | |
| 2. | Is the substance formulated or manufactured by a chemical process? [§6502(21)] | X | | | Vitamins can be produced using chemicals, fermentation, excluded method, or extraction from natural materials sources. [See 2013 Aquatic Animals TR, pgs. 13-19]. (7 CFR 205.105) prohibits certain excluded methods, including use of genetically modified organisms (GMO) 2008 NOSB aquaculture recommendation - 205.252(j) (6) prohibits the use of any GMO or any organism produced by any other excluded method |
| 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)] | Х | | | See #1 |
| 4. | Is the substance created by naturally occurring biological processes? | | X | | See #1 |

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

| | Question | Yes | No | N/A | Comments/Documentation (TAP; petition; regulatory agency; other) |
|----|--|-----|----|-----|---|
| | [§6502(21)] | | | | |
| 5. | | X | х | | There are natural sources such as forage fish, wild caught fish, shrimp, zooplankton and a combination plant-based and animal based feeds. The best source is fish meal. However, the availability and fragile commercial supply make is a major impediment in formulating fish diets. See 2013 Aquatic Animals TR, pgs. 28-29]. |
| 6. | Is there an organic substitute? | | | | 29]. |
| | [§205.600(b)(1)] | Χ | Χ | | See #5 |
| 7. | Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)] | X | Х | | See #5 |
| 8. | Are there any alternative substances? [§6518(m)(6)] | Х | Х | | Vitamins are essential. Forage fish, wild caught fish, shrimp, zooplankton and a combination plant-based and animal based feeds. [See 2013 vitamins for Aquatic Animals TR, pgs. 28-29]. |
| 9. | Are there other practices that would make the substance unnecessary? [§6518(m)(6)] | Х | Х | | See #8. However, the issue of commercially availability and viable alternatives are major impediments. [See 2013 Vitamins for Aquatic Animals TR, pgs. 28-29]. |

NOSB Evaluation Criteria for Substances Added To the National List Livestock

Category 3. Is the substance compatible with organic production practices? Substance: Vitamins for 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)] | х | | | Synthetic vitamins are consistent with organic farming principles of several organic entities to include (1) European Union, (2) Canadian General Standards Board, (3) United Kingdom (UK) Soil Association, (4) IFOAM, and (5) Naturland Organics. [See 2013 Vitamins for Aquatic Animals TR, pgs. 11-13]. |
| | Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)] | Х | | | See #1. |
| 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)] | | Х | | |
| 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 | | Х | | |
| | toxins derived from bacteria | | Х | | |
| | pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals | Х | | | |
| | livestock parasiticides and medicines | | Х | | |
| | production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers | | Х | | |