PETITION (Revised) FOR LISTING
ON
NATIONAL LIST OF APPROVED AND PROHIBITED
SUBSTANCES
SEC. 2118. [7 U.S.C. 6517] NATIONAL LIST

Petitioner name: Aquaculture Working Group, % George S. Lockwood, Chair
Address: PO Box 345
Carmel Valley, CA 93924

Telephone number: 831-659-4145
Email address: GeorgeSLockwood@aol.com

Date of petition: January 6, 2012

Check applicable:

☐ § 205.609 Synthetic substances allowed for use in organic aquatic plant production.
☐ § 205.610 Nonsynthetic substances prohibited for use in organic aquatic plant production
☒ § 205.611 Synthetic substances allowed for use in organic aquatic animal production.
☐ § 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

Send to: National List Coordinator, National Organic Program,
USDA/AMS/TM/ NOP, Room 4008–So., Ag Stop 0268,
1400 Independence Ave., SW.,
Washington, DC 20250.

Summary of request:

Previous actions by NOSB and NOP have determined that various vitamins are substances allowed as a feed supplement or feed additive under § 205.237 Livestock feed.

This petition is a request for NOSB and NOP to determine that various vitamins qualify as feed supplements or feed additives for aquatic animals for listing on § 205.611 Synthetic substances allowed for use in organic aquatic animal production.

1. The substance’s chemical or material common name.

Vitamins, used for enrichment or fortification when FDA approved. These include, but are not limited to the following partial list:

Vitamin A,
Vitamins for Aquatic Animals
Revised submission January 6, 2012

B₁ (thiamine),
B₂ (riboflavin),
B₃ (niacin),
B₅ (pantothenic acid),
B₆ (pyridoxine),
B₇ (biotin and H),
B₈ (inositol),
B₉ (folic acid),
B₁₂ (Choline),
Vitamin C (ascorbic acid),
Vitamin D (various forms),
Vitamin E various (tocopherols), and
Vitamin K (menadione sodium bisulfate).

2. The manufacturer’s or producer’s name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.

Vitamins incorporated in fish feed are included in vitamin premixes containing 10-12 essential vitamins depending upon the species being fed. Three additional vitamins are added separately to the feed mixture, although for some species, only two are added because intestinal microflora produce sufficient quantities to supply the requirements of these fish species. There are various suppliers of vitamins and vitamin premixes, including but not limited to DSM Nutritional Products (formerly Roche).

There are no vitamins specifically manufactured for use in aquaculture feeds, with the exception of stable forms of ascorbic acid (vitamin C). In the case of stable ascorbic acid products, a compound such as a phosphate group or glucose is added to the second carbon or conventional ascorbic acid to prevent oxidation and loss of activity during feed manufacturing and storage.

The vitamins used in aquaculture feeds are the same vitamins, e.g., produced by the same processes and from the same manufacturers, as those used in human vitamin supplements and in feeds for livestock and companion animals.

Vitamin premixes for aquatic animals contain many of the same vitamins as are included in livestock feeds and supplements. The same vitamins will be included in feeds in organic aquatic animals as are now used in organic livestock feed. Please the letter in Exhibit 3 for further information.

As for specific information on the manufacturers of the ingredients in vitamin premixes, as stated in Exhibit 3, we are informed that vitamins are obtained from sources in a number of countries, including China. Manufacturing processes are proprietary.

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a descrip-
tion of the substance’s function in the product(s) \( e.g., \) ingredient, flavoring agent, emulsifier, processing aid).

Vitamin premixes are included as ingredients in feed pellets for aquatic animals at approximately 0.5% to 1.5% of feed pellet mass. They are not directly dissolved in growing water.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance’s rate and method of application must be described. If used for handling (including processing), the substance’s mode of action must be described.

For aquatic animals, vitamin premixes are included in feed pellets at a rate of approximately 0.5 to 1.5%.

Some aquatic animals such as catfish, are grown in ponds. Others, such as salmon, are grown in net pens. Rainbow trout are grown in raceways utilizing flow-through water. In aquaculture, there are a wide range of aquatic animals grown under different conditions.

Vitamins released into the environment, if anything, have a positive impact. There are no known harmful environmental impacts from vitamins. None are toxic. Any residual vitamins released into the environment will be at extremely low concentrations below any physiologically significant level, and are rapidly absorbed by microorganisms or degraded.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.

As indicated in B.2., there are a number of sources for vitamin premix packages for fish feed pellets, including but not limited to DSM Nutritional Products.

Vitamins are obtained from sources in a number of countries, including China. Manufacturing processes are proprietary. Please see letter from DSM Nutritional Products copied in Exhibit 3.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.

In livestock, under § 205.603 (d) as feed additives (3) “Vitamins are allowed for use for enrichment or fortification when FDA approved.”

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

Vitamins added to animal and fish feeds must be approved by the U.S. Food and Drug Administration (FDA). State regulatory approval is also required, generally
by Departments of Agriculture in each state, although for vitamins, approval is limited to registration. Vitamins (forms and products) used in animal and fish feeds are classified as Generally Recognized As Safe (GRAS) by the FDA and therefore not subject to additional regulatory oversight. Please see Exhibit 2 for FDA references.

There are few international organizations with organic aquaculture standards. It appears that some await the lead of USDA in placing the 2009 recommendations of NOSB into the Final Rule.

Canadian draft aquaculture standards consider vitamins used in aquaculture the same as vitamins used in livestock and provide:

Vitamin - Used for enrichment or fortification of livestock feed. Synthetic vitamins may be used if non-synthetic sources are not commercially available.

In the United Kingdom, Soil Association Organic Standards June 2011 include:

30 Aquaculture
30.8 Feeding organic stock
30.8.6 With our approval, you may use vitamins and mineral supplements not of natural origin

Naturland in Germany considers vitamins in aquaculture as the same as vitamins in livestock.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.

   Please see Exhibit 2 for Vitamin References from OMRI, including references to Association of American Feed Control Officials (AAFCO) numbers. These references are examples only, and may not include all vitamins that may be necessary for aquatic animals.

9. The substance’s physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/ or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

   Please see prior petitions for vitamin additives in livestock.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

   We are informed that MSDS are not required for feed ingredients under applicable laws and are not normally provided.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which
present contrasting positions to those presented by the petitioner in supporting the substance’s inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

Please see: NRC (National Research Council), 2011. Nutrient Requirements of Fish and Shrimp. National Academy Press, Washington, D.C. 376 pp. This document is discussed in 12. below. Dr. Ron Hardy, a member of this Aquaculture Working Group, was chair of the international committee of fish nutrition experts that produced this document for the National Research Council. There are no contrasting positions regarding the essentiality of vitamins in the diets of fish, both farmed and wild.

12. A “Petition Justification Statement” which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.609 and 205.611
   • Explain why the synthetic substance is necessary for the production or handling of an organic product.

   Vitamins are essential nutrients for all forms of animal life to maintain normal body functions, such as growth, maturation and resistance to disease. Vitamin deficiencies resulting from inadequate intake cause well-defined clinical diseases and well as general signs of illness including poor growth and increased disease susceptibility.

   It is a well established organic principle that it is preferable to provide healthy living conditions that foster wellness and avoid sickness rather than to treat sick animals, and it is well established that adequate vitamin intake is essential to the good health of aquatic animals. If vitamins are not supplemented to aquaculture feeds, clinical signs of deficiency result, demonstrating that levels of vitamins supplied by feed ingredients are insufficient to meet dietary vitamins for all farmed species of fish.

   • Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

   There are no known natural alternatives for vitamins in aquaculture systems. As mentioned above, feed ingredients used in animal and/or fish feeds do not contain sufficient levels of vitamins to supply their dietary requirements, making it necessary to supplement feeds to prevent vitamin deficiency conditions and associated diseases as well as infectious diseases. The same synthetic vitamins used in aquaculture are allowed on the National List for organic livestock.
• Describe the beneficial effects to the environment, human health, or farm eco-
  system from use of the synthetic substance that support its use instead of the use
  of a non-synthetic substance or alternative cultural methods.

  Properly used, these substance can positively effect the health of aquatic
animals, human health and farm ecosystems. There are no substitute sub-
stances, nor alternative culture methods.

13. A “Confidential Business Information Statement” that describes the specific required
  information contained in the petition that is considered to be confidential business infor-
  mation or confidential commercial information and the basis for that determination.

  This petition does not contain any confidential business information.

Conclusions

Vitamins are essential for the healthy production of aquatic animals. They are
  safe, provide no environmental risks, and there are no natural alternatives.

  Previous actions by NOSB and NOP have determined that vitamins are allowed as
additives in livestock feed and are included in the National List for livestock in § 205.603
(d) as feed additives (3) as

    “Vitamins are allowed for use for enrichment or fortification when
    FDA approved.”

  This petition is a request for NOSB and NOP to determine that vitamins qualify as
  feed additives for aquatic animals for listing on § 205.611 Synthetic substances allowed
for use in organic aquatic animal production. This petition seeks a similar allowance with
an identical annotation for vitamins as feed additives for aquatic animals.

Aquaculture Working Group
  George S. Lockwood, Chair
# Exhibit 1

**Example Product Labels**

**Vitamin Premix Products for Aquatic Animal Feed**

**VITAMIN PREMIX; ARS 702**

FOR COOKING EXTRUDED PRODUCTS

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<tr>
<th>.5% inclusion</th>
<th>Common Sources</th>
<th>$/g</th>
<th>$/kg pm</th>
<th>Activity mg/g</th>
<th>Premix Conc. g/kg</th>
<th>Premix activ./kg</th>
<th>ARS Diet conc / kg diet</th>
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<td>3243 2400 0.85 0.74 0.83 0.74 a - Gabaudan and Hardy, 2000</td>
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<td>4.092</td>
<td>1,000</td>
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<td>13200.000</td>
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<td>0.1363</td>
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<td>0.470</td>
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a - Gabaudan and Hardy, 1994
b - Gabaudan and Hardy, 2000
c - Anderson and Sunderland, 2002
d - Marchetti et al, 1999
e - Li et al (1996)
# VITAMIN PREMIX; ARS 702
## FOR COOKING EXTRUDED PRODUCTS
### .5% inclusion

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| cost/kg premix | 9.3512 |

| Wheat flour | 968.568 |

1000.000

a - Gadient and Fenster, 1994
b - Gabaudan and Hardy, 2000
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## VITAMIN PREMIX; ARS 702
FOR COOKING EXTRUDED PRODUCTS; adjusted for processing and storage losses

<table>
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<th>Common Sources</th>
<th>$/g</th>
<th>$/kg pm</th>
<th>Activity mg/g</th>
<th>Premix Conc. g/kg</th>
<th>Premix activ. kg</th>
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<th>Composite retention %</th>
<th>After Losses Diet conc. / kg diet</th>
<th>93 NRC Trout / kg</th>
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<td>Vit. A palmitate; 500 IU/mg</td>
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<td>Wheat flour</td>
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- **Vitamin Premix; ARS 702**
- Revised submission January 6, 2012

<table>
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<th>Vitamin Premix; ARS 702</th>
<th>For Cooking Extruded Products; adjusted for processing and storage losses</th>
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<td>Cost/kg premix</td>
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<td>Total Cost</td>
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Vitamins for Aquatic Animals
Revised submission January 6, 2012

Exhibit 2
Vitamin References from Organic Materials Review Institute (OMRI)¹

Vitamin A
Carotene Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5245
Cod liver oil Allowed with Restrictions
AAFCO: 90.1 FDA: n/a
Cod liver oil with added vitamin A and D Allowed with Restrictions
AAFCO: 90.2 FDA: n/a
Vitamin A Allowed with Restrictions
AAFCO: n/a FDA: 582.5930
Vitamin A acetate Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5933
Vitamin A and D oil Allowed with Restrictions
AAFCO: 90.6 FDA: n/a
May not come from slaughter sources.
Vitamin A oil Allowed with Restrictions
AAFCO: 90.3 FDA: n/a
May not come from slaughter sources.
Vitamin A palmitate Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5936
Vitamin A propionate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
Vitamin A supplement Allowed with Restrictions
AAFCO: 90.14 FDA: n/a

Vitamin B complex
Inositol Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5370

Vitamin B1 (Thiamine)
Thiamine Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5875
Thiamine hydrochloride Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5875
Thiamine mononitrate Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5878

Vitamin B12 (Cyanocobalamin)
Cyanocobalamin Allowed with Restrictions
AAFCO: n/a FDA: 582.5945
May not be produced by excluded methods (GMOs).

Vitamin B12 supplement Allowed with Restrictions
AAFCO: 90.11 FDA: n/a
May not be produced by excluded methods (GMOs).

Vitamin B2 (Riboflavin)
Riboflavin Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5695
AAFCO refers to ‘crystalline riboflavin commercial feed grade.’
Riboflavin supplement Allowed with Restrictions
AAFCO: 90.13 FDA: n/a
Riboflavin-5-phosphate Allowed with Restrictions
AAFCO: 90.26 FDA: 582.5697

Vitamin B3 (Niacin)
Niacin supplement Allowed with Restrictions
AAFCO: 90.16 FDA: n/a
May not come from slaughter sources.
Niacin, Nicotinic acid Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5530
Niacinamide, nicotinamide Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5535

Vitamin B5 (Pantothenic acid)
Calcium pantothenate Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5212
Sodium pantothenate Allowed with Restrictions
AAFCO: n/a FDA: 582.5772

Vitamin B6 (Pyridoxine)
Pyridoxine hydrochloride Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5676

Vitamin B7 (Biotin)
Biotin Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5159
Vitamin B9 (Folic acid)
Folic acid, crystalline
folic acid feed grade Allowed with Restrictions
AAFCO: 90.25 FDA: n/a

Vitamin C
Ascorbic acid Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5013
Ascorbyl palmitate Prohibited
AAFCO: 18.1 FDA: 582.3149
Chemical preservative, not a nutrient.
Calcium ascorbate Allowed with Restrictions
AAFCO: 90.25 FDA: 582.3189
Calcium-L ascorbyl-2-monophosphate, magnesium L-ascorbyl-2 phosphate, L-ascorbyl-2-sulfate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
Erythorbic acid Allowed with Restrictions
AAFCO: 90.25 FDA: 582.3041
Iso-ascorbic acid.
L-ascorbyl, 2-polyphosphate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
L-ascorbyl-2-sulfate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
AAFCO & FDA limit to aquatic species (Salmon, trout, catfish, shrimp, and tilapia).
Magnesium L-ascorbyl-2 phosphate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
AAFCO & FDA limit to fish feeds only.
Sodium ascorbate Allowed with Restrictions
AAFCO: 90.26 FDA: n/a

Vitamin Choline
Betaine Allowed with Restrictions
AAFCO: 90.17 FDA: n/a
Hydrochloride or anhydrous. May not come from slaughter sources (stearyl betaine).
Choline bitartrate Allowed with Restrictions
AAFCO: 90.26 FDA: 582.5250
Choline chloride Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5252
Choline pantothenate Allowed with Restrictions
AAFCO: 90.25 FDA: n/a
Choline xanthate Allowed with Restrictions
Vitamins for Aquatic Animals
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AAFCO: 90.25 FDA: 573.300
Ferric choline citrate Allowed with Restrictions
AAFCO: 90.26 FDA: 582.5250

Vitamin D
Cholcalciferol
(D-activated animal sterol) Allowed with Restrictions
AAFCO: 90.7 FDA: n/a
May not be from slaughter byproducts.
Cod liver oil with added 
vitamin A and D Allowed with Restrictions
AAFCO: 90.2 FDA: n/a
Ergocalciferol
(D-activated plant sterol) Allowed with Restrictions
AAFCO: 90.8 FDA: n/a
Vitamin D oil Allowed with Restrictions
AAFCO: 90.5 FDA: n/a
Vitamin D2 Allowed with Restrictions
AAFCO: n/a FDA: 582.5950
May not be from slaughter byproducts.
Vitamin D2 supplement Allowed with Restrictions
AAFCO: 90.4 FDA: n/a
May not be from slaughter byproducts.
Vitamin D3 (cholcalciferol) Allowed with Restrictions
AAFCO: 90.7 FDA: 582.5953
May not be from slaughter byproducts.
Vitamin D3 supplement Allowed with Restrictions
AAFCO: 90.15 FDA: n/a
May not be from slaughter byproducts.

Vitamin E
α-Tocopherol acetate
Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5892
Tocopherols
Allowed with Restrictions
AAFCO: 90.25 FDA: 582.5890
Vitamin E supplement
Allowed with Restrictions
AAFCO: 90.12 FDA: n/a

Vitamin K
Menadione dimethylpyrimidinol bisulfite Allowed with Restrictions
AAFCO: 90.25 FDA: 573.620
FDA and AAFCO limits rates: Chickens and turkeys, 2g/ton of feed; Swine: 10g/ton of feed. NRC does not recommend for ruminants. May not come from slaughter byproducts.

**Menadione nicotinamide bisulfite**  
*Allowed with Restrictions*  
AAFCO: 90.25 FDA: 573.625  
FDA and AAFCO limits rates: Chickens and turkeys, 2g/ton of feed; Swine: 10g/ton of feed. May not come from slaughter byproducts.

**Menadione sodium bisulfite complex**  
*Allowed with Restrictions*  
AAFCO: 90.25 FDA: n/a  
AAFCO & FDA limit rate: Chickens and turkeys, 2g/ton of feed.
Exhibit C
Correspondence from DSM

Date
January 5, 2012

DSM Nutritional Products
395 Waydom Drive
Ayr, Ontario N0B 1E0
Canada

phone (519) 624-2789
fax (519) 623-4849
tamara.macdonald@dsm.com

DSM vitamin/mineral mixes for organic animal ag production

To Whom It May Concern:

You have inquired about our vitamin premixes used as feed ingredients in conventional livestock production in the United States, and our vitamin premixes use in organic livestock production. You have also inquired about our vitamins used in aquaculture.

Please be advised that we use the same vitamin and micro-nutrient premixes for conventional livestock that we include in our premixes for aquatic animals. Likewise, our intention is to provide the same vitamins and micro-nutrients for organic aquaculture as we now do for organic livestock use.

You have also requested specific information on the manufacturers of the ingredients in our vitamin and micro-nutrient premixes. Please be informed that we obtain our many vitamins and individual micro-nutrients from a wide range of sources in a number of countries, including China. In most cases, manufacturing processes are proprietary.

We will exercise the same diligence with vitamins and micro-nutrient ingredients for organic aquaculture feeds as we now exercise for organic livestock feeds in compliance with USDA organic production standards.

Kind regards

Tamara M. Macdonald, M.Sc (Agr.)
Nutritional Services Specialist

Registered as DSM Nutritional Products Canada Inc.