

PETITION 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: August 3, 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 vitamins are allowed in organic crop production under:

- § 205.601 Synthetic substances allowed for use in organic crop production
(j) As plant or soil amendments.
(8) Vitamins, B₁, C, and E.

This petition is a request for NOSB and NOP for listing on § 205.609 Synthetic substances allowed for use in organic production of aquatic plants in:

- “§ 205.609 Synthetic substances allowed in organic aquatic plant production
(x) Vitamins, B₁, B₁₂, and H.

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

Vitamins:

- B₁ (thiamine)
- B₁₂ (Choline)
- H (Biotin and B₇)

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.

There are various suppliers of vitamins, including but not limited to DSM Nutritional Products (formerly Roche).

There are no vitamins specifically manufactured for use in aquatic plant production. Vitamins used in aquatic plant production 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 terrestrial livestock and aquatic animals.

As for specific information on the manufacturers of the ingredients in vitamin pre-mixes, 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 description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).

Vitamins B₁, B₁₂, and H are dissolved in growing media for aquatic plants in very dilute solutions ranging from 0.4 to 0.02 parts per million (ppm). Media and plant cultures are in containers, such as on-shore tanks and ponds. This petition does not seek allowance for synthetic vitamins to treat aquatic plants in public waters.

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.

In aquaculture, there are a wide range of aquatic plants grown under different conditions from microscopic microalgae to large kelp macroalgae. Vitamins B₁, B₁₂, and H are maintained at levels of 0.4 to 0.02 parts per million (ppm).

Vitamins in growing media that may be released into the environment would have a positive impact. There are no known harmful environmental impacts from micronutrients when used in the prescribed amounts. None are toxic at these levels. Any residual vitamins released into the environment will be at extremely low concentrations below any physiologically significant level, and are rapidly absorbed by microorganisms and 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 vitamins B₁, B₁₂, and H for aquatic plants, 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 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.”

In crop production, under § 205.601 Synthetic substances allowed for use in organic crop production (j) As plant or soil amendments. “(8) Vitamins, B₁, C, and E.”

Organic Materials Review Institute (OMRI):

Vitamins

Status: Allowed

Class: Crop Fertilizers and Soil Amendments, Crop Management Tools and Production Aids

Origin: Synthetic/Nonsynthetic

Description:

Nonsynthetic sources of all vitamins and synthetic sources of vitamins B₁, C, and E may be used in certified organic crop production.

NOP Rule: 205.601(j)(8)

Vitamin B1

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

May be derived from thiamine hydrochloride and thiamine mononitrate. See also VITAMINS and Appendix A: Livestock Vitamins and Minerals.

NOP Rule: 205.237(a), 205.237(b)(2) & 205.603(d)(3)

Thiamine Hydrochloride

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

Source of vitamin B₁. See also VITAMINS.

NOP Rule: 205.237(a), 205.237(b)(2) & 205.603(d)(3)

Vitamin B12

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

May be derived from cyanocobalamin. See also VITAMINS and Appendix A: Livestock Vitamins and Minerals.

NOP Rule: 205.237(a), 205.237(b)(2) & 205.603(d)(3)

Cyanocobalamin

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

Source of vitamin B12. See also VITAMINS.

NOP Rule: 205.237(a), 205.237(b)(2) & 205.603(d)(3)

Biotin

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

See also VITAMINS and VITAMIN B COMPLEX.

NOP Rule: 205.237(a), 205.237(b)(2) & 205.603(d)(3)

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.

There are no EPA, FDA, or State regulations governing the use of vitamins for the production of aquatic plants.

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

EC apparently has no regulations for the use of vitamins in the production of aquatic plants.

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.

There is no reference to any vitamins in culturing aquatic plants.

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

This restriction applies to aquatic animals. There is no apparent restriction on the application of vitamins for aquatic plants.

Naturland in Germany considers vitamins in aquaculture as the same as vitamins in livestock but has no reference to their use in culturing aquatic plants.

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 do not include all vitamins that may be necessary for aquatic plants such as Vitamin H (biotin).

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.

It is unknown to petitioner what interactions, including toxicity, occur with vitamins B₁, B₁₂, and H and other substances. These vitamins are in regular use in human and animal health, and have a long history in organic production. In addition, the levels of use are very low (see #4 above).

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. However, MSDS for certain vitamins employed in culturing aquatic plants are:

Vitamin B 1 (Thiamine) see:

<http://www.sciencelab.com/msds.php?msdsId=9925232>

Vitamin B12 (Cyanocobalamin) see:

<http://www.sciencelab.com/msds.php?msdsId=9927143>

Vitamin H (biotin) see: http://www.pharma-chemical.com/detail_119.html .

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.

The two leading papers that develop the necessity of vitamins in the culture of aquatic plants are:

Provasoli, L., J. J. A. McLaughlin and M. R. Droop (1957)
The Development of Artificial Media for Marine Algae
Biomedical and Life Sciences, Archives of Microbiology
Volume 25, Number 4, 392-428, DOI: 10.1007/BF00446694

Guillard, R.L. 1975. Culture of phytoplankton for feeding marine invertebrates, p. 29 - 60. In: P.B. Smith (ed) Culture of Marine Invertebrates. Plenum Press, New York.

Other papers on this subject include:

Dupuy, J.L., N.T. Windsor and C.E. Sutton. 1977. Manual for Design and Operation of an Oyster Seed Hatchery for the American Oyster, Special Report No. 142 in Applied Marine Science and Ocean Engineering of the Virginia Institute of Marine Science, Gloucester Point, Virginia

Richmond, Amos ed., Handbook of Microalgal Culture: Biotechnology and Applied Phycology. 2008, John Wiley and Sons

Stein, J.R.. 1973 Handbook of Phycological Methods, Cambridge University Press, Cambridge, England.

United Nations Food and Agriculture Organization

The hatchery culture of bivalves: a practical manual... Part 3 Hatchery operation: culture of algae Table 3: Guillard's F/2 media used for culturing algae in bivalve hatcheries from Guillard (1975).

<http://www.fao.org/docrep/007/y5720e/y5720e08.htm>

There are no contrasting positions regarding the essentiality of vitamins in the culture of aquatic plants.

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 B₁, B₁₂, and H are essential for aquatic plant life to maintain normal physiological functions, such as growth, maturation and resistance to disease. Vitamin deficiencies resulting from inadequate intake result in unhealthy cultures, often with sudden die-offs, or crashes, well as poor growth and increased disease and parasite 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 cultures, and it is well established that adequate vitamin intake is essential to the good health of aquatic plants. If vitamins are not supplemented to aquatic plant growth media, signs of deficiency result, demonstrating that levels of vitamins supplied in the source water and through

supplements are insufficient to meet dietary vitamins needs for farmed species of aquatic plants. In many cases the entire culture of algae dies.

- 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 B₁, B₁₂, and H in plant aquaculture systems. As mentioned above, normal culture waters used in plant growth media do not contain sufficient levels of vitamins B₁, B₁₂, and H to supply physiological requirements, making it necessary to supplement culture media to prevent vitamin deficiency conditions and associated diseases.

- Describe the beneficial effects to the environment, human health, or farm ecosystem 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 plants, aquatic animals, human health and farm ecosystems. There are no substitute substances, 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 information or confidential commercial information and the basis for that determination.

This petition does not contain confidential business information.

Conclusions

Vitamins B₁, B₁₂, and H are essential for the healthy production of aquatic plants. 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 plant or soil amendments, and are included in the National List for crops in:

- § 205.601 601 Synthetic substances allowed for use in organic crop production
- (j) As plant or soil amendments.
- (8) Vitamins, B₁, C, and E.

This petition is a request for NOSB and NOP for listing on § 205.609 Synthetic substances allowed for use in organic production of aquatic plants in:

- “§ 205.609 Synthetic substances allowed in organic aquatic plant production
- (x) Vitamins B₁, B₁₂, and H.”

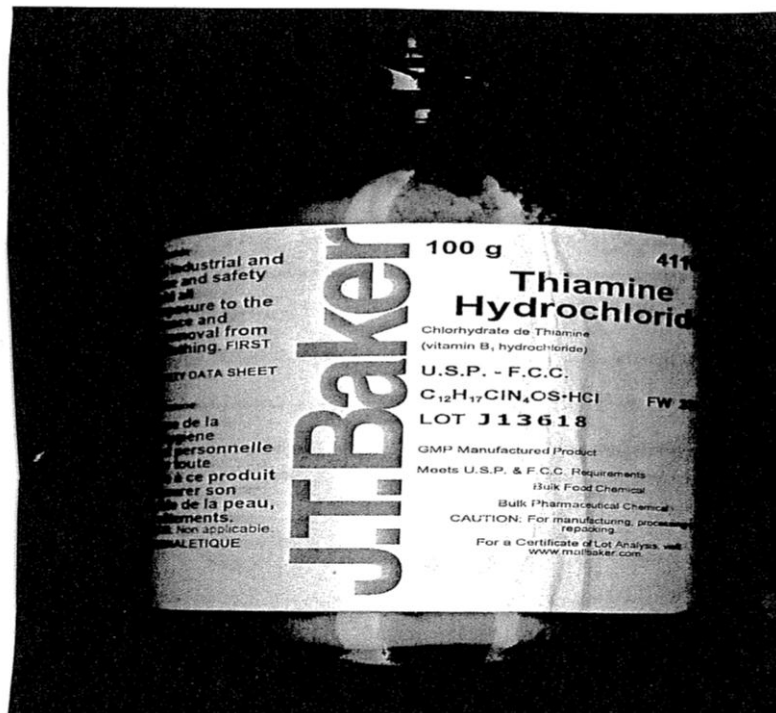
Aquaculture Working Group
George S. Lockwood, Chair

Exhibit 1

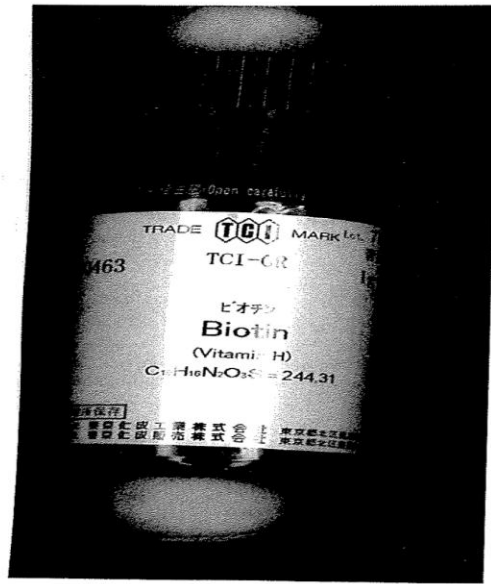
Example Product Labels

For product information for Thiamine (Vitamin B1), please go to:

http://www.basf.cl/carechemicals/nutricionhumana/infogeneral/vitaminas/hidrosolubles/vitamina_b1.pdf



For Biotin (B7), see: <http://www.asp-inc.com/products/documents/prodinfo/b/biotin2.pdf>



For Choline (B12), see <http://www.asp-inc.com/products/documents/prodinfo/c/cholinebit.pdf>.

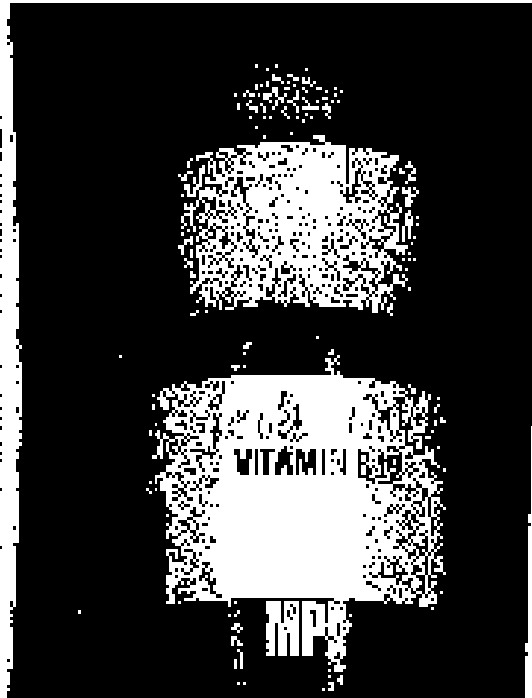
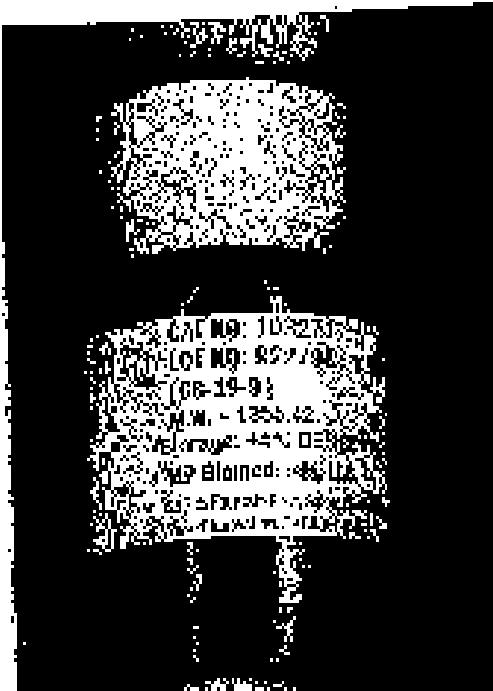


Exhibit 2

Vitamin References from Organic Materials Review Institute (OMRI)¹

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

Vitamin B7 (Biotin)

Biotin Allowed with Restrictions

AAFCO: 90.25 FDA: 582.5159

AAFCO: 90.26 FDA: n/a

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 Choline (B12)

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

AAFCO: 90.25 FDA: 573. 300

Ferric choline citrate Allowed with Restrictions

AAFCO: 90.26 FDA: 582.5250

¹ From OMRI Policy and Standards Manual 2010, Appendix, starting on page 157. AAFCO: Refers to the Association of American Feed Control Officials (AAFCO) *Official Publication* FDA: Food and Drug Administration rules at 21 CFR 582 and 573

Exhibit C
Correspondence from DSM



DSM Nutritional Products

395 Waydom Drive
Ayr, Ontario NOB 1E0
Canada

phone 519-622-2200
fax 519-623-4849

Date January 5, 2012
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

A handwritten signature in black ink, appearing to read 'Tamara Macdonald', is written over a light blue horizontal line.

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