

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: March 27, 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/ NOP, Standards Division,
1400 Independence Ave., SW.,
Room 2648–So., Ag Stop 0268
Washington, DC 20250-0268.

Summary of request:

Previous actions by NOSB and NOP have determined that various trace minerals are substances allowed as a feed supplement or feed additive under § 205.237 Livestock feed. Minerals for livestock nutrients were first added to the National List in 1995

This petition is a request for NOSB and NOP to determine that various trace minerals 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.

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

Zinc Sulfate

Manganese sulfate
Copper
Potassium iodide
Ethanediamine dihydroiodide
Ferric sulfate
Ferric citrate
Sodium chloride
Cobalt chloride
Sodium selenate
Sodium selenite

This represents a sample and is only a partial list of trace minerals. This petition is to allow trace minerals as feed ingredients for aquatic animals without specific notation.

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.

Trace minerals incorporated in fish feed are included in premixes containing three to six essential minerals depending upon the species being fed. There are various suppliers of trace minerals and trace mineral premixes, including but not limited to DSM Nutritional Products (formerly Roche). Another source is Murray Elevator and Wilbur-Ellis Company for which a label is attached in Exhibit B.

There are no trace minerals specifically manufactured for use in aquaculture feeds. The trace minerals used in aquaculture feeds are the same minerals, e.g., produced by the same processes and from the same manufacturers, as those used in human mineral supplements and in feeds for livestock and companion animals.

Trace mineral premixes for aquatic animals contain many of the same trace minerals as are included in livestock feeds and supplements. The same minerals will be included in feeds for organic aquatic animals as are now used in organic livestock feed. Please see the letter in Exhibit D for further information.

As for specific information on the manufacturers of the ingredients in trace mineral premixes, as stated in Exhibit D, we are informed that various trace minerals 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).

Trace mineral premixes are included as ingredients in feed pellets for aquatic animals at approximately 0.1% to 0.2% of feed pellet mass. They are not directly dissolved in growing water but intended to be consumed.

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, trace mineral premixes are included in feed pellets at a rate of approximately 0.1 to 0.2%.

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 animal of many species that are grown under different conditions.

Trace minerals released into the environment, if anything, have a positive impact. There are no known harmful environmental impacts from trace minerals when used in the prescribed amounts. None are toxic at these levels.

Exhibit E, using zinc as an example, demonstrates that the amount of trace elements discharged to the environment from uneaten feed from an ocean net pen of 12 parts per billion is negligible for an otherwise harmless substance. Any residual trace minerals released into the environment are at extremely low concentrations below any physiologically significant level, and are rapidly absorbed by microorganisms.

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 Exhibit B., there are a number of sources for trace mineral premix packages for fish feed pellets, including but not limited to DSM Nutritional Products.

Trace minerals 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 D.

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 (2) "Trace minerals, used for enrichment or fortification when FDA approved."

Organic Materials Review Institute (OMRI)

Minerals – feed & health care

Status: Allowed with Restrictions

Class: Livestock Feed Ingredients, Livestock Health Care

Origin: Synthetic/Nonsynthetic

Description:

Minerals that are allowed by FDA regulation or listed in the AAFCO publication may be used in feed, except for those derived from mammalian and poultry slaughter by-products. Minerals may not be used to stimulate growth or production. May not be fed in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage in life. See also CARRIERS listings; ANIMAL BY-PRODUCTS; GENETICALLY MODIFIED ORGANISMS; and MINERALS – MANAGEMENT TOOL, PRODUCTION AID. See Appendix A: Livestock Vitamins and Minerals.

NOP Rule: 205.237(a), 205.238(a)(2) & 205.603(d)(1) [N]onsynthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements. Provision of a feed ration sufficient to meet nutritional requirements, including... Minerals. As feed additives... Trace minerals, used 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.

Trace minerals 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 trace minerals, approval is limited to registration. Trace minerals (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 C 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.

The European Union allows:

1. FEED ADDITIVES

1.1. Nutritional additives

(b) Trace elements

E1 Iron:

- ferrous (II) carbonate
- ferrous (II) sulphate monohydrate and/or heptahydrate
- ferric (III) oxide;

E2 Iodine:

- calcium iodate, anhydrous
- calcium iodate, hexahydrate
- sodium iodide;

E3 Cobalt:

- cobaltous (II) sulphate monohydrate and/or heptahydrate
- basic cobaltous (II) carbonate, monohydrate;

E4 Copper:

- copper (II) oxide
- basic copper (II) carbonate, monohydrate
- copper (II) sulphate, pentahydrate;

E5 Manganese:

- manganous (II) carbonate

- manganous oxide and manganic oxide
 - manganous (II) sulfate, mono- and/or tetrahydrate;
- E6 Zinc:
- zinc carbonate
 - zinc oxide
 - zinc sulphate mono- and/or heptahydrate;
- E7 Molybdenum:
- ammonium molybdate, sodium molybdate;
- E8 Selenium:
- sodium selenate
 - sodium selenite.

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

Minerals, Trace Minerals, Elements - Non-synthetic chelated or sulphated minerals such as but not limited to calcium chloride. Synthetic nutrient minerals may be used when non-synthetic sources are not commercially available. Minerals may not be used to stimulate growth or production.

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

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 B for Trace Mineral References from Organic Materials Review Institute (OMRI), including references to Association of American Feed Control Officials (AAFCO) numbers. These references are examples only, and may not include all trace minerals that may be necessary for aquatic animals.

A typical label for a trace mineral product for an aquatic animal feed ingredient is included in Exhibit B.

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 trace mineral additives in livestock for valuable information where each of these questions are addressed. They apply to aquatic animals as well.

Item (c) may, in some facilities, be different for aquatic animal growing systems relative to terrestrial livestock production. For aquatic animals the various trace

minerals are incorporated at the part per million level, or less, in feed pellets. In the event that some pellets are wasted to the environment in a net pen facility, for example, calculations show that the introduction of any individual mineral to the environment would be at the level of 10^{-9} to 10^{-12} grams of minerals per grams of water. As discussed in #7. above, trace minerals (forms and products) used in animal and fish feeds are classified as Generally Recognized As Safe (GRAS) by the FDA. There would be no environmental threat for these trace minerals at these levels of introduction.

It should be noted that with dairy livestock, for example, manure is spread on fields where trace minerals leach into soil and percolate into underlying aquifers.

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 trace minerals in the diets of fish, both farmed and wild.

Also: Hardy, R.W. 2002. Rainbow trout, *Oncorhynchus mykiss*. Pp. 184-202 in: *Nutrient Requirements and Feeding of Finfish for Aquaculture*, C.D. Webster and C.E. Lim, editors. CABI Publishing, New York, NY., and

Barrows, F.T., Gaylord, T.G., Sealey, W.M., Porter, L., and Smith, C. E. 2008. *The effect of vitamin premix in extruded plant-based and fish meal based diets on growth efficiency and health of rainbow trout, Oncorhynchus mykiss*. Aquaculture 283 (2008) 148–155.

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.

Trace minerals are essential nutrients for all forms of animal life to maintain normal body functions, such as growth, maturation and resistance to disease. Mineral 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 trace mineral intake is essential to the good health of aquatic animals. If trace minerals are not supplemented to aquaculture feeds, clinical signs of deficiency result, demonstrating that levels of trace minerals supplied by feed ingredients are insufficient to meet dietary minerals 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 trace minerals in aquaculture systems. As mentioned above, feed ingredients used in animal and/or fish feeds do not contain sufficient levels of minerals to supply their dietary requirements, making it necessary to supplement feeds to prevent mineral deficiency conditions and associated diseases as well as infectious diseases. The same synthetic trace minerals used in aquaculture are allowed on the National List for organic livestock.

- 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 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 any confidential business information.

Conclusions

Trace minerals are essential dietary nutrients 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 trace minerals are allowed as additives in livestock feed and are included in the National List for livestock in:

“§ 205.603
(d) as feed additives
(2) Trace minerals, used for enrichment or fortification when FDA approved.”

Minerals for livestock nutrients were first added to the National List in 1995

This petition is a request for NOSB and NOP to allow minerals as feed additives for aquatic animals under:

“§ 205.611 Synthetic substances allowed for use in organic aquatic animal production
(x) feed Additives
(x) trace minerals, used for enrichment or fortification when FDA approved.”

This petition seeks a similar allowance with an identical annotation for trace minerals as feed additives for aquatic animals.

Aquaculture Working Group
George S. Lockwood, Chair

Exhibit A
Example Premix Product Contents
Typical Trace Minerals in Aquatic Animal Feed ¹

Table 2. Semi-purified diet formulations for salmonids (H-440, Oregon test diet (OTD), and Guelph test diet for trout).

Ingredient	H-440	OTD	Guelph
Vitamin-free casein	38.0	49.5	40.0
Gelatin	12.0	8.7	4.0
Dextrin	28.0	15.6	9.0
Starch	----	----	11.5
Alpha-cellulose	----	7.7	3.0
Carboxymethylcellulose	----	1.3	----
DL-methionine	----	----	0.5
L-arginine	----	----	1.0
Fish oil (marine origin)	----	10.0	15.0
Vitamin E	----	0.2	in vitamin premix
Choline chloride	----	1.0	in vitamin premix
Mineral mix	4 ¹	4.0 ⁴	8.0
Vitamin premix	9 ²	2.0 ⁵	3.0
Oil premix	9 ³	----	

¹ Mineral mix contains the following (g/kg premix): calcium biophosphate, 135.7; calcium lactate, 326.9; ferric citrate, 29.7; magnesium sulfate, 132; potassium phosphate (dibasic), 239.8; sodium biophosphate, 87.2; sodium chloride, 43.5; $AlCl_3 \cdot 6H_2O$, 0.15; KI, 0.15; $CuCl_2$, 0.1; $MnSO_4 \cdot H_2O$, 0.8; $CoCl_2 \cdot H_2O$, 1.0; $ZnSO_4 \cdot H_2O$, 3.0.

⁴ Mineral mix contains the following (g/kg premix): $CaCO_3$, 21; $CaHPO_4 \cdot 2H_2O$, 735; K_2HPO_4 , 81; K_2SO_4 , 68; NaCl, 30.6; $Na_2HPO_4 \cdot 6H_2O$, 21.4; MnO, 25.0; $FeC_6H_5O_7 \cdot 3H_2O$, 5.58; $MnCO_3$, 4.18; $2CuCO_3 \cdot Cu(OH)_2$, 0.34; $ZnCO_3$, 0.81; KI, 0.01; NaF, 0.02; $CoCl_2$, 0.2; citric acid, 6.88.

¹ Hardy, R.W. 2002. Rainbow trout, *Oncorhynchus mykiss*. Pp. 184-202 in: *Nutrient Requirements and Feeding of Finfish for Aquaculture*, C.D. Webster and C.E. Lim, editors. CABI Publishing, New York, NY.

Table 6. Essential dietary minerals for rainbow trout.

Macrominerals	Microminerals (trace elements)
Calcium*	Iron
Phosphorus*	Manganese
Sodium*	Copper
Potassium*	Zinc
Chlorine*	Cobalt
Magnesium*	Selenium
Sulfur*	Iodine*

*Required in the diet, but generally not supplemented in practical feeds

Table 7. Mineral premix specifications for several open-formula salmonid diets.

Element (form*)	U.S. Fish and Wild- life Service trace mineral premix #3 g element/kg premix	Ontario Ministry of Natural Resources mineral premix MIN-9504 g element/kg premix
Zn (as ZnSO ₄ · 7H ₂ O)	75	12.0
Mn (as MnSO ₄)	20	17.64
Cu (as CuSO ₄ · 5H ₂ O)	1.54	1.5
I (as KIO ₃)	10	1.5
or		
I (C ₂ H ₈ N ₂ 2HI)	--	--
Fe (as FeSO ₄ · 7H ₂ O)	--	2.6
NaCl	--	240

From Barrows, et al. (for reference see question 11. above)

Table 1

Ingredient composition (g/100 g) of base mix for experimental diet

<u>Ingredient</u>	<u>Base mix</u>	
	<u>Plant-based</u>	<u>Fish meal based</u>
Soy protein concentrate ^a	14.66	
Corn gluten ^b	16.91	–
Wheat gluten ^b	7.04	–
Soybean meal ^b	15.84	19.22
Wheat flour ^b	26.76	28.14
Fish meal ^c	–	30.97
Blood meal ^d	–	9.93
Fish oil	13.44	11.10
Lysine-HCL	1.26	–
Taurin ^e	0.50	–
Vitamin premix ^e	0.40	0.40
Choline CL	0.11	0.11
Stay-C	0.03	0.03
Trace min. premix ^f	0.10	0.10
Dicalcium phosphate	2.55	–
Sodium chloride	0.28	–
Potassium chloride	0.56	–
Magnesium oxide	0.05	–

^a ADM, 82% protein.

^b Silver Cup Fish Feeds, Murray, UT.

^c Peruvian anchovy, 70% protein, Silver Cup Fish Feeds, Murray, UT.

^d Blood meal, 82% protein, Silver Cup Fish Feeds, Murray, UT.

^e Contribution varied with diet.

^f Trace mineral premix; contributed in mg/kg of diet: zinc, 37; manganese, 10; iodine, 5; copper, 1.

Exhibit B
Sample Label for Trace Minerals as Feed
Ingredients for Aquatic Animals.

Net Weight 50 pounds (22.68 kg)

CUSTOM TM #3
MURRAY ELEVATOR
051700

ANALYSIS PER POUND

Zinc.....	34.0 gm	Copper.....	0.70 gm
Manganese.....	9.1 gm	Iodine.....	4.54 gm

INGREDIENTS

Calcite, Zinc Sulfate, Manganese Sulfate,
Ethylenediamine Dihydriodide, Copper Sulfate, Mineral
Oil.

DIRECTIONS

Use for further manufacturing only.

Manufactured by:

Wilbur-Ellis Company
Ogden, Utah 84402

Manufactured for:

MURRAY ELEVATOR
Murray, Utah 84017

Prod. Number: MURRE001
LOT NUMBER: 349873

Exhibit C

Trace Mineral References from Organic Materials Review Institute (OMRI)²

Zinc sulfate Allowed with Restrictions

AAFCO³: 57.118 FDA: 582.80, 582.5997

Manganese sulfate Allowed with Restrictions

AAFCO: 57.96 FDA: 582.80, 582.5461

Copper sulfate Allowed with Restrictions

AAFCO: 57.69 FDA: 582.80

Potassium iodide Allowed with Restrictions

AAFCO: 57.104 FDA: 582.80

Ethylenediamine dihydriodide (EDDI) Allowed with Restrictions

AAFCO: 57.75 FDA: 582.80

FDA does not permit use as an animal drug and limits amount fed to 50 mg/head/day in dairy cattle. See Compliance Policy Guide 7125.18 from the FDA (http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg651-100.html).

Ferric sulfate Allowed with Restrictions

AAFCO: 57.129 FDA: 582.80

FDA refers to "iron sulfate."

Sodium chloride Allowed with Restrictions

AAFCO: 57.31 FDA: n/a

Nonsynthetic.

Cobalt chloride Allowed with Restrictions

AAFCO: 57.60 FDA: 582.80

Sodium selenate Allowed with Restrictions

AAFCO: 57.120 FDA: 573.920

FDA regulations limit use.

Sodium selenite Allowed with Restrictions

AAFCO: 57.119 FDA: 573.920

FDA regulations limit use.

² 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

³ The Association of American Feed Control Officials <http://www.aafco.org/>

Exhibit D Correspondence from DSM



DSM Nutritional Products

395 Waydon Drive
Ayr, Ontario N0B 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

Exhibit E

ENVIRONMENTAL IMPACT OF MICRONUTRIENT WASTE IN OCEAN NET PENS

Dimensions of pen (meters)		
depth (meters)	20.1	
width (meters)	28.2	
length (meters)	28.2	
volume (cubic meters)		16,000
Density of seawater (kg per cubic meter)	1,027	
Mass of seawater in pen (kg)		16,432,204
Maximum salmon biomass (kg)		420,000
Daily water change with two tide cycles (cubic meters)		64,001
kg seawater		65,728,817
Maximum mass of feed per day (kg)		4,200
Percent feed ingested by fish	99.000%	
wasted	1%	
wasted (gram)		42,000
Percent of feed that is trace mineral premix	0.15%	
weight of wasted premix (grams)		63.0
Zinc (for example) content of premix	1.2%	
weight of wasted zinc per day (grams)		0.756
Amount of wasted zinc in water (parts per billion)	(10 ⁻⁹)	12