

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

August 6, 2013

***Reviewed and revised February 3, 2014**

Summary of Proposed Action:

Synthetic minerals are proposed to be added to the National List at 205.611 for use in production of aquatic animals. Section 205.611 of the National List will contain the list of synthetic substances allowed in organic aquatic animal production.

Synthetic Trace Minerals are presently approved at 205.603(d)(2) for use in livestock production, used for “enrichment and fortification when FDA approved”.

Minerals are essential for production of healthy animals. In the case of nutrient requirements for fish and shrimp, the National Research Council (NRC) defines essential trace minerals as “required”. Petitioner requests addition to the National List of trace minerals without specific notation to include but not to be limited to the following: Cobalt Chloride, Copper, Potassium iodide, Ethanediamine dihydroiodide, Ferric Sulfate, Ferric citrate, Manganese sulfate, Sodium Selenate, Sodium Selenite Sodium Chloride, and Zinc Sulfate.

Minerals are produced using chemical synthesis and extraction from either natural or reclaimed sources and while a range of potential environmental impacts may occur from excess and improper disposal during manufacture, under normal animal feeding the risks to the environment are low, and human health effects specifically related to trace minerals in aquatic animal feeds have not been reported.

Minerals are included as ingredients in feed pellets at approximately 0.1% to 0.2% of feed pellet mass. The dietary importance of a given trace mineral is conditional on the animal species being grown.

In considering alternative sources for trace minerals as petitioned it should be noted that feeding wild caught fish, fish meal, other animal based meals, together with plant based feeds such as soy, corn, cottonseed etc. could provide a balanced diet without the fortification of feed with synthetic trace minerals.

In reviewing whether minerals are compatible with organic agriculture the subcommittee took into consideration the Organic Food Production Act (OFPA) which limits the use of synthetics to various categories, one of which is “pheromones, soaps, horticultural oils, fish emulsions, treated seeds, vitamins and minerals”.

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 NOSB Recommendations voted in 2007, 2008, and 2009

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

	Criteria Satisfied?		
1. Impact on Humans and Environment	x <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	x <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	x <input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category: N/A

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Motion to classify Minerals as synthetic:

Motion by: Francis Thicke

Seconded by: C. Reuben Walker

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0#

Listing Motion: Motion to list Minerals at §205.611 of the National List.

Motion by: Francis Thicke

Seconded by: C. Reuben Walker

Yes: 6 No: 1 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): None

Basis for annotation: 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 February 3, 2014

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

Category 1. Adverse impacts on humans or the environment? Minerals (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		When used as petitioned trace minerals from unconsumed feed pellets have the potential to persist in treated bodies of water, ground water, sediments and bioaccumulate in animal tissues. Data regarding persistence of trace minerals resulting from uses in aquaculture are limited. (TR 657-659). Overall the risk of lethal effects from bioconcentration is considered low (TR685-686)
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		Industrial effluents consisting of trace minerals may contribute to deleterious growth algal blooms as found in India (TR810-811), but under normal regulated operation risks are low
3. Are there any adverse impacts on		X		When used as petitioned trace minerals

biodiversity? (§205.200)				in the minute amounts used (.01-0.2% in feed) adverse impact on biodiversity is low risk
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X		No (TR 548)
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		No direct interactions between trace minerals and other aquatic animal feed additives were identified (TR 825) The petitioned trace minerals are chemically equivalent to trace minerals used in fortification of organic livestock feed for terrestrial animals.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		There is a wide range of toxicities associated with the range of trace minerals especially at excessive levels (TR 697-821) However a negligible potential for toxicity exists under the prescribed use. (TR 738-740)
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Data on persistence in aquatic systems is limited (TR 658) Overall the risk of lethal effects from bioconcentration of the petitioned trace elements is considered low. (TR 685-686)
8. 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		Environmental concentrations of trace minerals are unlikely to cause adverse health effects in humans except during improper disposal (TR 920-926) and human health effects specifically related to trace minerals in aquatic animal feeds have not been reported (TR 927-928)
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		No reported toxicity has been observed in non-target wildlife or livestock and toxicity in the ago-ecosystem is unlikely. Accidental release of industrial effluent may lead to ecological impairment.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		Trace elements are required by soil organisms, crops and livestock, so if the usage rates are kept within requirements for aquatic animals there should be no detrimental effects.

Category 2. Is the Substance Essential for Organic Production? Minerals (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	X		Trace minerals are produced using chemical synthesis and extraction from either natural or reclaimed sources. (TR 556-557)
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			See 2 above
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See 2 above
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		There are no direct substitutes for trace minerals (TR 993) There are natural sources- fish meal being the best source, but availability and resource demands to use them widely make them an unrealistic source. Many trace minerals can be found in vegetable oils, kelp, raw animal meat and so forth (TR 994-1044) Further the fish industry is working to mitigate demand for wild fish as fish feed.(TR 1068-1076) In the early years of aquaculture raw horsemeat was used (TR 403-404)
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		See 5 above A combination of plant based and animal based feeds may meet dietary requirements thereby precluding supplementation by synthetic trace minerals (TR 1109-1118)
8. Are there any alternative substances? [§6518(m)(6)]	X			See 5 above
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			There is debate as to whether vitamin or trace minerals are necessary to meet nutritional requirements of farmed fish. (TR 1052-1054) (TR 1096) However when fish are reared in high density indoor system or other closed systems they need to be provided with complete, fortified diets (TR 1096-1098)

Category 3. Is the substance compatible with organic production practices? Minerals (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			Minerals are presently on the National List at 205.603(d)(3) and Minerals are listed in the OFPA at 6517 (c) (1)(B)(i)
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			Trace minerals enrich and fortify feed
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]		X		
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	X			Some trace minerals include sulfur and copper compounds (TR 540-544)
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			Trace minerals
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 - Minerals for aquatic animals 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, because of the broad coverage of the term “minerals;” alternative natural materials and management methods; and compatibility with organic practices. The review in five (5) years provides an opportunity for the NOSB to reevaluate and vote for the continued or modified use of the material under the same standard of review that is used to approve the material initially.

The minority also has the following concerns:

- The listing for “minerals” without qualification of either specific synthetic substance or specific use or application, is inconsistent with (§6517(b) of OFPA: “The list established under subsection (a) of this section shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) of this section or each natural substance prohibited under subsection (c)(2) of this section.”)
- The listing for “minerals” includes many substances that should not be allowed in organic production (e.g., arsenic compounds), or used in aquatic situations (e.g., copper sulfate).
- The listing for “minerals” without qualification or specific identification does not allow an informed vote on either classification or other OFPA criteria. It is impossible to judge the health and environmental impacts of or the need for unspecified minerals.
- The petitioner has not made a case for a need for synthetic “trace minerals” in general, and certainly not for synthetic “minerals.”
- It is incompatible with organic agriculture to allow the routine use of synthetic materials to fulfill essential system functions.