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National Organic Standards Board
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San Antonio, TX

Re. LS Aquaculture Materials

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Beyond Pesticides opposes the recommendations of all petitioned materials for use in aquaculture –for production of either aquatic plants or aquatic animals– until the NOP adopts final practice standards for aquaculture. Our comments address general issues, those related to animal aquaculture, and those related to plant aquaculture.

1. Issues in common to plant and animal aquaculture.

a. Inputs must be judged in the context of an aquaculture system.

Organic aquaculture systems are possible on different scales. A large sustainable aquaculture system was made famous by Dan Barber in "How I fell in love with a fish." See (http://www.youtube.com/watch?v=4EUAMe2ixCI). As in other organic systems, the fish in the 8,000 acre farm at Veta la Palma (Spain) described by Dan Barber are not fed by outside inputs, but by the ecological system. Harvestable fish are a product of building biodiversity in this restored wetland. On the opposite extreme, *The Integral Urban House*[1] describes a small-scale aquaculture

Photo: Herminio Muñiz

[1] Sim Van der Ryn, Helga Olkowski, Bill Olkowski, and Farallones Institute, 1978. The Integral Urban House: Self-Reliant Living in the City. Sierra Club Books, San Francisco, CA.

system integrated into the ecology of an urban homestead. A polyculture of fish and crustaceans consumes naturally occurring algae and daphnia as well as worms raised in chicken sawdust and droppings, and the water is run through a biofilter to remove wastes. In both cases, the system itself generates food for the animals.

Even though organic food production is envisioned in the *Organic Foods Production Act* (OFPA) as a soil-based ecological system, organic and related ecological principles can and must be applied to other systems. The first of the "NOSB Principles of Organic Production and Handling" adopted October 17, 2001, is:

> 1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

In terrestrial organic agriculture, the focus is on building a healthy soil that provides nutrients for plants and animals. How do we review materials for aquatic aquaculture in a system where there is no soil? Organic aquaculture, like other forms of organic agriculture, must rely on the underlying ecology to feed plants and animals, rather than outside inputs. Synthetic materials must not be used to fulfill system functions, but must be only non-routine inputs and should not serve to make up for an improperly designed or overcrowded system. The review of materials should reflect the same concern for water that we have for soil: healthy biota, no toxicity, and no excess nutrients to support unwanted production.

All of the NOSB Livestock Subcommittee proposals, except chlorine for aquatic animals, include the following disclaimer, "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 of Standards voted in 2007, 2008, and 2009." In addition, the proposal for tocopherols for aquatic animals states, "Therefore the livestock subcommittee recommends *reassessment* [emphasis added] of this material when regulations for open and closed systems are in place." We believe that both of these statements do not fulfill the NOSB's responsibility to conduct a full assessment on organic compatibility and essentiality within the system defined by OFPA and the Board to be organic. In fact, since the Board cannot conduct a full review of the need for the petitioned materials and their compatibility with the system, it cannot at present meet its statutory responsibility. Moreover, the Board cannot make a reasoned determination of the policy prescription to be issued by USDA and NOP because recent events have demonstrated that the agency is willing to deviate significantly from NOSB recommendations. For example, the unilateral actions by USDA that are out of sync with Board recommendations include the following: (i) changed listings for carrageenan, cellulose, and List 3 inerts proposed in a May 3, 2013 Federal Register notice; (ii) the failure to collaborate with the NOSB in developing guidance for use of biobased biodegradable bioplastic mulch; (iii) and allowing the certification of hydroponics, despite an NOSB recommendation to disallow it.

The High Standards of the Petition Process Must Apply for New Materials in Organic Systems
From a strict process perspective, in the context of reviewing a petition, the process of approving, then *reassessing* materials "when regulations for open and closed systems are in place," as suggested by the Livestock Subcommittee for tocopherols, subjects the allowance of aquaculture materials to a lower and less rigorous standard for listing on the National List of Allowed and Prohibited Substances than other materials evaluated in the context of known and defined production systems. As the Board knows, under the petition process, new materials or new material uses, as is the case with materials to be listed for organic aquaculture use, are only listed with a decisive majority or two-thirds vote. While this has always been a high bar, it assures that the majority of stakeholder groups represented on the Board concurs with the decision and protects public trust in the organic food label. While an interesting thought, under the Livestock Subcommittee proposal, the "reassessment" of the petitioned materials "when regulations for open and closed systems are in place" both recognizes that the systems policy could affect the material review assessment, and subjects the complete and adequate material review, as required by law, to a lower threshold for allowance than envisioned by the petition process.

In fact, the Subcommittee's approach is made unworkable by recent USDA/NOP imposed changes in sunset policy, which will necessarily subject the "reassessment" to a two-thirds vote to simply de-list and not allow for any annotations that the Board might deem necessary in light of the new policy, and which should be considered when a petition decision is made by the Board. For an annotation during the "reassessment" to be considered by the Board under the new USDA/NOP sunset policy, there would have to be a petition filed and it is neither clear that it would make its way to the full Board nor certain that it would happen in a reasonable time frame. Even if a petition of this sort did make its way to the Board, the original material that the Livestock Committee suggests it could subject to "reassessment" would now be subject to a two-thirds vote to remove from the list, thus applying a different and less rigorous legal standard than required by the decisive vote being applied at this meeting for listing new materials. There is an unfortunate inconsistency between the petition and the new USDA-declared sunset process that requires the Board to postpone voting on petitions to list new materials without full and complete information on the systems in which they will be used.

b. Aquaculture standards, including allowed materials, must be species-specific.

The standards for salmon should be different from the standards for catfish, just as the standards for poultry are different from the standards for cows. Different species have different needs, and the NOSB cannot properly consider the essentiality of petitioned substances in the absence of information about the species in the system. Internationally, other organic standards-setting organizations reflect this need in their standards. The Soil Association of the UK[2] has separate sections in its standards for Atlantic salmon, trout and arctic charr, shrimp, bivalves, and carp. KRAV[3] (Danish standards) include specific standards for salmonids, perches,

[2] http://www.soilassociation.org/LinkClick.aspx?fileticket=pM14JxQtcs4%3d&tabid=353.
[3] http://organicrules.org/1098/1/KRAVStandardsJanuary2006.pdf.

sea muscles, algae, and catch-based aquaculture –the last of which has a general section that applies only to those species covered by specific standards. The Naturland[4] Standards for Organic Aquaculture include specific regulations for a range of aquaculture commodities, such as pond culture of carp and accompanying species; culture of trout, salmon and other salmonids in ponds and net cages; rope culture of mussels; pond culture of shrimp; culture of tropical freshwater fish in ponds and net cages. The European Union[5] also has species-specific requirements.

c. Materials in aquaculture must be reviewed for their aquaculture use.

Information gathered in support of other uses –Technical Reviews, for example– can be used to supplement, but not replace aquaculture-specific information. The use of the material is an essential factor –using CO2 as synthetic fertilizer is different from using it to produce carbonated drinks.

i. OFPA requires that National List substances be considered by specific use.

§6517(b) states, "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." OFPA requires that the Secretary determine that" the use of such substances would not be harmful to human health or the environment…" and that "the specific exemption is developed using the procedures described in subsection (d) of this section." Therefore, the NOSB must consider information relating to the aquaculture use and not depend on information relating to other uses of the material.

ii. The aquatic environment transports materials in a form that is accessible to many organisms.

Materials –both biological and chemical– in the aquatic environment are often dissolved or suspended in the water. This makes them easily transportable –in some cases globally by organisms that are very mobile– and means that the impacts of materials added to an aquaculture system must be considered very broadly. Similarly, the aquaculture system may receive synthetic or non-organic inputs that have travelled a long distance and may vary over time. In this sense, natural alone does not define organic, since there are potential contamination issues that have to be evaluated as they relate to ocean net pens, closed systems, and defined, multitrophic, ecological-based systems.

The comments submitted by the Center for Food Safety in the fall of 2013 point out the implications of the Fukushima meltdown for ocean-based aquaculture. (See original for footnotes.)

[4] http://www.naturland.de/fileadmin/MDB/documents/Richtlinien_englisch/Naturland-Standards_Aquaculture.pdf.
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:204:0015:0034:EN:PDF.

Radiation from Fukushima continues to leak into the ocean. Cesium-134, cesium-137, and cobalt-60 from Fukushima have been detected in fish, soil, and marine plant samples from Japan.[47] Tritium[48] and strontium-90[49] have leaked into the ocean in sizable quantities as well.[50] With half-lives ranging from 5-30 years for the more hazardous cobalt,[51] strontium,[52] and cesium,[53] these radionuclides will be present in the Pacific for decades to come.[54] Models of radiation transfer in the ocean have predicted that radiation will reach the U.S. West Coast by 2014[55] and mix to depths of 1500 meters.[56]

i. The radioactivity from Fukushima offers a critical way to track contaminants in seafood and other wild marine organisms (thus including fish meal). This information is pertinent to the contamination of the seas and seafood by all sorts of toxic materials that we haven't bothered to track. Bioaccumulation of contaminants can result in plant and animal products that fail to meet expectations of organic consumers.

In particular, the presence of bioaccumulative contaminants in non-organic (wild-harvested) ocean fish or other organisms used for feed would increase the concentration of those contaminants in the aquaculture-fed fish. However, even fish grown organically may contain bioaccumulative toxic contaminants due to fallout from the air. Raising carnivorous fish organically therefore raises significant problems in meeting consumer expectations.

ii. Containment of aquatic organisms can be difficult.

The evaluation of the movement of materials offsite must include movement in organisms and their metabolic products. If fish are fed food containing bioaccumulative toxic materials, for example --such as the wild-caught fish meal whose use tocopherols are meant to facilitate— then we must evaluate whether the fish may escape and cause the toxic materials to be further bioaccumulated in their predators.

iii. Impacts of removal, as well as addition, of materials to the aquatic ecosystem must be considered.

When wild-harvested organisms are considered as food sources, the impacts of depletion of their populations should be considered. In addition, the addition of pens of fish and farms of bivalves to the ecosystem can have impacts on the local biology and chemistry of the water, and these are also materials considerations, as they include food that is not organic.

This includes genetic material. If the cultivated species is not native, escapes (which are almost guaranteed) of introduced non-native species will compete with others. If the species is native, it is usually bred to some extent to favor genes that perform well under cultivation, and these can contaminate the natural gene pool, which has been honed by natural selection to favor characteristics that favor survival in the wild. This genetic contamination through interbreeding with wild individuals can weaken the species as a whole.

d. Key distinctions need to be defined.

The Board must distinguish among various systems when describing the appropriate uses of materials. Those systems need to be defined.

i. Open vs. closed systems

Although the aquaculture recommendations previously passed by the NOSB mention "open water organic systems" and "closed containment organic systems," those terms are not defined. Completely open systems, such as net pens in the ocean, and completely closed systems, such as recirculating systems with no discharges, are two extremes of a continuum. If the NOSB is to make recommendations regarding materials used in aquaculture, then terms defining the degree to which materials are shared with the external environment must be defined.

ii. "Integrated Multitrophic Aquaculture"

"Integrated multitrophic aquaculture" (IMTA) is often identified as a possible organic model. However, IMTA is not itself well-defined. If practiced in land-based systems, it may allow greatly reduced discharges from the system. If practiced intensively in the ocean, it may be that "aquaculture of fed organisms (finfish or shrimp) is combined with the culture of organisms that extract either dissolved inorganic nutrients (seaweeds) or particulate organic matter (shellfish) and, hence, the biological and chemical processes at work are balancing each other."[6] On the other hand, it may be practiced extensively in a natural/restored/artificial ecosystem like that shown in the video cited above. IMTA is not automatically sustainable, organic, or less consumptive of resources. Further definition is needed if the term were to be applied in materials annotations.

iii. "Recirculating Aquaculture Systems"

The term "recirculating aquaculture system" (RAS) also applies to a wide variety of different systems and has also been proposed as a possible organic model. Like IMTA, the crucial element is using nutrients from animals to feed plants. Like IMTA, RAS is not automatically sustainable, organic, or less consumptive of resources. Further definition is needed if the term were to be applied in materials annotations.

e. Synthetic inputs must not be routine.

Synthetic inputs may be needed to respond to unusual conditions or fine tune the system, but in organic production, they cannot be routine. There must be in place regulations defining an organic aquaculture system that integrates plants, animals, and microorganisms. Evaluating the use of synthetic materials outside of defined practice norms that do not depend on synthetics is contrary to OFPA.

f. Decisions concerning organic aquaculture cannot rely on NPDES permits to protect water.

This should not need to be stated. If other laws were adequate to achieve the objectives of OFPA, we would not need OFPA.

A number of reports have criticized the level of protection afforded by EPA's regulation of aquaculture facilities.[7] A recent report (2012) by the Harvard Law School Emmett

[6] Thierry Chopin, 2006. Integrated Multi-Trophic Aquaculture, Northern Aquaculture, March 2006. http://www2.unb.ca/chopinlab/articles/files/Northern%20Aquaculture%20IMTA%20July%2006.pdf

[7] In addition to the 2012 report cited below, these include: T.R. Head, III, 2003. *Fishy Business—Regulating Aquaculture Operations in the U.S.* http://www.balch.com/files/Publication/47d3f292-e868-4f9b-9ae5-

Environmental Law and Policy Clinic, Environmental Law Institute, and the Ocean Foundation, *Offshore Aquaculture Regulation under the Clean Water Act,*[8] offers the following facts:

- Because EPA has not issued water quality standards for ocean waters, ocean discharge criteria cannot be based on water quality, but must be technology-based.
- Concentrated aquatic animal production (CAAP) facility effluent limitation guidelines (ELG) do not include numeric limitations and apply only to large facilities.
- Ocean discharge criteria contain little specific guidance on implementation.

They offer the following recommendations:

- Reduce CAAP facility production limits or apply case-by-case discretion to ensure that all aquaculture facilities in federal ocean waters –and particularly those projects using novel or untested technologies– are subject to effective National Pollutant Discharge Elimination System (NPDES) permitting.
- Revise the aquaculture ELGs to set numeric standards for facilities located in federal waters.
- Identify information needed for undue degradation determinations for offshore aquaculture facilities and develop guidelines for data generation and submission, as well as default monitoring requirements, for offshore aquaculture NPDES permits.

The state of Maine regulates salmon aquaculture facilities through a general permit,[9] which was issued in 2008 and weakened in 2011.[10] In order to be covered by a general permit, the facility must issue a notice of intent to operate under the permit, demonstrate a legal leasehold, and submit a fee. General permits are generally regarded as a weak form of permitting.[11]

g. The NOSB should use annotations to restrict the use of synthetic materials to those cases justifiable by OFPA.

As stated above, OFPA requires that National List substances be considered by specific use. The petitioned substances must meet all three OFPA criteria –essentiality, absence of adverse effects on humans and the environment, and compatibility with a system of organic and sustainable agriculture. Ensuring that the listing meets all three criteria requires at the least a delineation of the use conditions under which the substance is essential.

8a10032b43eb/Presentation/PublicationAttachment/a83c0a25-f681-4ad2-8aab-00aae4ba0086/Fishy%20Business%20-%20THead.pdf and RJ Goldburg, MS Elliot, and RL Naylor, *Marine Aquaculture in the United States: Environmental Impacts and Policy Options*, Pew Oceans Commission, Arlington, VA. http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Protecting_ocean_life/env_pew_oceans_aquaculture.pdf

[8] http://eli-ocean.org/fish/files/CWA-aquaculture.pdf

[9] http://www.maine.gov/dep/water/wd/atlantic_salmon_aquaculture/MEG130000_2008.pdf

[10] http://www.maine.gov/dep/water/wd/atlantic_salmon_aquaculture/MEG130000_2008_MOD2011.pdf

[11] JM Gaba, 2007. Generally Illegal: NPDES General Permits under the Clean Water Act. *Harvard Law Review* 31: 409-473. http://www.law.harvard.edu/students/orgs/elr/vol31_2/gaba.pdf

h. The NOSB should annotate all aquaculture materials with a five-year expiration date.

Aquaculture materials, more than any others, should not be approved without the certainty that they will be considered *de novo* after five years. Without regulations in place, it is impossible to define the essentiality and compatibility of synthetic materials because the nutrients supplied by the system cannot be identified without describing the system. It is also impossible to characterize the impacts without knowing how much of the material may leave the system and where it will go.

Every aquaculture material motion should be annotated with "until May 1, 2019 or five years from the date that use is allowed."

2. Issues of concern to animal aquaculture

a. The system makes a difference.

Determining whether a material is appropriate for use in net pens involves different issues from the use in recirculating land-based systems. Salt water is different from fresh water. Integrated multitrophic systems are different from monocultures. These differences should be reflected in annotations.

b. The use of fish meal and fish oil and their implications for organic aquaculture should be revisited.

Feed for aquacultured fish should be included on the list of things the NOSB reviews as materials. Criteria for feed should include:

- appropriateness to species - carnivorous species should be fed species similar to their natural food, raised organically.
- same prohibitions as for other livestock (no GE crops as fish feed).
- environmental impact of feed (wild fish especially).
- human health impact (bioaccumulation of POPs in fish-based feed).
- biodiversity impact (ecosystem impacts of harvesting wild fish to use as feed).

The fact that some fish that might be raised in aquaculture are predators will require materials considerations in aquaculture for situations that do not have a strict counterpart in terrestrial agriculture. In terrestrial agriculture, we have not had to consider the presence of bioaccumulating toxic materials in nonsynthetic feed because our livestock animals are fed vegetarian feed. However, if wild-caught fish are used as a feed source for fish in aquaculture, then the "incidental" level of synthetic bioaccumulative toxic chemicals must be seen as a synthetic input.

c. Petitioned materials for animal aquaculture should not be approved.

Beyond Pesticides opposes the listing of vaccines, synthetic vitamins, synthetic trace minerals, synthetic tocopherols, and chlorine materials for use in animal aquaculture. All these materials, which have been petitioned as routine inputs, have not been evaluated for essentiality in the context of an organic aquaculture system in which synthetic inputs are not routine. The NOSB should consider whether annotations are needed to restrict the uses under consideration to

"closed" systems and should propose annotations specifying a five-year expiration date. Specific comments are below.

i. Vitamins

In addition to the general issues we have raised, we oppose the petition for vitamins for the following reasons.

Neither the petition nor the subcommittee's proposal justifies the blanket approval of all synthetic vitamins. Are any vitamins available as nonsynthetics? It appears that the Livestock Subcommittee has not considered the impacts of possible enrichment of the aquatic environment due to feed falling through net pens or being released in discharges from other systems. The checklist states that some vitamins can be produced by fermentation, and that some of those may be considered nonsynthetic, but the LS does not try to determine which synthetic vitamins are essential (that is, cannot be provided in a nonsynthetic form.) The LS states in response to Category 2, question 9, "When possible a diet comprised of forage fish is the most natural means of incorporating proteins and vitamins into diets of carnivorous and omnivorous fish (TR 1247-1249) but the fish industry is working to mitigate demand for wild fish as fish feed (TR 1277-1285)." The LS should consider this as an indication that organic aquaculture may not be possible at this time for carnivorous and omnivorous fish, given the requirement in §205.239(a), which state, "The producer of an organic livestock operation must establish and maintain year-round livestock living conditions which accommodate the health and natural behavior of animals."

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 years with the same threshold for allowance as is required by the petition process. To do this, the NOSB must adopt a five-year expiration date as an annotation to the listing.

ii. Minerals

In addition to the general issues we have raised, we oppose the petition for vitamins for the following reasons.

Neither the petition nor the subcommittee's proposal justifies the blanket approval of all synthetic minerals. Are any minerals available as nonsynthetics? It appears that the Livestock Subcommittee has not considered the impacts of possible enrichment of the aquatic environment due to feed falling through net pens or being released in discharges from other systems. Harmful algal blooms as a result of iron enrichment are well known.[12]

[12] See, for example, Heisler, J.; Glibert, P. M.; Burkholder, J. M.; Anderson, D. M.; Cochlan, W.; Dennison, W. C.; Dortch, Q.; Gobler, C. J.; Heil, C. A.; Humphries, E.; Lewitus, A.; Magnien, R.; Marshall, H. G.; Sellner, K.; Stockwell, D. A.; Stoecker, D. K.; and Suddleson, M., 2008. "Eutrophication and harmful algal blooms: A scientific consensus" *U.S. Environmental Protection Agency Papers.* Paper 169. http://digitalcommons.unl.edu/usepapapers/169

We agree with the minority opinion that 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 years with the same threshold for allowance as is required by the petition process. To do this, the NOSB must adopt a five-year expiration date as an annotation to the listing.

We concur with the following additional concerns of the minority report:

- 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 –arsenic compounds, for example– or used in aquatic situations – copper sulfate, for example.
- 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.

iii. Tocopherols

Beyond Pesticides opposes the listing of synthetic tocopherols for animal aquaculture. Tocopherols are petitioned as a preservative (antioxidant) for fish meal. Synthetic preservatives are incompatible with organic production. Furthermore, organically produced livestock need organic feed, so fish meal should not be fed to fish unless it is produced organically. We agree with the minority statement that this use is "inconsistent with use of vitamins in terrestrial animals, where they are restricted to use for, 'enrichment or fortification when FDA approved.'"

We agree with the minority opinion that 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 years with the same threshold for allowance as is required by the petition process. To do this, the NOSB must adopt a five-year expiration date as an annotation to the listing.

Last fall when the LS introduced a proposal on tocopherols, it contained an annotation, "Tocopherols derived from vegetable oils, not extracted using volatile synthetic solvents…" It is difficult to understand why this annotation was removed if, as is indicated in the minority statement, the subcommittee received information that there is a consistent supply of

tocopherols not derived from genetically engineered organisms and extracted without synthetic solvents. This calls into question the essentiality of synthetic tocopherols.

The checklist states, "No sources were identified that discussed alternative practices that would make the use of an antioxidant unnecessary in aquatic animal feed." However, there are at least two that come to mind: (1) Feed only fresh fish to carnivorous species, or (2) Do not raise carnivorous or omnivorous species for the organic label.

iv. Chlorine

The chlorine petition is really two distinct petitions for disinfection of –(i) hard surfaces, which is similar to other uses of chlorine in organic livestock production, and (ii) culture water. We are pleased to see that the LS has not proposed to list the use for disinfection of culture water, having removed the reference that was in the proposal published in the fall,[13] which is a distinct use that is not in any delineated category in OFPA §6517 (c)(1)(B)(i). The LS-proposed chlorine annotation clearly does not allow use of chlorine in culture water. We support this limitation and note that any proposed changes to this annotation during the NOSB meeting would be a new and substantive change in the LS recommendation, not subject to full public consideration and therefore not allowed under new NOP rules described in the February 27, 2014 memo to the NOSB. The use in culture water is clearly different from the use allowed under §6517 (c)(1)(B)(i) of OFPA, which identifies "production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers," under which chlorine has been permitted in terrestrial crops and livestock. In fact, the LS states, "Given that the materials' use in aquaculture applications is identical to existing uses in other production categories, the committee has not requested a new Technical Evaluation Report, but it is instead relying on recent TRs developed for Handling and Crops uses of this group of materials." Since the use of chlorine materials in other production categories is limited to disinfection of hard surfaces, the LS can only apply this reasoning if its proposal addresses only this use. In addition, the LS has checked the N/A column for all of the OFPA categories, which is incorrect. If a synthetic material is to be used in production, it must be in one of the OFPA categories.

Beyond Pesticides opposes the listing of chlorine compounds for use in animal aquaculture for reasons given below. In addition, 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 years with the same threshold for allowance as is required by the petition process. To do this, the NOSB must adopt a five-year expiration date as an annotation to the listing.

For the disinfection of surfaces, nonchemical alternatives include steam sterilization and UV radiation.[14] Furthermore, the environmental community has for years supported a move away from chlorine chemistry, so no additional uses of chlorine should be added to the National List.

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[13] "Residual chlorine levels in the water in direct animal contact (for example, culture water) shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act."

[14] See Crops TR for Chlorine, January 31, 2011, lines 611-622.

There are now resources associated with "Green Chemistry" programs, such as the one at the University of Massachusetts in Lowell, and the Design for the Environment program at EPA that address chemical alternatives to chlorine as a disinfectant when such nonchemical approaches as steam are not appropriate. These need to be considered in evaluating alternatives. See, for example, the following websites:

The Presidential Green Chemistry Challenge Awards Program (http://www.epa.gov/greenchemistry/pubs/docs/award_entries_and_recipients2005.pdf) (p. 30 (p. 34 of pdf)

Overview of Design for the Environment (http://www.aocs.org/files/AMPresentation/38156_fulltext.pdf), disinfectants p. 20

Green Product Certification and Labeling: Quick Reference (http://www.nhhealthyschoolenvironments.org/documents/AppendixB.1.SelectingGreenerDisinfectants.pdf).

To category 1, question 1, "Is there a probability of environmental contamination during use or misuse?," the LS responds "no" and explains:

> 2006 Crops TR lines 212-266. The TR identities several areas of potential environmental impact, but notes that existing EPA regulations and the annotation restricting effluent to the levels of the Safe Drinking Water Act are sufficient to mitigate any environmental impact. The petitioner and a number of producers have confirmed that chlorine materials are not used in direct contact with the environment (e.g. ponds and net pens) and the restrictive annotation would prohibit such uses regardless.

The limits set under the Safe Drinking Water Act (SDWA) are not set at a level to protect aquatic life. In fact, the SDWA standard of 4 mg/L is 363 times as high as the aquatic life protection criterion of 11 ug/L set under the CWA.[15] Neither, however, equates to the OFPA criterion of "no harm."

We support the following additional statements made in the minority opinion of the proposal use of chlorine with aquatic plants, which strongly suggest that alternatives to chlorine should be used in the aquatic environment:

> With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:
> • The fact that aquaculture systems are closer to water, which could be contaminated by effluent than terrestrial agricultural systems, raises unique concerns that require close scrutiny and not reliance on other standards for terrestrial production.
> • Misuse can kill plants and soil organisms and raise soil pH and kill fish and invertebrates. (2011 Crops TR lines 386-390; 270-271)
> • TRI data includes 5.7 million pounds of chlorine per year released by facilities making and using chlorine. (ATSDR Tox Profile p. 162)

[15] EPA Ambient Water Quality Criteria for Chlorine, http://water.epa.gov/scitech/swguidance/standards/upload/2001_10_12_criteria_ambientwqc_chlorine1984.pdf

• When mixed with organic materials (e.g., algae, dirt), hypochlorite produces trihalomethanes (THMs), which are carcinogenic. Currently, the maximum contaminant level (MCL) for total THMs is 0.080 mg/L (EPA 2009). (2011 Crops TR lines 277-280) Depending on the source of water, this could result in the presence of THMs in culture water and its concentration in algae when used to disinfect water. (Chloroform MSDS http://datasheets.scbt.com/sc-239527.pdf)
• Due to high reactivity, the petitioned substances do not persist in the environment. But many products are possible from reactions, and some may be persistent. This is particularly an issue for water disinfection. (2011 Crops TR lines 476-491)
• Human health effects of chlorine include burning, pain, inflammation, irritation to respiratory system, etc. (2011 Crops TR lines 496-514)
• Chlorine may harm the beneficials inherent in an aquaculture system when used to disinfect water, or when discharged. (2011 Crops TR, lines 270-271)
• Chlorine compounds are used to kill algae, an important part of the aquatic ecosystem. (2011 Crops TR, lines 62, 87)

With regard to checklist Category 2, Essentiality, the minority believes the following need to be considered:

- "[T]he following non-synthetic materials are allowed as drip irrigation cleaners and could be used on hard surfaces: acetic acid, vinegar, citric acid, and other naturally occurring acids." (2011 Crops TR 519-520)
- The petition does not describe any limitations of alternative substances. It simply states that the alternatives are not used. The petition also does not distinguish between the disinfection of equipment and water. Some alternatives may be useful for one and some the other.
- Other alternative substances are hydrogen peroxide, electrolyzed water, alcohols, peracetic acid, copper sulfate, and soap algaecides for hard surfaces. Ozone for water disinfection (2011 Crops TR 535-606) See EPA Green Chemistry award for alternatives.[16]

[16] The Presidential Green Chemistry Challenge Awards Program Summary of 2005 Award Entries and Recipients, p. 30. http://www.epa.gov/greenchemistry/pubs/docs/award_entries_and_recipients2005.pdf
Almost all traditional, widely used disinfecting and sanitizing products contain ingredients that are toxic or potentially toxic, are environmentally hazardous, or have a high potential for accidents. For example, oxidizing chemicals, such as hypochlorite, peracetic acid, hydrogen peroxide, ozone, and chlorine dioxide, kill microorganisms by indiscriminate oxidation of organic matter, potentially destroying antioxidants, nutrients, and vitamins while forming unknown or toxic byproducts, including cancer-causing free radicals. The non-oxidizing microbicidal quaternary ammonium compounds (QACs; other traditional disinfectants) inhibit butyl cholinesterase in blood plasma, liver, pancreas, and the white matter and are unsafe for use on fruits and vegetables because they leave large residues.

Microcide uses ingredients listed by the FDA and EPA in volumes 21 and 40 of the Code of Federal Regulations (CFR) as biodegradable, generally recognized as safe (GRAS), food additives, safe, and/or nonpolluting. With these ingredients, Microcide develops broad-spectrum microbicidal products as alternatives to toxic and oxidizing chemicals for the food processing, personal care, and health industries. Their products use surface-active agents at low pH. Raising the pH diminishes the microbicidal properties, allowing safe environmental disposal and biodegradation of the products after use. These products selectively kill microorganisms on food-contact surfaces,

- For other practices, see Toxics Use Reduction Institute CleanerSolutions Database.[17]

Under Category 3, Compatibility, the minority points out the following:

- Chlorine does not enhance water life and properties; is not from renewable resources; and has negative impacts on biodiversity. (2011 Crops TR 270-271, 278-279, 349-352).
- Natural alternatives exist. (2011 Crops TR 270-271, 278-279, 349-352, 519-530)
- The use for culture water disinfection is not included in any of the OFPA categories of §6517(c)(1)(B)(i).

v. Biologics—Vaccines for aquatic animals

Beyond Pesticides opposes the listing of vaccines in aquaculture systems. Vaccines, like other materials, should not be approved in the absence of regulations that define an organic aquaculture system.

In addition, we support the minority proposal to add the annotation, "Until May 1, 2019 [or sunset date]." We agree that "[I]n 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." We agree with the minority that issues relating to health or environmental impacts and alterative natural materials and management methods have already arisen, and that the review in five (5) years provides must allow the NOSB to reevaluate, possibly modify use conditions, and vote using the same standard of review that is used to approve the material initially.

In addition, we agree with the minority that answers (yes/no) checked often do not conform to the evidence presented in the comments/documentation column, and in particular, we agree with the following observations:

With regard to checklist Category 1, Adverse Impacts on Humans and the Environment, the minority believes the following need to be considered:

• The following statements in response to the question, "Is there a probability of environmental contamination during use or misuse?" suggest that the answer should be *yes* instead of *no*:

o In the case of killed and modified live vaccines there is potential for incomplete inactivation for a particular vaccine lot leaving live pathogen and the reversion to virulence of the modified vaccine inadvertently precipitating a new epizootic through vaccination. (TR 656-659)

o Modified live vaccines are desirable and highly effective in closed systems. However the virus is still capable of infection. These vaccines have not usually been considered acceptable due to the environmental risk that non-virulent viruses could revert to

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on fresh fruits and vegetables, and on body parts (including mucosal and skin surfaces) without covalent chemical reactions. The technology presents alternative products safe for manufacturing, transportation, and use without accident potential. Two of Microcide's products, PRO-SAN and PRO-SAN L, are EPA-registered pesticides.

[17] http://www.turi.org/Our_Work/Cleaning_Laboratory/Does_It_Clean/CleanerSolutions_Database

virulent forms or that attenuated viruses that are not virulent in vaccinated species could prove virulent to other species in open systems. (TR 296-299)

- The following responses to, "Is there potential for detrimental chemical interaction with other materials used in organic farming systems?" suggest that the answer should be *yes* instead of *no*:
  - o Many chemicals are used in producing fish vaccines. Formaldehyde and ethyleneimine for example are not on the National List, yet they are presently used in production of approved vaccines. Adjuvants are added to vaccines to promote antigenicity and are not considered excipients. (TR 338-348)
  - o Polyvalent vaccines should always be used under veterinary supervision as adverse events could occur between vaccines from different sources. (TR 349-354)
- The following response to, "Is there a toxic or other adverse action of the material or its breakdown products?" suggests that the answer should be *yes* instead of *no*:
  - o Some reports have described autoimmune disease development in farmed salmon after vaccination with oil adjuvated vaccines. There is possibility of increased infection with unvaccinated pathogens as a result of vaccine induced autoimmunity. (TR 630-634)
- The following responses to, "Are there adverse biological and chemical interactions in the agro-ecosystem?" indicate that not enough is known to justify the *no* answer:
  - o There is one DNA vaccine to control an infectious virus (hematopoietic necrosis) but little is known about impacts of this in net pens or tanks. (TR 714-728; 642-656)
  - o Ongoing research will be needed to evaluate impacts after regulations are promulgated. (TR 728-738)

3. Plant aquaculture concerns

NOP guidance puts the role of NOSB decisions in question. The NOP Policy Memorandum of September 12, 2012 on Production and Certification of Aquatic Plants states,

> This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List of Allowed and Prohibited Substances at 7 Code of Federal Regulations (CFR) 205.601-205.602, as the basis for the production and certification of cultured and wild crop harvested aquatic plants.

This statement makes the purpose of petitioning materials for aquatic plant production very unclear. None of the materials on §205.601 has been approved and listed for use in aquaculture. For the NOP to approve such use is in conflict with OFPA §6517(d)(2), which prohibits the Secretary from allowing exemptions for synthetic materials not recommended by the NOSB. It is also in conflict with §6517(b), which requires that exemptions be by specific use or application. (See 1.b. above.)

Furthermore, the new NOP sunset process will make it much more difficult to remove the aquaculture materials or annotate them in the future if the Board thinks it necessary. Because we believe the NOP process is contrary to the statute, and will therefore not subject the

aquaculture materials to the required assessment to determine re-listing at sunset in the future, we sincerely urge NOSB members to oppose these aquaculture materials petitions and any others where removal or annotation might conceivably be needed based on health, environmental, and essentiality issues unless accompanied by an annotation for a five-year expiration date. Clearly, the NOSB needs to reconsider the approval in five years with the same threshold for allowance as is required by the petition process. To do this, the NOSB must adopt a five-year expiration date as an annotation to the listing.

a. Micronutrients

Beyond Pesticides opposes the listing of micronutrients in aquaculture systems. Micronutrients, like other materials, should not be approved in the absence of regulations that define an organic aquaculture system.

If the NOSB decides to move forward with this proposal, we urge the addition of the annotation, "Until May 1, 2019 [or sunset date]." In the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB should reconsider the approval in five (5) years. Issues relating to health or environmental impacts and alterative natural materials and management methods have already arisen, so the review in five (5) years provides must allow the NOSB to reevaluate, possibly modify use conditions, and vote using the same standard of review that is used to approve the material initially.

In order to be consistent with organic regulations, synthetic inputs cannot be the norm. Synthetic inputs may be needed to tweak the system or to respond to unusual situations. However, this petition requests a synthetic input to be allowed as a normal part of the system. In addition, the lack of an organic aquaculture policy for plant production that defines the integration of plants and fish introduces a difficulty in creating the parameters necessary to establish systems that are compatible with OFPA and resulting organic methods. Evaluating the use patterns of synthetic materials permitted on the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which no synthetics are added.

The April, 2010 recommendation[18] grew out of Board discussions going back to 1995, and includes many of those earlier discussions as appendices. The following excerpts from that recommendation are helpful to understanding our viewpoint.

> Observing the framework of organic farming based on its foundation of sound management of soil biology and ecology, it becomes clear that systems of crop production that eliminate soil from the system, such as hydroponics or aeroponics, cannot be considered as examples of acceptable organic farming practices. Hydroponics, the production of plants in nutrient rich solutions or moist inert material, or aeroponics,

[18] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5084677.

a variation in which plant roots are suspended in air and continually misted with nutrient solution, have their place in production agriculture, but certainly cannot be classified as certified organic growing methods due to their exclusion of the soil-plant ecology intrinsic to organic farming systems and USDA/NOP regulations governing them.

An appendix to the 2010 document said:

1. Over the long run, can the systems become more sustainable with less reliance on outside inputs?

Aquaponic systems combine the features of both hydroponics and aquaculture. This is done by recirculating the effluent from fish tanks and using it as a source of nutrients for vegetables grown hydroponically. Using sand or gravel as media. Nitrifying bacteria convert the fish effluent, primarily ammonia, to nitrite and then nitrate, which the plants can use. Diver (Aquaponics-Integration of Hydroponics With Aquaculture, *2000)* points out several sustainable aspects of aquaponic systems include the following:

Waste materials from one biological system are used as a source of food or fuel for a second system;

The integration of the production of fish and plants increase diversity, and in turn, system sustainability;

Biological filtration cleanses the water before it leaves the system; and

It is possible that the only fertility input would be the fish feed.

In order to be consistent with organic law and previous NOSB recommendations, synthetic inputs cannot be the norm. In general, the agro-ecosystem feeds the crop, and synthetic inputs may be needed to tweak the system or to respond to unusual situations. However, this petition requests a synthetic input to be allowed routinely in the absence of a defined organic aquaculture system. This is analogous to the hydroponic model, and is not consistent with organic and sustainable agriculture.

The petition states that all materials petitioned for use in organic production of aquatic plants would be used only in contained systems, “as in on-shore tanks and ponds.” We urge the NOSB to define “contained systems” and through an annotation restrict this substance (and all substances petitioned for use in production of aquatic plants) to contained systems.

The LS proposes to list “micronutrients” without qualification or annotation. How can the subcommittee judge the essentiality or environmental impacts of an unrestricted list of materials? Has the subcommittee investigated possible toxicity of every possible micronutrient compound? Furthermore, the LS cannot rely on the listing of micronutrients for (terrestrial) crops as justification because the crops listing is specifically limited to a defined list of eight micronutrients, prohibits those made from nitrates or chlorides, and limits their use to documented soil deficiencies. Furthermore, at least one micronutrient –nickel– was not approved when petitioned individually. In addition, as discussed below, micronutrients can have impacts on aquatic ecosystems that are different from impacts on terrestrial ecosystems

We have a number of concerns about responses to checklist questions. For example, the LS answers "No" to category 1, question #1, "Is there a probability of environmental contamination during use or misuse?" The justification for this is:

> Because micronutrients are used at very low concentrations there is little probability of environmental contamination. Petition (pg.4): "Any residual trace elements released into environment will be extremely low concentrations below any physiologically significant level, and will be rapidly absorbed by microorganisms."

Thus the answer is justified by a statement from the petition. However, just as micronutrients may be a limiting factor in the growth of cultivated plants, they are also often a limiting factor in the growth of algal blooms in natural waters: "In the marine environment, iron has been the subject of increasing interest because recent studies have shown that this metal limits primary production in some open ocean waters.40 Iron can also act synergistically with nitrogen to enhance algal production in coastal and ocean waters.41"[19] Since the proposal does not limit the use of micronutrients to contained systems, the NOSB must assume that they could be used in the culture of seaweeds in open water, for example.

Briefly, here are some other concerns about checklist responses in Category 1, adverse impacts on humans or the environment:

- Is there a probability of environmental contamination during, manufacture or disposal? The answer given is "No" despite "Little specific information is available on micronutrient manufacturing in either the petition or TR, other than that micronutrients are manufactured in many different ways."
- Are there any adverse impacts on biodiversity? "No," in spite of cited effects, based on, "However, there would be no incentive to add micronutrients at higher-than-needed levels for aquatic plant production." The answer checked does not match the evidence cited.

With regard to Category 2, essentiality, the LS statement (third paragraph of proposal) argues against it:

> Previous to the development of micronutrient media for plant aquaculture systems, it was common practice to add aqueous extracts of soil to culture water to supply micronutrients. Today, there are available micronutrient mixtures –such as the Guillard f/2 media– that are commonly added to culture water to supply micronutrients for plant aquaculture.

In other words, the board is being asked to approve synthetic inputs as a substitute for natural inputs that have been used. The NOSB must decide not the essentiality of micronutrients, but the essentiality of <u>synthetic</u> micronutrients.

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[19] Deborah L. Swackhamer, Hans W. Paerl, Steven J. Eisenreich, James Hurley, Keri C. Hornbuckle, Michael McLachlan, David Mount, Derek Muir, and David Schindle, 2004. Impacts of Atmospheric Pollutants on Aquatic Ecosystems, Ecological Society of America Issues in Ecology, p. 7.

In Category 3, compatibility with organic production practices, the LS checks "Yes" for both "Is the substance consistent with organic farming and handling?" and "Is the substance compatible with a system of sustainable agriculture?" No justification is given, despite the above statement that indicates the existence of a natural, sustainable alternative practice.

b. Carbon dioxide

Beyond Pesticides opposes the listing of carbon dioxide for plant aquaculture. The lack of an organic aquaculture policy for plant production introduces difficulty in creating the parameters necessary to establish systems that are compatible with OFPA and resulting organic methods. Evaluating the use of synthetic materials for the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which no synthetics are added.

We are glad to see that in this case, the LS has added the annotation, "for use in contained systems such as tanks and ponds." However, we agree with the minority position that any continuing discussion of the use of carbon dioxide and other synthetic materials in aquaculture should adopt an annotation for a five-year expiration date that "allows the Board to monitor the use of the material, incentivize alternatives, update its scientific and essentiality review, and vote on the continuation of use pending the receipt of a petition requesting that use be continued."

We agree with the minority concerning the underestimated environmental impacts of carbon dioxide: "While carbon dioxide may not seem very hazardous, the atmospheric concentration has reached the all-time high of 400ppm, elevating to extreme levels the threat of global climate change. Organic production may not be a large contributor, but the use of synthetic carbon dioxide, which is not captured, as opposed to using carbon dioxide produced by animals in the system, does contribute to the problem."

With regard to essentiality, we point out to NOSB members the statement in the minority position:

> The Crops Subcommittee received information that indicates that additions of synthetic carbon dioxide are not essential. An NOP survey of certifiers who certify organic aquatic plant production found that very few inputs were used. Sometimes natural alkali, carbon dioxide, and sodium bicarbonate were used. Integrated systems[20] control pH and alkalinity, as well as other parameters, by balancing the organic components of the system.

[20] See, for example, Siew-Moi Phang, 1992. Role of algae in livestock-fish integrated farming systems. Proceedings of the FAO/IPT Workshop on Integrated Livestock-Fish Production Systems, 16–20 December 1991, Institute of Advanced Studies, University of Malaya, Kuala Lumpur, Malaysia.

Regarding compatibility with organic practices, we first point out that none of the boxes in question 7 of Category 3 were checked "Yes," indicating that carbon dioxide does not belong in any of the categories of allowed synthetics under OFPA §6517 (c)(1)(B)(i).

In addition, the petition states,

> Application rates are impossible to determine since the amount of carbon dioxide necessary to maintain optimum pH values varies depending upon such factors as the density of culture, rate of growth, its stage of growth, and the size of the culture container. The amount of CO2 consumed by the plants is self-regulating since if excessive amounts of this gas are introduced to the culture, the resulting pH value is driven lower to the point where the rate of algae growth and uptake of CO2 is reduced.
>
> Carbon dioxide is consumed by algae as cultures grow and can drive the pH level above the desired optimum. Since aquatic animals eliminate carbon dioxide as a metabolic product, the presence of aquatic animals in an algal culture reduces demand for carbon dioxide introducing another variable.

This indicates to us that carbon dioxide acts as a synthetic macronutrient in plant aquaculture, making it incompatible with organic production practices.

c. Chlorine

The proposal for the use of chlorine in plant aquaculture "follows the same logic as the Livestock Subcomittee's proposal for chlorine in aquatic animal production" and is nearly identical. (See our comments above at 2.c.iv.)

d. Lignin sulfonate

Beyond Pesticides opposes the listing of lignin sulfonate for plant aquaculture. The lack of an organic aquaculture policy for plant production introduces difficulty in creating the parameters necessary to establish systems that are compatible with the OFPA and resulting organic methods. Evaluating the use of synthetic materials for the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which no synthetics are added.

With respect to Category 1 of the checklist, health and environmental impacts, we would like the NOSB to consider the following that lignin sulfonate is a by-product of paper pulping. Pulp and paper is the third largest industrial polluter to air, water, and land in both Canada and the United States, and releases well over 100 million kg of toxic pollution each year. Runoff or discharges can pollute waterways.[21]

With regard to Category 2, essentiality, the need for lignin sulfonate must be considered in tandem with the need for micronutrients because lignin sulfonate is used to deliver the

[21] TR lines 239-258; Wikipedia, citing Canadian National Pollutant Release Inventory http://en.wikipedia.org/wiki/Paper_pollution

micronutrients. The LS statement (third paragraph of micronutrients proposal) argues against essentiality:

> Previous to the development of micronutrient media for plant aquaculture systems, it was common practice to add aqueous extracts of soil to culture water to supply micronutrients. Today, there are available micronutrient mixtures –such as the Guillard f/2 media– that are commonly added to culture water to supply micronutrients for plant aquaculture.

In other words, the Board is being asked to approve synthetic inputs as a substitute for natural inputs that have been used. The NOSB must decide not the essentiality of micronutrients, but the essentiality of synthetic micronutrients and the lignin sulfonate used to chelate them.

Similarly, In Category 3, compatibility with organic production practices, the LS checks "Yes" for both "Is the substance consistent with organic farming and handling?" and "Is the substance compatible with a system of sustainable agriculture?" No justification is given for ignoring the existence of a natural, sustainable alternative practice.

If the NOSB decides to move forward with this proposal, we urge the addition of the annotation, "Until May 1, 2019 [or sunset date]." In the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB should reconsider the approval in five (5) years. Issues relating to health or environmental impacts and alterative natural materials and management methods have already arisen, so the review in five (5) years provides must allow the NOSB to reevaluate, possibly modify use conditions, and vote using the same standard of review that is used to approve the material initially.

e. Vitamins B1, B7 (H), B12

Beyond Pesticides opposes the listing of synthetic vitamins B1, B7 (H), and B12 for use in plant aquaculture. The lack of an organic aquaculture policy for plant production introduces difficulty in creating the parameters necessary to establish systems that are compatible with the Organic Foods Production Act and resulting organic methods. Evaluating the use of synthetic materials for the National List outside of a defined policy on whole aquaculture systems for plants and animals runs contrary to organic process and practice because the use of a synthetic material must be evaluated relative to a practice norm in which no synthetics are added.

We have the following concerns relating to Category 1 of the checklist:

- Vitamin B1: Commercial production involves a six-step synthetic procedure beginning with ethyl 3-ethoxypropionate as the feedstock and reactants including ethyl formate, acetamidine hydrochloride, phosphorus(V) oxychloride, alcoholic ammonia, hydrobromic acid, and 4-methyl 5-hydroxyethyl thiazole. TR lines 594-600.
- A search of the patent literature revealed two methods for vitamin B1 (thiamine) production by fermentative methods that appear to use genetically engineered bacteria. TR lines 601-606.
- Vitamin B7 (H, biotin): The synthesis begins with fumaric acid as the starting material and involves 15 linear synthetic steps, including vicinal bromination of fumaric acid,

benzylamine, oxalyl chloride, acetic anhydride, zinc, acetic anhydride, acetic acid, dihydrogen sulfide, potassium hydrosulfide, zinc/acetic acid, an appropriate Grignard reagent, hydrogen over palladium, hydrobromic acid, silver d-camphorsulfonate, sodium diethyl malonate, and hydrobromic acid. TR lines 660-672.

- Microbial fermentation methods have been developed to produce only the biologically active isomer of biotin. As an example, a microorganism of the genus Kurthia (bacteria) was developed with resistance through exposure to a mutagen, selecting lines capable of producing d-biotin under aerobic conditions (Hoshino, 2002). TR lines 673-679.
- MSDSs for several feedstock chemicals and other chemical reagents used in the synthesis of biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. TR lines 946-946.
- Vitamin B12. Microorganism fermentation is the exclusive commercial method of synthesizing vitamin B12. Some strains are genetically engineered. TR lines 770-773.
- All: The fermentative production of vitamins presents a slight risk of product contamination from genetic material in the fermentation broth and any chemicals used during processing. TR lines 918-920.
- Many of the feedstock chemicals and reagents used in vitamin synthetic procedures are considered petrochemicals or may be obtained from genetically modified organisms (GMOs). Acetone, for example, is a commonly used chemical reagent derived from petroleum as well as from GMOs such as corn. TR lines 955-958
- Waste streams resulting from the fermentative production of vitamins may also pose risks to the environment. In general, the EPA assumes “no control features for the fermentor offgases, and no inactivation of the fermentation broth for the liquid and solid waste releases,” suggesting that environmental exposure to these waste streams is likely. Some potential risks to the environment include the transfer of novel genes into crops, poisoned wildlife, and the creation of new and more potent viruses, in addition to a host of unknown risks. TR lines 959-966.
- Release of large amounts of vitamins into the environment may result in eco-toxic events, such as the promotion of algal blooms and red tides. TR lines 985-987.
- Unicellular photosynthetic algae require nutritional intake of vitamin B1 (thiamine), B7 (biotin), and B12 (cobalamin) (NAS, 1969). These vitamins, as well as other macro- and micronutrients, can be a limiting growth factor for environmentally beneficial and deleterious algae. TR lines 976-979
- Excessive vitamin loadings can lead to synergistic and/or antagonistic effects for the absorption and bioavailability of minerals and other trace nutrients. TR lines 1011-1012.
- Overloading aquatic ecosystems with nutrients, such as vitamins, could potentially lead to depletion of the dissolved oxygen content and eutrophication. This is commonly manifested through occurrences of algal blooms and red tides, fish kills, and overall loss of biodiversity from the aquatic system. TR lines 1075-1077.
- Results from various studies indicate that a large proportion of animal feed nutrients introduced into the environment have the ability to accumulate in bottom sediments (Wu, 1995). This phenomenon may lead to high sediment oxygen demand, anoxic sediments, production of toxic gases, and a decrease in benthic diversity. In particular,

laboratory studies suggest that the accumulation of these nutrients, including vitamins, may encourage the growth of algal blooms and red tide species (Wu, 1995). TR lines 810-815.

With regard to Category 2, essentiality, we point out that the TR mentions the following natural sources of the vitamins:

Vitamin B1: Dried brewers yeast, wheat middlings, wheat mill run, rice bran, rice polishings, dried torula yeast, groundnut (peanut) meal, wheat bran, barley, dried fish solubles, cottonseed meal, soybean meal, linseed meal, dried distillers solubles, broad beans, lima beans, dried delactose whey, glandular meals (liver/kidney), green leafy crops, outer coat or germ of cereals.

Vitamin B7: Dried brewers yeast, dried torula yeast, dried distillers solubles, rapeseed meal, safflower seed meal, sunflower seed meal, whole hens eggs, rice polishings, dried brewers grains, liver and lung meal, rice bran, dried delactose whey, cottonseed meal, groundnut meal, soybean meal, dried skim milk, alfalfa meal, oats, sorghum, dried blood meal, dried fish solubles, fish meal, wheat bran, wheat mill run, legumes, green vegetables.

Vitamin B12: Animal by-products, liver, kidney, heart, muscle meats, fish meals, shellfish, meat and bone meal, condensed fish solubles, and poultry by-product meal. TR lines 1189-1192; 1207-1211; 1237-1238.

Finally, with respect to Category 3, compatibility with organic production, the following points are relevant:

- Synthetic vitamins permitted for animals only when natural vitamins are not available in EEC, UK, Japan, and IFOAM standards. TR lines 495-525.
- In order to be consistent with organic law and previous NOSB recommendations, synthetic inputs cannot be the norm. In general, the agro-ecosystem feeds the crop, and synthetic inputs may be needed to tweak the system or to respond to unusual situations. However, this petition requests a synthetic input to be allowed routinely in the absence of a defined organic aquaculture system.

If the NOSB decides to move forward with this proposal, we urge the addition of the annotation, “Until May 1, 2019 [or sunset date].” In the absence of regulations defining acceptable practices in organic aquaculture, essentiality in particular cannot be judged at this time, so the NOSB should reconsider the approval in five (5) years. Issues relating to health or environmental impacts and alterative natural materials and management methods have already arisen, so the review in five (5) years provides must allow the NOSB to reevaluate, possibly modify use conditions, and vote using the same standard of review that is used to approve the material initially.

Conclusion

We began by describing a couple of possible approaches to organic aquaculture. In spite of the existence of other labels designating fish and other seafood that are safe for human consumption and do not harm the aquatic environment, there is a demand for organically-raised fish. Those systems we described might prove to be appropriate models for aquatic

aquaculture. They are not the systems we see vying for the organic label, nor are they the systems that require the routine use of the materials petitioned by the Aquaculture Working Group. They are as different from industrial aquaculture as organic farms were from industrial agriculture when OFPA was passed. We may never see the commercialization of such systems in the United States –not because it is impossible, but because following the lead of industrial aquaculture creates disincentives for systems that might be truly organic. The illegal allowance of the sale of imported aquaculture products under the USDA organic label was certainly a major factor in promoting the industrial model and disincentivizing more appropriate organic models. We call upon the USDA to enforce a ban on imported "organic" fish and seafood products until regulations are in place that define organic aquaculture. And we call upon the NOSB to reject all petitions for aquaculture materials until such regulations are in place, and to revisit aquaculture recommendations keeping in mind the "NOSB Principles of Organic Production and Handling" and the models presented here.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors