AWG Bivalve Mollusc Working Paper

April 14, 2009

On March 17, 2009, the Livestock Committee of the National Organic Standards Board posted a memorandum providing their response to Aquaculture Working Group (AWG) regarding proposed organic standards for bivalves. This memorandum is included at the end of this document as Appendix A, and is posted at:
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5075830&acct=nosb .

Five points of concern expressed by the Livestock Committee are:

1. Feed control; the system is generally one that is based on background water flow to supply feed material, the bivalves are not fed 100% organic feed and the system is not highly managed in terms of feed, and the bivalves eat 100% wild feed.

2. Water quality input; primarily marine systems; concerns exist over the quality of water flowing over the bivalves as tides flow and the bivalves are exposed to any possible contaminate that may exist.

3. Control of harvest sediment; this concern is in response to discussions regarding environmental issues as they relate specifically to harvest and the disturbance of tidal or sensitive areas.

4. Using sanitation measures as indicator for other toxins; there are concerns regarding what is monitored for sanitation – coliforms & e.coli and not other toxins.

5. Containment – barrier from growing areas to everything else; in terrestrial systems buffers or barriers are utilized to minimize any contamination from surrounding activities, in aquatic systems sited in tidal areas this is difficult or impossible.

AWG response to *1. Feed Control.* AWG recognizes that there are concerns by members of NOSB about uses of wild sources of food in organic systems. However, the AWG proposal involves highly managed systems unlike natural food production systems in conventional bivalve production.

Use of wild feed is allowed in the Organic Food Production Act under Sec. 2107(c) Wild Seafood. Wild phytoplankton grown in the sea is covered in this section pertaining to food.

In addition, Sec. 2114(f) Management of Wild Crops provides:

An organic plan for the harvesting of wild crops shall –

(1) designate the area from which the wild crop will be gathered or harvested;
(2) include a 3 year history of the management of the area showing that no prohibited substances have been applied;
(3) include a plan for the harvesting or gathering of the wild crops assuring that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop; and
(4) include provisions that no prohibited substances will be applied by the producer.

The Final Rule, § 205.207 Wild-crop harvesting practice standard provides:

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Kelp, a marine macroalgae, is certified organic under these provisions. Therefore, phytoplankton, being marine microalgae, also qualify under these provisions for wild crops.

To comply with these conditions, proposed (b)(3) provides extensive management requirements to prevent contamination by prohibited substances. These include careful evaluations in locating sites to avoid sources of contamination, and then careful monitoring for contamination. These management activities provide a high level of diligence that are substantially different than conventional practices.

This marine situation can be likened to terrestrial pastures that are fed water by creeks and streams that have their origin at distant locations and the water flows through conventional agriculture operations prior to the organic system thereby potentially being exposed to contamination. Another situation is the lack of control an organic farmer has over air qualities since the air passes over and through sources of contamination. The AWG proposal is intended to manage to prevent and minimize potential contamination.

In addition to (b)(3) that pertains to wild food production, (c) provides for bivalve production integrated with another ocean based organic production facility such as a net pen where the bivalves feed largely upon the metabolic products of that production.

The Act and the Final Rule provide for wild feed in organic systems under certain conditions. AWG has developed the proposed regulations in both (b) and (c) to comply with applicable conditions in the Act and the Final Rule. The AWG proposal provides a very high level of management to avoid contamination, to minimize environmental disruptions, and for other reasons. This proposal is substantially different than conventional production.

AWG response to *2. Water quality input.* Water quality in the ocean varies substantially from place to place, and at some locations, from time to time. A remote island location off the coast of Maine has a substantially lower potential for contamination by prohibited substances than does a location such as New York Harbor. As discussed above, (b) and (c) require extensive prequalification evaluations for proposed organic bivalve mollusc operations to assure high quality waters free of contamination in organic growing areas.

Paragraphs (e) and (f) require frequent monitoring of indicator organisms and sentinel animals to detect possible contamination by prohibited substances.

Careful site selection coupled with frequent monitoring for potential contamination assure good water quality.

AWG response to *3. Control of harvest sediment.* Virtually any form of bivalve harvest from Geoduck clams buried two feed deep into sediment to long-line mussels cause some sediment disturbance, whether on the bottom or from small particulate matter that has settled on shells. In the initial site survey, these proposed standards require the identification of biologically sensitive areas where re-suspended sediment could injure marine life, with harvesting prohibited within specified distances of ecologically sensitive areas.

The proposed standards in (i)(6) ii, and in various sections of (j) require minimal impacts including mitigation measures where appropriate. Low impact dredges are specified in (j)(4). Suction devices and escalator harvesters are prohibited. Burrowing clams cannot be extracted from the substrate greater than 8-inches.

This marine situation can be likened to the worthy objective of no till terrestrial agriculture. Much human effort is directed towards this aspiration with a trend towards better soil conversation, yet some loss remains.

In developing these recommendations, AWG studied related documents.[1]

Numerous precautions are incorporated in the proposed standards to prevent sediment damage to marine life. Like no-till agriculture, the AWG proposal is distinctively different from conventional practices and promotes a trend towards highly managed control of harvest sediments.

AWG response to *4. Using sanitation measures as indicator for other toxins.* There is a wide range of potential contaminants of concern in coastal aquaculture including agricultural chemicals, persistent organic compounds, and heavy metals. These potential contaminants can enter bivalve growing waters through point discharges such as sewage and industrial outfalls, or from terrestrial runoff, such as from contaminated streams or from agricultural crops.

Establishment of an organic farming area will include determination of the source of marine water that flows over the farmed shellfish. This water contains feed and material filtered by the shellfish and would include any substances of concern such as toxins or contaminants. The area of water that is supplied to the farmed shellfish is referred to as the hydrologic zone of influence or HZI. Establishing the HZI when the proposed organic farm site is first surveyed will enable the farmer to determine the absence of any contaminant sources of concern to the farm and understand the water area which potentially could pose contaminant risk to the farm. Thus the known HZI will be a geographic area of water that is influences the organic farming area.

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[1] Goodwin, Lynn, Pease B., Moran, David, Pacific Geoduck Clam, Biological Report 82 (11.120) TR EL-82-4, December 1989, US Army Corps of Engineers and Fish and Wildlife Service.

The State of Washington Commercial Geoduck Fishery Management Plan, Washington Department of Natural Resources Aquatic Resources Division, May 23, 2001, Washington State Department of Natural Resources.

Supplemental Environmental Impact Statement, State of Washington Commercial Geoduck Fishery, May 23, 2001, Washington State Department of on Natural Resources.

Wilber, Dara H. and Douglas G. Clarke, Biological Effects of Suspended Sediments: A Review of Suspended Sediment Impacts on Fish and Shellfish with Relation to Dredging Activities in Estuaries, North American Journal of Fisheries Management 21:855-875, 2001, American Fisheries Society.

Prior to establishing an organic bivalve growing facility under our proposed standards, a thorough site evaluation is required, with one objective of this evaluation being to locate all point discharges that could contribute contamination.

A major contamination contribution also is made from storm water run-off where terrestrial contaminants are washed into the ocean. While it is impractical to sample ocean waters for each potential contaminant on a routine basis, indicator organisms are widely used to measure potential contamination of environmental samples. The use of indicator organisms is based upon the premise that elevated levels of the subject organism indicates the presence of other contaminants that have been washed from land into the sea. The presence of coliform bacteria, such as *E. coli*, in surface water is a common indicator of contamination. Their presence is closely correlated with contamination.

In addition to monitoring for bacterial indicator organisms, these proposed standards in (f)(7) require monitoring for contamination with sentinel animals by sampling tissue of bivalve molluscs for a large number of contaminants. The US National Oceanic and Atmospheric Administration operates a comprehensive program of monitoring bivalve tissue contamination through the Mussel Watch Program. In this program, certain species of bivalve molluscs (including the American oyster *Crassostrea virginica* in some regions) are sampled from approximately 300 coastal stations around the country, generally once a year, including in the Great Lakes. These filter feeding molluscs concentrate and retain pollutants and have been found to be reliable indicators of contamination.

Mussel Watch samples are analyzed for a comprehensive list of analytes listed in Appendix B at TDI-Brooks, a laboratory affiliated with Texas A&M University, College Station, Texas, according to established protocols that have been developed and perfected over many years. Approximately 100 analytes are analyzed for each sample. These include metals, metalloids and related compounds (Mercury, Methyl-mercury, etc.); petroleum and combustion forensics (Benzanthracene, Pyrene, etc.); industrial contaminants (PCB, BDE, PBB, etc.); pesticides (Dibutyltin, DDT, etc.); and flame retardants.

It has been found with few exceptions, that samples from NSSP determined "Approved" and "Conditionally Approved" bivalve growing areas do not exceed the posted FDA action levels, tolerances and guidance levels for deleterious substances and harmful elements. Conversely, samples from "Prohibited" areas often are contaminated. In general, samples from high human population density regions, such as New York Harbor, are high in substances of concern. However, some contamination is aerosol. In this proposed standard, only growing areas in NSSP Approved and Conditionally Approved areas can be certified organic.

The cost of each analysis is $1,700 for the full suite of substances including recently added flame retardants at the College Station laboratory. It is proposed that the grower sample at least two animals at least quarterly at each site. As long as the level of any analyte in the sentinel animals exceeds the action levels, tolerances and guidance levels established by the FDA, it is assumed that the bivalve mollusc growing area is subjected to contamination by that analyte and other substances. In this case, production from that area cannot be labeled organic until analyte concentrations in the sentinel animals are below the FDA listed action levels, tolerances and guidance levels.

Monitoring for *E. coli*, as proposed, is a proven and widely employed means for indicating a wide range of biological and chemical contamination from terrestrial run-off waters. In addition, it is proposed that tissue of sentinel animals be tested for a comprehensive list of substances and metals. Concentrations of any analyte above FDA action levels, tolerances, and guidance levels disqualifies bivalve molluscs from that particular site until analyte concentrations in sentinel animals are below FDA action levels, tolerances and guidance levels.

AWG response to *5. Containment – barrier from growing areas to everything else.* In (b) and (c), extensive surveying and evaluations are required that essentially provide wide buffers between sources of potential contamination and growing areas. Surrounding activities are identified, and where incompatible with the requirements of this section, organic certification will be withheld. In addition, (b)(3) iv and (c)(2) iii requires the organic system plan to include specific distances, or buffers, between potential sources and the growing site.

The HZI is a means of creating an effective barrier for the shellfish growing area. The HZI established during the inception of the organic shellfish farm describes the exact water area that flows over the farm. Therefore the organic farmed has established the boundary of influence on the farm and all control measures and standards required in the organic farming plan are applied to this area defined by the HZI boundary. The HZI forms the boundary of the buffer zone that protects the farm from influences not allowed by its organic certification.

The proposed standards include wide buffers between sources of contamination and the growing site to minimize contamination from surrounding activities.

Requested table to compare proposed organic bivalve production with conventional. The table that follows is in response to this request.

Management Method	Conventional Aquaculture	Proposed Organic Standard
Conversion Period	None	Organic management for 3 yrs.
Map	NSSP for sewage discharge points	Sewage and industrial points of discharge.
Organic control points	None	Establishment of hydraulic zone of influence using hydraulic modeling and field studies.
	None	Initial site survey to determine if any contaminants are present.
	None	Identification of all point and non-point sources of prohibited substances plus other potential contaminants.
	None	Documentation of adjacent land uses including affidavits from contiguous land users that prohibited substances have not been applied during the past three years.
	None	Establishment of a water quality monitoring program conducted by grower.
	None	Ongoing contaminant monitoring of a wide range of substances both using sentinel bivalves.
Measures to minimize impacts to surrounding ecosystems and wildlife	None	Waste management plan with schedule for recycling, reuse , and surveillance and clean up of farm originated waste in surrounding ecosystem.
	None	Sensitive flora and fauna mapping and avoidance.

	None	Ecosystem impact minimization program as part of organic system plan.
		Biosecurity program.
	Optional	Altering seafloor with dikes and leveling prohibited
	Allowed	Impact on ocean bottom and on non-farmed species must be mitigated and minimized
	Not required	
	None	Harvest dredges with specified sediment penetration limits
	Allowed	Suction and hydraulic escalator harvesters prohibited
	Allowed	Harvesting within 100 feet of submerged beds of vegetation, fish spawning areas and ecologically sensitive habitats prohibited
	Allowed with permit	Use of quicklime, biocides, pesticides, herbicides and other chemical toxins for predator control prohibited.
	Allowed	Use of antifoulants and treated lumber prohibited
	Optional	Multitrophic production methods required
	None	Densities and animal numbers designed to prevent changes to surrounding benthos and avoid impacting primary productivity in surrounding ecosystems.
Responsible community relations	None	Plan for resolution of multi-stakeholder issues.
Animal health and welfare	Hatchery seed free of reportable shellfish infections	Hatchery seed free of reportable shellfish infections
	Optional	Handling, growing area management and biosecuri-

	None None	ty practices designed to minimize stress and exposure to pathogens Densities designed to optimize animal health and welfare Predator and pest control plan required
Origin of mollusks	None	Hatchery seed required (with exception) with wild seed prohibited. Triploidy prohibited.
NSSP designation	Harvesting from areas classified as remote, approved, conditionally approved, restricted and conditionally restricted allowed under certain conditions. Emergency closures determined by state authorities. Closure for major pollution impacts determined by state authorities.	Only remote or approved allowed. Closure for an additional seven days after reopening and grower testing for contamination indicators. Closure for at least an additional fourteen days and grower testing for contamination indicators.
Contamination monitoring	By state authorities using *E. coli* as indicator.	Same as NSSP (state authorities) additional monitoring by grower using direct monitoring within the hydraulic Zone of Influence
Contamination indicator technology updates	None	Annual review with inclusion in Organic System Plan where reliable.
Coliform indicators for closure	bacteria cells per 100 m.	14 cells per ml or more.

Testing of seston for persistent organic compounds and heavy metals.	Not required.	Required to be below FDA action levels, or closure.

REVISED PROPOSED STANDARDS

For Organic Bivalve Molluscs

§ 205.2 TERMS DEFINED

HACCP. Hazard Analysis Critical Control Point, a mandatory program for seafood processors under the U.S. Food and Drug Administration and the National Oceanic and Atmospheric Administration. The program requires the analysis and management of critical processing variables that impact upon the healthiness and safety of seafood products.

NSSP. National Shellfish Sanitation Program operated under jurisdiction of the U.S. Food and Drug Administration and designated state and foreign shellfish control authorities.

Bivalves. The term "bivalve" applies to bivalve molluscs including oysters, clams, mussels, and scallops. Gastropod molluscs, such as abalone and conch, and cephalopods, such as octopus and squid, are not included.

Seed, juvenile or spat. The stage of development after the larval, free-swimming stage, which, having developed an eye spot, foot, and gills, settles onto a suitable substrate (on shell, for example). This life state is also sometimes referred to as "*spat*."

Seston. Particulate matter suspended in water including plankton, organic detritus, and inorganic material.

Specific pathogen free. Hatchery bivalve seed must be certified free of reportable shellfish infectious disease agents in accordance with applicable state and/or federal regulations pertaining to the location of origin and use.

Submerged aquatic vegetation (SAV). A collective term that describes rooted macrophytes, including marine angiosperms, such as the true sea grasses, and freshwater macrophytic algae. Submerged aquatic vegetation provides food and shelter for juvenile estuarine and marine organisms and improves water quality by causing the sedimentation of suspended matter and the removal of dissolved nutrients through primary productivity.

§ 205.257 BIVALVE MOLLUSCS

(a) Bivalve molluscs general:

(1) Except as otherwise provided, all provisions of § 205.250 through § 205.259, Aquaculture, and § 205.600 through § 205.604, National List, in this subsection apply to bivalves.

(2) An organic bivalve producer must maintain records to preserve the identity of all organically managed bivalves and edible and non-edible products to assure reliable traceability from growing area to market.

(3) All applicable laws, regulations and procedures of national and local governments, including NSSP, HACCP, and environmental laws and regulations, must be obeyed.

(4) Bivalves that are removed from a certified operation and subsequently managed on a non-certified operation may not be sold, labeled or represented as organically produced.

(5) Depuration of bivalve molluscs for the purpose of eliminating or reducing amounts of prohibited substances is prohibited.

(6) Bivalves grown in onshore ponds, tanks, and other containers may be fed organic aquatic plants produced under § 205.258 Farmed aquatic plants and other organic seston in an integrated organic production system.

(b) Organic system plan for ocean based bivalve production where feed is natural seston:

(1) Ocean based bivalve growing areas must be under organic management for at least three years before production can be certified organic.

(2) A producer of organic bivalve molluscs must develop an organic system plan in accordance with the provisions of § 205.201.

(3) The organic system plan for bivalve production that is fed wild microalgae and other natural seston must include:

i. A map of the growing area that indicates the boundaries of organically managed areas, adjacent natural areas, and non-organically managed areas that may influence the operation, and water circulation patterns. The location of all industrial or domestic point sources of contamination must be included on the map. The map also must include locations of beds of eel grass, submerged aquatic vegetation, and other ecologically sensitive flora and fauna.

ii. The organic system plan must include an approximate delineation of the hydraulic zone of influence (HZI) for forage production for the shellfish farm. The HZI is the zone of production for forage consumed by the farmed bivalve molluscs.

iii. Determination of the HZI may be based on hydraulic models, field observations that measure and define circulation, and/or tracer studies. The organic system plan shall include a map of the HZI with grids representing forage production areas for the farm that contain 10% or less of the surface area of the HZI. In addition, methods for delineating the HZI must be described, as well as locations of any freshwater sources and other factors impacting production of forage for organic bivalve molluscs. The HZI determination may include approaches and methods such as:

a. establishing the tidal prism by measuring tidal amplitude.

b. determining water circulation patterns by drogue studies (Lagrangian methods) or comparable drift methods, tracer studies using dye, and current meters.

c. locating sources of fresh water inflow.

d. establishing Depth/Salinity/Temperature relationships.

e. Calculation of the HZI using a mathematical model if sufficient preexisting data is available.

The analysis shall determine estimated average and extreme ranges of circulation, and if vertical mixing occurs. The results of this analysis must include drawings or images of circulation patterns and how prevailing or storm wind conditions effect the HZI.

The HZI must be estimated under a representative range of typical conditions. Identification or quantification of extreme climatic conditions that could affect the HZI must be discussed in the organic system plan.

iv. Identification and location of all point and non-point sources of prohibited substances and other potential contaminants, such as heavy metals, from urban, residential, industrial and agricultural sources that may adversely affect the area of natural forage production and the bivalve growing facility. The plan must include a determination of the distance from the bivalve growing site to any point or identified area from which there is a significant risk of contamination;

v. Documentation of environmental conditions in the growing area, including water quality and land use in contiguous watersheds; Documentation shall include affidavits from contiguous agricultural and industrial users that prohibited substances have not been applied during the past three years.

vi. A description of a water quality monitoring program that indicates parameters measured, frequency of measurement, and location of sampling stations;

vii. A description of the procedures used for the culture and harvest of bivalve molluscs, including materials used for rafts, nets, or other structures;

viii. A description of measures that will be implemented to minimize impacts of culture operations on ocean ecosystems and wildlife, including discussions of:

a. the impacts of farm structures (if any), growing practices, and harvest methods.

b. benthic deposition.

c. estimates of nutrient flows, including recycling of nutrients from anthropogenic sources and adequacy of wild forage in the water column.

d. predator control methods.

e. species that use the habitat, including those designated as threatened or endangered. If threatened or endangered species are present, the plan must

indicate how culture and harvest activities are in compliance with applicable laws that protect such species.

ix. A description of biosecurity practices to prevent to the occurrence and spread of diseases or parasites;

x. A waste management plan that provides for:

a. reuse, recycling and proper disposal of nets, ropes, waste shell, grade-outs and dead-stock.

b. composting or recycling of waste biological materials, including shells, to the extent practicable.

c. control of offensive odors.

xi. A schedule for surveillance and methods of removing accidentally released culture materials or equipment from beaches or natural waters adjacent to the culture site;

xii. A process for the resolution or mitigation of complaints, conflicts, and other multi-stakeholder issues.

xiii. The Sanitary Survey for the operation as required under NSSP.

(c) Organic system plan for bivalve production integrated with another ocean based organic production facility such as a net pen where the bivalves feed largely upon the metabolic products of that production:

(1) The producer must develop an organic system plan in accordance with the provisions of § 205.201.

(2) The organic system plan for bivalve production where the feed is largely metabolic products of that production must include:

(i) A map of the growing area that indicates the boundaries of organically managed areas, adjacent natural areas, and non-organically managed areas that may influence the operation, and water circulation patterns. The location of all industrial or domestic point sources of contamination must be included on the map. The map also must include locations of beds of eel grass, submerged aquatic vegetation, and other ecologically sensitive flora and fauna.

(ii) The Sanitary Survey for the operation as required under NSSP.

(iii) The Sanitary Survey must be reviewed and updated if necessary at least annually by the grower and supplemented with particular attention given to possible contamination by any one or more prohibited substances from any source. It must include the identification and location of all point and non-point sources of prohibited substances and other potential contaminants, such as pesticides, herbicides, and heavy metals. Point and non-point sources can be from urban, residential, industrial and agricultural areas that may pollute the area of natural forage production and the bivalve growing facility. This may include domestic waste (including municipal sewage treatment plants and

private septic tanks), agricultural contamination from farms, feedlots, slaughterhouse operations, and crop spraying, and all forms of industrial discharges that could impact the growing waters. The plan must include the distance from the bivalve growing site to any point or identified area from which there is a significant risk of contamination. The required Sanitary Survey shall be further supplemented whenever there is a material change.

(iv) The Sanitary Survey supplement must include a representative range of meteorological and oceanographic typical conditions that might be expected over a ten year period. Identification or quantification of extreme climatic conditions, such as hurricanes and floods, that could affect the zone of forage production must be considered in the organic system plan with plans for dealing with such events.

(v) The Organic System Plan must include plans for action for events that trigger any form of pollution contribution to the area of the Sanitary Survey.

(vi) Documentation of environmental conditions in the zone of forage production, including water quality and land use in contiguous watersheds. Documentation shall include affidavits from contiguous agricultural and industrial users that prohibited substances have not been applied during the past three years.

(vii) A description of a water quality monitoring program including the parameters measured, frequency of measurement, and location of sampling stations.

(viii) A description of the procedures used for the culture and harvest of bivalve molluscs, including materials used for rafts, nets, or other structures.

(ix) A description of measures that will be implemented to minimize impacts of culture operations on ocean ecosystems and wildlife, including discussions of:

a. the impacts of farm structures (if any), growing practices, and harvest methods.

b. benthic deposition.

c. estimates of nutrient flows, including recycling of nutrients from anthropogenic sources and adequacy of wild forage in the water column.

d. predator control methods.

e. species that use the habitat, including those designated as threatened or endangered. If threatened or endangered species are present, the plan must indicate how culture and harvest activities are in compliance with applicable laws that protect such species.

(x) A description of biosecurity practices to prevent to the occurrence and spread of diseases or parasites.

(xi) A waste management plan that provides for:

a. reuse, recycling and proper disposal of nets, ropes, waste shell, grade-outs and dead-stock.

b. composting or recycling of waste biological materials, including shells, to the extent practicable.

c. control of offensive odors.

(xii) A schedule for surveillance and methods of removing accidentally released culture materials or equipment from beaches or natural waters adjacent to the culture site;

(xiii) A process for the resolution or mitigation of complaints, conflicts, and other multi-stakeholder issues.

(d) Origin of bivalves molluscs:

(1) The use of hatchery produced seed is required.

i. However, where commercially available seed in not available in the same geographic region, or where the use of hatchery seed would preclude commercial production of market sized animals, the collection of larvae or natural set seed from the ocean is allowed for a period of seven years from the date these regulations are adopted, under the following conditions:

(A) wild seed only can be collected from wild animals that are actively managed by the appropriate government resource management agency to ensure sustainable wild populations. The organic system plan must include provisions that consider and control the impacts of wild seed collection activities and methods to monitor those impacts.

(B) wild seed collection methods must not compromise the ecological integrity of the aquatic ecosystem in which they are being used.

(C) the organic system plan must include provisions to minimize overset of wild seed.

Prior to the expiration of this exemption period, a reevaluation shall be made of whether to extend this exemption for specific species where the use of hatchery seed would preclude commercial production of market sized animals.

(2) Production of triploid bivalves is prohibited by § 205.251 Origin of aquaculture animals, paragraph (e).

(e) Bivalve mollusc forage production in ocean based production systems:

(1) Bivalves may forage on wild microalgae and other seston at locations classified by appropriate government authorities under the NSSP as “remote”, or “approved” subject to specific provisions of these standards. Bivalves grown at locations that are not classified, or classified as “conditionally approved,” “restricted,” “conditionally restricted,” or “prohibited” may not be sold, labeled or represented as organically produced.

(2) In the event of an emergency closure ordered by a state shellfish control authority for environmental reasons, the waters under organic production must remain closed for an additional seven days after these waters are reopened by that authority and testing by the grower after reopening determines that requirements under (f) Contamination indicators are satisfied. In the event of a closure due to major pollution impacts, including sewage or chemical spills, closure shall extend until at least 14 days after the waters are reopened by the shellfish control authority and testing by the grower determines that requirements under (e) are satisfied.

(f) Contamination indicators for all ocean based production:

(1) Measuring fecal coliforms as an indicator for contamination by prohibited substances is required.

(2) In addition to monitoring by government agencies for indicator organisms required under NSSP, the organic system plan must include monitoring by the producer for microbial indicators of possible contamination by prohibited substances for each site with periodic testing of seawater. Monitoring must be site specific with specifications determined by the initial site analysis in the Sanitary Survey and ongoing evaluation of potential contamination. The organic system plan must consider historical information and must be updated annually.

(3) The annual review of the organic system plan shall consider incorporating new technologies for monitoring contamination when new technologies become available and can be used with reliable and consistent interpretation.

(4) Locations for sample stations must be identified in the organic system plan and indicated on the site map. There must be at least two sampling stations for each farm site. At least one station must be located near the boundary of the farm closest to any potential source of contamination. Additional sample stations must be utilized where potential sources of contamination exist near other boundaries of the farm site.

(5) Periodic sampling and testing for fecal coliform indicators must occur at least twice each month at approximately two week intervals with records maintained for at least five years. All stations must be sampled within the same 12 hour period, or within the same tidal cycle, whichever is shorter. Sampling and testing should be conducted using standard industry protocols and may include multiple samples per station. At least twice each year a third party independent FDA certified laboratory must verify at least one set of samples.

(6) Harvesting of bivalves is allowed from the farm site when fecal coliform water sample testing results for each sampling event indicate a geometric mean or median for all stations that does not exceed 14 bacteria cells per 100 ml. This determination can be made by most probable number (MPN) or membrane filter methods. When the geometric mean or median exceed 14 bacteria cells per 100 ml of seawater, bivalves may not be harvested for organic sale until sample results are 14 bacteria cells per 100 ml or less. Should two consecutive sampling dates indicate an geometric mean or median of greater than 14 bacteria cells per 100 ml

then harvesting for organic sale must be suspended until two consecutive sample dates, separated by at least 24 hours, yield consecutive acceptable (≤14 bacteria cells per 100ml) results.

Methods for determination of fecal coliform indicator organisms are described in the U.S. Food and Drug Administration Guide for the Control of Molluscan Shellfish, 2005 (or subsequent editions), IV. GUIDANCE DOCUMENTS, II-Growing Areas, .10 Approved National Shellfish Sanitation Program Laboratory Tests. [http://www.cfsan.fda.gov/~ear/nss3-42j.html].

(7) The Organic system plan must include monitoring of sentinel animals by tissue sampling of bivalve molluscs for prohibited and other substances, at least quarterly and approximately 90 days apart, of the bivalve molluscs being grown, or if cultured animals are not available of an appropriate size, wild bivalve molluscs of the same species utilized in that region by the Mussel Watch Program of the US National Oceanic and Atmospheric Administration [http://ccma.nos.noaa.gov/about/coast/nsandt/musselwatch.html], that are collected within the establish site boundaries under sampling and analytical protocols established by the Mussel Watch program for all analytes evaluated by that program. Should the value of any analyte in the sentinel animals exceed those values listed in Table 1, Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood found in US Food and Drug Administration National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2007, [http://www.cfsan.fda.gov/~ear/nss4-42d.html], the bivalve product cannot be labeled organic until two subsequent samples of sentinel animals are found to be below the action levels, tolerances and guidance levels for all analytes listed. These subsequent samples must be spaced at least two months apart.

During the three year conversion period to organic production, should two successive samples of sentinel animals that are taken within 90 days exceed these action levels, tolerances and guidance levels, the site cannot be certified for the organic production of bivalves for a period of at least three years.

Copies of all results shall be saved for at least five years.

(g) Animal health care practices:

(1) Hatchery seed must be certified to be free of reportable shellfish infectious disease agents according to applicable State and Federal regulations.

(2) Handling and growing area management practices must minimize the occurrence and spread of diseases and parasites.

(3) Biosecurity measures must protect against entry of new pathogens, parasites or pests, or their spread. Such biosecurity measures must be specified a specific biosecurity or health section of the organic system plan.

(4) Saline and freshwater dipping, rinsing or spraying may be employed to destroy shell parasites, predators or bacteria.

(h) Living conditions:

(1) Bivalves must be under continuous organic management from the time seed is placed in a growing area. All product labeled organic must achieve at least 95 percent of its biomass while under organic management.

(2) Ocean based sites must provide appropriate rates of water exchange with sufficient tidal currents to assure a good supply of food for bivalve crops while maintaining a healthy environment for other marine organisms.

(3) Bivalves shall be stocked at densities and total numbers that:

i. optimize the health and growth of the bivalves.

ii. do not result in changes to the benthos except in the farm site.

iii. do not remove quantities of plankton or microorganisms from the water sufficient to cause damage in ecosystems on or adjacent to the farm.

(4) With ocean based production systems, the producer must assure adequate protection of bivalves from predators with a pest management plan for each location. Where possible, the plan should provide for pest removal without using lethal means of predator control. The use of quicklime (CaO), biocides, pesticides, herbicides, and other chemical toxins are prohibited to control or eliminate predators and other nuisance organisms unless allowed under § 205.601 or § 205.603.

(5) With ocean based production systems removal of biofouling, pests, or predators using benign means including hand removal and hose washing of bivalves in a manner that minimizes environmental impacts from the discharge of fouling organisms and sediment is allowed.

(i) Ocean based bivalve growing facilities:

(1) Bivalves must be grown in integrated production systems with other organically raised aquatic animals, such as finfish.

(2) Bivalve growing areas must be geographically defined. The farm must have exclusive rights to manage and harvest bivalves in each defined area. Bivalves grown on public grounds that are not leased for private use cannot be certified organic.

(3) Bivalves may be grown on the substrate, or in off-bottom containers, including bags on racks, lantern nets, trays, or on long-lines, poles or other bags or containers which employ off-bottom methods. Rafts and other floating structures for suspending bivalves in the water column may be employed.

(4) Structures used for raising bivalves may not contain lumber treated with arsenate or other synthetic anti-foulants or preservatives, or any non-synthetic substances prohibited under 205.604, except as provided in 205.603.

(5) Burrowing bivalves such as clams may be grown in the substrate.

(6) Farms that grow bivalves must include in their organic system plan specific and measurable steps that will be taken to minimize environmental impacts of farm practices. Such steps may include but not are not limited to:

i. minimize disturbance of the benthic sediments during seeding and harvest of subtidal leases by using only shallow draft vessels during high tide.

ii. subtidal leases with fine bottom sediments must be harvested with the least disruptive mechanical or manual harvesting method that are practicable and must comply with (j) Harvesting ocean based bivalve shellfish.

(7) The seafloor of non-private growing areas cannot be altered with dikes, or leveling.

(j) Harvesting ocean based bivalve shellfish:

(1) Harvest methods must cause minimal impact to the substrate, benthos, and to organisms that live on the ocean bottom and in bottom sediments. Impacts must be minimal to assure sustainability of habitat. Where possible, mitigation measures must be employed.

(2) For all methods of harvest the organic system plan must include an assessment of the potential for incidental kill of non-farmed species that occupy the farming habitat and a plan to minimize the occurrence of such incidental kill.

(3) Manual harvest of bivalves by divers using self contained breathing apparatus (SCUBA) or surface supplied air is permitted. Diving activities within the United States must comply with either State or Federal regulations, whichever is applicable. Diving activities in foreign jurisdictions must comply with pertinent diving regulations established by the United States Occupational Safety and Health Administration.

(4) Dredges or other mechanical methods employed to harvest bivalves must scrape farmed animals from the benthic surface and minimize penetration into the substrate to no more than the depth of the market sized bivalves being harvested. Sediment penetration must only be by a harvesting bar, blade or tooth, with the body of the dredge held off the bottom by sled runners or by other means to ensure that the dredge does not penetrate the substrate.

(5) Suction devices and hydraulic escalator harvesters are prohibited for harvesting burrowing molluscs.

(6) Harvesting of molluscs is not allowed within 100 feet of beds of submerged aquatic vegetation or other light-sensitive aquatic ecosystems, known spawning areas of fish, or ecologically sensitive habitats. These areas must be shown on the site map.

(7) Equipment for harvesting non-burrowing seafloor surface dwelling bivalves that creates a negative water pressure above the substrate to sweep the animals into the dredge without the dredge penetrating the substrate is allowed. With this dredge

design, the equipment must be held off the bottom by sled runners or other means to assure that the apparatus does not penetrate the substrate.

(8) The organic system plan must include a description of the design of dredges and other harvest equipment employed including drawings or photographs.

(9) Clams and other burrowing molluscs that grow in the substrate in intertidal areas may be hand dug for a depth of not greater than 8 inches with particular care to minimize disruption of the seabed. Harvest must occur during periods of beach exposure at low tide to minimize the distribution of marine sediments.

(10) Intertidal harvest of clams or other substrate dwelling shellfish may be accomplished with tractor driven or self-propelled harvesting machines with a maximum depth of harvest of 8-inches. Mechanical harvesting equipment must be designed and operated to minimize disturbance of the substrate through the use of low weight equipment with low pressure tires that are designed to minimize loading on the substrate. This equipment must have a total weight of less than 3,000 pounds including the weight of operators. In no case shall substrate loadings exceed 10 pounds per square inch for any tire. This calculation shall be made in the field by dividing the weight of the harvester carried by each tire by the horizontal contact area of the tire on the substrate determined by multiplying the contact width by the contact length of the tire impression in the substrate. Tracked crawler equipment meeting these specifications also may be employed.

(9) Hand raking of clams is allowed to a depth of 8-inches.

(k) Handling and transport of bivalve molluscs:

(1) All national and local regulations controlling the disposal of processing wastewater must be obeyed.

(2) After shucking and during packing exposure to fresh water shall not exceed 20 minutes.

(3) Packing materials and controls must conform to NSSP requirements throughout shipping, and distribution.

(4) Packing date must be clearly marked on the retail sales container as well as estimated shelf-life or “sell by” and the product must conform to local, state or federal standards pertinent to shelf-life and quality.

(5) Placing bivalves in waters of lower salinity after harvest for purposes of increasing weight or volume (“soaking”) is prohibited. Placing bivalves in waters of greater salinity for purposes of improving taste (“salting”) is allowed with the provision that the lease or facility used for this practice has been under continuous organic management.

Appendix A
National Organic Standards Board
Livestock Committee
Response to Aquaculture Working Group (AWG)
Regarding Proposed Organic Standards for Bivalves
March 17, 2009

Document Objective: Over the past several months it has become very evident that the issues surrounding organic bivalve production are difficult for both the NOSB Livestock Committee (LC) and the Aquaculture Working Group (AWG) to grapple with. This short document is intended to list the points of concern in a simple format for each of the partners to address.

Recap of AWG Document: 1st paragraph of AWG's recommendation.

"Developing organic standards for bivalve mollusks involves special considerations. Bivalves are farmed on seafloor parcels, and in the water column above, that are owned by the producer or on public owned seafloor parcels, and waters above, leased to the producer by a public body, rather than on privately owned farmland. Different states have different means for leasing publicly owned water bottoms or areas, and the water columns above, but practically all coastal states lease public water bottoms or areas, and their waters, to private entities. Wild bivalves are not considered for organic certification."

Based on the discussions over this time period (Nov. 2008 through February 2009) the LC has come up with (5) concerns that the AWG should address in order to better advise the LC and NOSB.

Five points of concern:

> **1. Feed control;** the system is generally one that is based on background water flow to supply feed material, the bivalves are not fed 100% organic feed and the system is not highly managed in terms of feed, and the bivalves eat 100% wild feed.
>
> **2. Water quality input;** primarily marine systems; concerns exist over the quality of water flowing over the bivalves as tides flow and the bivalves are exposed to any possible contaminate that may exist.
>
> **3. Control of harvest sediment;** this concern is in response to discussions regarding environmental issues as they relate specifically to harvest and the disturbance of tidal or sensitive areas.
>
> **4. Using sanitation measures as indicator for other toxins;** there are concerns regarding what is monitored for sanitation – coliforms & e.coli and not other toxins.
>
> **5. Containment – barrier from growing areas to everything else;** in terrestrial systems buffers or barriers are utilized to minimize any contamination from surrounding activities, in aquatic systems sited in tidal areas this is difficult or impossible.

In delivering this to the AWG we discussed the possibilities of addressing these concerns through fresh water production systems and/or poly culture systems that include a multi species system. These production systems may or may not include land based tanks or other possible scenarios.

It is generally agreed that the current AWG document does not adequately address these five concerns

making it difficult for the LC to move forward. It is the goal of the LC to address these concerns and develop a guidance standard document that fully supports the production of organic bivalves that truly meets the goals of organic agriculture. The LC looks forward to feedback and comments from the public on these points as well.

Motion: Kevin Engelbert, Second: Tina Ellor

Committee Vote:

Yes – 6 No – 0 Absent – 1 Abstain – 0

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5075830&acct=nosb

Appendix B

Mussel Watch Program List of Analytes

Metals, metalloids and related compounds

Core	Aluminum, Antimony, Arsenic, Cadmium, Chromium, Copper, Iron, Lead, Manganese, Mercury, Nickel, Selenium, Silicon, Silver, Tin and Zinc.
Intermittent	Methyl-mercury

Petroleum and combustion forensics

Core	Benz[a]anthracene, Benzo[a]pyrene, Benzo[b]fluoranthene, Benzo[e]pyrene, Benzo[g,h,i]perylene, Benzo[k]fluoranthene, Benzothiophene, Chrysene, Dibenzo[a,h]anthracene, Fluoranthene, Indeno[1,2,3-c,d]pyrene, Perylene, Pyrene, Acenaphthene, Acenaphthylene, Anthracene, Biphenyl, Fluorene, Naphthalene and Phenanthrene.
Core	C1-Benzothiophene, C1-Chrysenes, C1-Decalin, C1, Dibenzo(a,h)anthracene, C1-Dibenzo[a,h]anthracene, C1-Dibenzothiophenes, C1-Fluoranthenes/Pyrenes, C1-Fluoranthenes_Pyrenes, C1-Fluorenes, C1-Naphthalenes, C1-Naphthobenzothiophene, C1-Phenanthrenes/Anthracenes, C1-Phenanthrenes_Anthracenes, C2-Benzothiophene, C2-Chrysenes, C2-Decalin, C2-Dibenzo(a,h)anthracene, C2-Dibenzo[a,h]anthracene, C2-Dibenzothiophenes, C2-Fluoranthenes/Pyrenes, C2-Fluoranthenes_Pyrenes, C2-Fluorenes, C2-Naphthalenes, C2-Naphthobenzothiophene, C2-Phenanthrenes/Anthracenes, C2-Phenanthrenes_Anthracenes, C3-Benzothiophene, C3-Chrysenes, C3-Decalin, C3-Dibenzo(a,h)anthracene, C3-Dibenzo[a,h]anthracene, C3-Dibenzothiophenes, C3-Fluoranthenes/Pyrenes, C3-Fluoranthenes_Pyrenes, C3-Fluorenes, C3-Naphthalenes, C3-Naphthobenzothiophene, C3-Phenanthrenes/Anthracenes, C3-Phenanthrenes_Anthracenes, C4-Chrysenes, C4-Decalin, C4-Naphthalenes, C4-Phenanthrenes/Anthracenes, C4-Phenanthrenes_Anthracenes, Carbazole, Decalin, Dibenzothiophene, Naphthobenzothiophene, 1,6,7-Trimethylnaphthalene,1-Methylnaphthalene, 1-Methylphenanthrene, 2,6-Dimethylnaphthalene and 2-Methylnaphthalene

Industrial contaminants

Core	PCB101_90, PCB105, PCB110_77, PCB118, PCB128, PCB138, PCB138_160, PCB146, PCB151, PCB153_132_168, PCB158, PCB170_190, PCB174, PCB18, PCB180, PCB183, PCB187, PCB194,

	PCB195_208, PCB195_208, PCB199, PCB201_173_157, PCB206, PCB209, PCB28, PCB29, PCB31, PCB44, PCB45, PCB49, PCB52, PCB66, PCB70, PCB8_5, PCB95 and PCB99
Intermittent	BDE 1 (2-MonoBDE), BDE 1 [2-MonoBDE], BDE 10 (2,6-DiBDE), BDE 10 [2,6-DiBDE], BDE 100 (2,2',4,4',6-PentaBDE), BDE 11 (3,3'-DiBDE), BDE 116 (2,3,4,5,6-PentaBDE), BDE 118 (2,3',4,4',5-PentaBDE), BDE 119 (2,3',4,4',6-PentaBDE), BDE 12 (3,4-DiBDE), BDE 126 (3,3',4,4',5-PentaBDE), BDE 13 (3,4'-DiBDE), BDE 138 (2,2',3,4,4',5'-HexaBDE), BDE 15 (4,4'-DiBDE), BDE 153 (2,2',4,4',5,5'-HexaBDE), BDE 154 (2,2',4,4',5,6'-HexaBDE), BDE 155 (2,2',4,4',6,6'-HexaBDE), BDE 166 (2,3,4,4',5,6-HexaBDE), BDE 17 (2,2',4-TriBDE), BDE 181 (2,2',3,4,4',5,6-HeptaBDE), BDE 183 (2,2',3,4,4',5',6-HeptaBDE), BDE 190 (2,3,3',4,4',5,6-HeptaBDE), BDE 2 (3-MonoBDE), BDE 25 (2,3',4-TriBDE), BDE 28 (2,4,4'-TriBDE), BDE 3 (4-MonoBDE), BDE 30 (2,4,6-TriBDE), BDE 32 (2,4',6-TriBDE), BDE 33 (2',3,4-TriBDE), BDE 35 (3,3',4-TriBDE), BDE 37 (3,4,4'-TriBDE), BDE 47 (2,2',4,4'-TetraBDE), BDE 49 (2,2',4,5'-TetraBDE), BDE 66 (2,3',4,4'-TetraBDE), BDE 7 (2,4-DiBDE), BDE 71 (2,3',4',6-TetraBDE), BDE 75 (2,4,4',6-TetraBDE), BDE 77 (3,3',4,4'-TetraBDE), BDE 8 (2,4'-DiBDE), BDE 85 (2,2',3,4,4'-PentaBDE) and BDE 99 (2,2',4,4',5-PentaBDE).
Intermittent	PBB 1 (2-MonoBB), PBB 10 (2,6-DiBB), PBB 103 (2,2',4,5',6-PentaBB), PBB 15 (4,4'-DiBB), PBB 155 (2,2',4,4',6,6'-HexaBB), PBB 18 (2,2',5-TriBB), PBB 2 (3-MonoBB), PBB 26 (2,3,',5-TriBB), PBB 3 (4-MonoBB), PBB 30 (2,4,6-TriBB), PBB 31 (2,4',5-TriBB), PBB 4 (2,2'-DiBB), PBB 49 (2,2',4,5'-TetraBB), PBB 52 (2,2',5,5'-TetraBB), PBB 53 (2,2',5,6'-TetraBB), PBB 7 (2,4-DiBB), PBB 77 (3,3',4,4'-TetraBB), PBB 80 (3,3',5,5'-TetraBB) and PBB 9 (2,5-DiBB).

Pesticides

Core	Dibutyltin, Monobutyltin, -Tetrabutyltin and Tributyltin.
Core	Alpha-Chlordane, Heptachlor, Heptachlor-Epoxide and Trans-Nonachlor
Core	4'-DDD 2,4'-DDE, 2,4'-DDT, 4,4'-DDD, 4,4'-DDE and 4,4'-DDT
Core	Aldrin and Dieldrin
Core	Alpha-Hexachlorocyclohexane, Beta-Hexachlorocyclohexane, Delta-Hexachlorocyclohexane and Gamma-Hexachlorocyclohexane
Core	1,2,3,4-Tetrachlorobenzene, 1,2,4,5-Tetrachlorobenzene, Cis-Nonachlor, Endrin, Gamma-Chlordane, Hexachlorobenzene, Mirex, Oxychlordane, Pentachloroanisole and Pentachlorobenzene.
Core	Chlorpyrifos, Endosulfan I, Endosulfan II and Endosulfan Sulfate.