Revisions To The

SUPPLEMENT TO INTERIM FINAL REPORT
(Bivalve molluscs)

Of the

Aquaculture Working Group

Summer 2007

In Response to Public Comments

Summer 2008

U.S. Department of Agriculture
National Organic Program

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The National Organic Program Aquaculture Working Group

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EXECUTIVE SUMMARY
OVERVIEW

The Aquaculture Working Group

In response to the growing interest in the certification of aquatic animals as organic, in 2005, the National Organic Standards Board (NOSB) and National Organic Program (NOP) announced the formation of an Aquatic Animal Task Force. This task force was to be comprised of two working groups; aquaculture and wild fisheries.

The Aquaculture Working Group (AWG) is a diverse group of experienced professionals consisting of representatives from universities, trade associations, aquaculture producers and suppliers, and environmental interests. Included in this group are present and former growers of bivalve molluscs and scientific experts in this field. With the submission of our *Interim Final Report* dated January 13, 2006,[1] the AWG partially satisfied the objective established by the January 24, 2005, Federal Register notice (FR 70 3356) to develop draft organic production and handling standards for aquatic animals produced in aquaculture.

At that time, the Aquaculture Working Group was considering the adoption of standards for bivalve molluscan shellfish.. Due to complexities involved, the Working Group required additional time to prepare this supplemental proposal. Bivalve molluscs of interest include oysters, clams, mussels and scallops.

On July 9, 2007, AWG submitted its *Supplement To Interim Final Report* (Bivalve molluscs). This document was posted for public comments.[2] One comprehensive set of public comments was received dated November 8, 2007 from the Pacific Coast Shellfish Growers Association.[3] The AWG has carefully considered these comments, and has amended the *Supplement* accordingly.

As before, our decisions were guided by the Organic Food Production Act,[4] the Final Rule[5] (including its Preamble[6]), our *Interim Final Report*, the National Organic Standards Board Livestock Committee's February 20, 2007, report *Aquaculture Standards* -- adopted by the NOSB on March 29, 2007,[7] and the May 30, 2001, NOSB Aquatic Animal Task Force May 30, 2001 *Recommendation on Operations that Produce Aquatic Animals*.[8]

The AWG performed its work through conference calls and email exchanges. Formal public review of this document that includes revisions to our Interim Final Report will occur through normal NOSB processes involving public comment.

Aquaculture Working Group
George S. Lockwood, Chair

September 8, 2008

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[1] http://www.ams.usda.gov/nop/TaskForces/AATFInterimFinalReport.pdf

[2] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5062437&acct=nopgeninfo

[3] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5065080

[4] http://agriculture.senate.gov/Legislation/Compilations/AgMisc/OGFP90.pdf

[5] http://www.ams.usda.gov/nop/NOP/standards.html

[6] http://www.ams.usda.gov/nop/NOP/standards/FullText.pdf

[7] http://www.ams.usda.gov/nosb/CommitteeRecommendations/March_07_Meeting/Livestock/AquacultureRec.pdf

[8] http://www.ams.usda.gov/nosb/lscommRMR/recommendations/aquatic_animals.html

INTRODUCTION

Developing organic standards for bivalve molluscs 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.

Farmed bivalves typically consume wild feed (microalgae and other seston) that they filter from natural waters, rather than feed which is prepared for them. As a result, we drew on several different organic production systems in drafting organic standards for molluscs. These included: a) harvest of wild crops and kelp from relatively unmanaged lands or waters; b) honey production where bees forage from a relatively wide area that is usually not entirely managed by organic producers; and c) organic production of poultry and mammals.

This document, *Revisions To The Supplement To Interim Final Report (Bivalve molluscs) of the Aquaculture Working Group Summer 2007 in Response to Public Comments Summer 2008,* is submitted to NOSB for consideration for their recommendation to the National Organic Program as an amendment to the Final Rule to allow the organic certification of bivalve molluscs under certain conditions. Based upon public comments, private comments, and internal AWG considerations, the original bivalve proposal of Summer 2007 has been extensively modified.

BACKGROUND INFORMATION

The Recommendations of *Operations that Produce Aquatic Animals* of May 30, 2001, include the following relative to considerations of organic bivalve molluscs:

MOLLUSC PRODUCTION

In considering the mollusc production as a complete system, the Task Force concludes that there is insufficient compatibility with the requirements of the OFPA to warrant the development of certification standards for such systems. The Task Force concludes that mollusc producers are not called upon to make a sufficient number of the management decision imposed by the statute nor could certification standards create significant differentiation between organic and nonorganic operations.

The Preamble to the Final Rule considers:

Crop Production - Changes Based on Comments

(8) Greater Rigor in the Wild Harvest Production Organic System Plan. A number of commenters stated that the wild-crop harvesting practice standard was insufficiently descriptive and that the proposed rule failed to apply the same oversight to wild harvest operations as it did to those producing crops and livestock. Some commenters maintained that the proposed rule did not require a wild harvest producer to operate under an approved organic system plan. These commenters proposed specific items, including maps of the production area that should be required in a wild harvest operation's organic system plan. One commenter recommended that the definition for "wild crop" be modified to allow the harvest of plants from aquatic environments.

We amended the practice standard for wild-crop harvesting to express the compliance requirements more clearly. Wild-crop producers must comply with the same organic system plan requirements and conditions, as applicable to their operation, as their counterparts who produce crops and livestock. Wild harvest operations are production systems, and they must satisfy the general requirement that all practices included in their organic system plan must maintain or improve the natural resources of the operation, including soil and water quality. We modified the practice standard to emphasize that wild harvest production is linked to a designated site and expect that a certifying agent would incorporate mapping and boundary conditions into the organic system plan requirements. Finally, we changed the definition of "wild crop" to specify that harvest takes place from a "site" instead of "from land," thereby allowing for aquatic plant certification.

Bivalve molluscs grown in the ocean forage upon natural phytoplankton (microalgae that are wild aquatic plants) and other seston. In view of the above, and with other considerations discussed below, AWG established criteria for the proposed standards for organic bivalve molluscs.

THIS PROPOSAL

Organic system plan. We propose that operators of organic bivalve mollusc farms develop organic system plans that include maps of mollusc production areas as well as maps of zones of forage production. A wide variety of management considerations must be included in the organic system plan.

Organic honey and kelp. Some certifiers of organic honey operations require growers to obtain affidavits from adjacent land owners within the bee forage area that they do not use pesticides and other prohibited substances. In the case of wild kelp harvested from the ocean, the harvester of this wild aquatic plant crop must demonstrate that there are no discharges of prohibited substances nearby that could contaminate the kelp.

Organic certification of honey bees and marine kelp provides valuable precedents for wild food sources for organic production.

Process not safety. Bivalve molluscs forage upon marine seston, principally microalgae. On occasion this seston can include human pathogens. Food safety is the jurisdiction of the U.S. Food and Drug Administration and not U.S. Department of Agriculture and its National Organic Program. The organic claim is a process claim, not a food safety claim.

Therefore, our proposal does not include efforts to improve on the U.S. National Shellfish Sanitation Program, a bivalve food safety program. [See: http://www.cfsan.fda.gov/~ear/nss2-toc.html] However, all possible inputs into zones of forage production are important since prohibited substances may be included in these inputs. We have therefore developed criteria based upon the Sanitary Survey required under NSSP for delineating zones of forage production and propose that the organic system plan identify potential sources of prohibited substances that flow into such zones, including but not limited to sewage and farmed animal manure. Sewage is a source of contamination of a wide range of substances, some prohibited, not just human pathogens.

Zone of forage production. Our proposal includes the delineation of the zone of forage production. To accomplish this we originally propose that hydraulic modeling investigations provide information about how shoreline currents influence the zone of forage production, and where water exchanges might be important considerations.

We have replaced hydraulic modeling requirements with inclusion of the NSSP Sanitary Survey that is actually a government mandated modeling program. With this, we propose that organic certifica-

tion be prohibited for waters that receive sewage and other point discharges, waters with adjacent land activities involving prohibited substances, and waters where marinas, boats, and similar activities influence the zone of forage production.

Use of sewage indicator organisms. While the use of sewage indicator organisms for microbial food safety concerns is not appropriate in this context , we propose their use as indicators of other forms of man-made contamination. Sewage discharges, both human and storm runoff, in many cases are the principle source of prohibited substances flowing into the zone. Therefore, requiring the certified grower to monitor for indicator organisms on a regular basis is proposed.

Origin of livestock-hatchery seed. From the background documents, it is clear that organic system plans must demonstrate managed farming systems. Obtaining bivalve mollusc seed from the wild involves low levels of system management, while obtaining seed from hatcheries requires greater management effort. These proposed standards require that bivalve molluscs be raised in discrete populations that are proactively managed consistent with requirements in the Act for origin of terrestrial livestock and poultry. Even if some molluscs such as mussels are not now hatchery produced in some areas of the country, the technology and capability to do this is well established.

Environmental considerations. A clear mandate articulated in the Preamble to the Final Rule is that all practices included in the organic system plan must maintain or improve the natural resources of the operation. We therefore propose numerous conditions on growing and harvesting that are intended to protect other forms of life on the ocean floor and surrounding areas. Moreover, a healthy bivalve farm substantially reduces water turbidity from microalgae and other seston. This reduction can be environmentally beneficial where turbidity results from increased flows of nutrients and organic matter from human activities.

Differentiation from conventional bivalve production. The proposed regulations provide for substantial differentiation from conventional bivalve aquaculture in many respects. In order to prevent inclusion of prohibited substances, bivalve growing areas and zones of forage production are delineated, frequently monitored, and managed. Certain materials for facilities are prohibited. Special attention is provided to assure a minimum of environmental disturbance from bivalve growing and harvest activities.

Revisions in this document The criteria in developing these revisions have been maintained. They include demonstrating a managed system, preventing prohibited substances from contaminating bivalve aquatic animals, and minimizing disruption to the environment.

In developing these revisions, AWG spend considerable effort considering the substitution of the NSSP Sanitary Survey for the hydraulic modeling required in the Summer 2007 proposal. Considerable effort was also spent in developing standards for burrowing molluscs such as clams. These animals reside in the substrate and efforts were directed to develop standards that minimize disruption to the biota in the substrate, as well as on and above the seafloor, and to nearby wildlife.

Another area of concern is the sediment plume that develops when harvesting molluscs on the seabed such as oysters, as well as when harvesting burrowing molluscs, such as clams, from the substrate. In establishing a maximum plume density of 200 mg/L we were guided by the work of Wilber and Clarke.[9]

[9] Wilber, Dara H and Douglas G Clarke. 2001. *Biological Effects of Suspended Sediments*, North American Journal of Fisheries Management 21:855-875.

Public comments One comprehensive public comment document was received that addressed 23 concerns. One private comment received addressed sediment plume and hand raking of clams. In addition, members of AWG carefully reviewed each proposed paragraph in this document in terms of meeting our established criteria, clarity, workability, and the ability of growers and certifiers to clearly understand these provisions for preparing organic system plans.

RESPONSES TO PUBLIC COMMENTS RECEIVED

The first comment in the comprehensive public comment paper received sought that the proposed standards should "*not* allow wild-harvested, unmanaged systems, to be included in these standards." In the AWG proposed standards, bivalve shellfish from wild, unmanaged systems are proscribed from organic certification.

The original Supplement of Summer 2007 proposed the delineation of a zone of forage production. To accomplish this we proposed that hydraulic modeling investigations provide information about how shoreline currents influence the zone of forage production, and where water exchanges might be important considerations.

Once the hydraulic zone of influence (HZI) was established, we proposed that organic certification be prohibited for waters that receive sewage and other point discharges, waters with adjacent land activities involving prohibited substances, and waters where marinas, boats, and similar activities influence the zone of forage production.

A comment was received that under the National Shellfish Sanitation Program, shellfish growing areas are monitored and frequently disallowed due the potential for contamination. Since the Food Drug Administration and the National Shellfish Sanitation Program address food safety concerns, and for other reasons, the AWG proposal is not concerned with food safety *per se.* Of concern, however, is the potential for contamination by prohibited substances, such as industrial and agricultural chemicals. As is explained in the *Supplement*, certain monitoring techniques in the AWG proposal are modeled after NSSP requirement since these techniques also allow the assessment of contamination by prohibited substances.

The commenter also claimed that the monitoring program is redundant with the legal requirements under NSSP, and that the proposed organic standards should specify such matters as frequency of monitoring and which indicators are to be monitored. In response, AWG has attempted to make these factors clear in this proposal. This proposal requires considerable more producer management than under NSSP.

The AWG Supplement contained a section on Origin of livestock-hatchery seed, that proposes "From the background documents, it is clear that organic system plans must demonstrate managed farming systems. Obtaining bivalve mollusc seed from the wild involves low levels of system management, while obtaining seed from hatcheries requires greater management effort. Even if some molluscs such as mussels are not now hatchery produced in some areas of the country, the technology and capability to do this is well established."

The commenter stated "This requirement will effectively eliminate vast growing areas around the country that have managed systems for collecting natural-set spat on cultch. Furthermore, you can not prevent wild seed from setting on the managed farm area. If high levels of system management is indeed the criteria, then natural spat collection should not be summarily disallowed. In fact, under the strict regulations imposed by the NSSP, seed CAN be produced even in prohibited areas, but it must be grown out for a minimum of 6 months in an approved area. "

It is the proposal of AWG that organic certification be limited to highly managed bivalve growing systems, and not include vast growing areas around the country. AWG does not believe that the collection

of wild shellfish larvae represents the degree of management for which AWG has the burden to demonstrate. In this revised proposal, certain wild-set bivalve shellfish would be allowed under certain conditions for a limited time.

REVISED PROPOSED STANDARDS
For Organic Bivalve Molluscs

In order to provide further clarity to the proposed bivalve standard, additions have been made to Terms Defined for *Specific pathogen free* and *Submerged Aquatic Vegetation*;

§ 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*."

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.

Bivalve Molluscs In this section, (a)(6) has been added.

§ 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) Offshore bivalve growing areas must be under organic management for at least three years before production can be certified organic.

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

(5) 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.

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

Organic system plan for bivalve production. In response to public and internal comments, AWG has substantially modified (b) to exclude the requirement for the determination of the Hydraulic Zone of Influence. Upon careful review, AWG found that the Sanitary Survey required under NSSP that applies to all bivalve shellfish growing areas accomplishes the same purpose. Therefore, (b) has been modified to read:

(b) Organic system plan for bivalve production:

A producer of organic bivalve molluscs must develop an organic system plan in accordance with the provisions of§ 205.201. The organic system plan for bivalve production must include:

(1) 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.

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

(3) For bivalve molluscs that forage on pelagic wild microalgae and other seston, the organic system plan must include an approximate delineation of the zone of production for forage consumed by the farmed bivalve molluscs. This must be at least the area included in the NSSP Sanitary Survey. This area is expected to be at lease as large as the area in the sanitary survey.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

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

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

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

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

ii. benthic deposition.

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

iv. predator control methods.

v. 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.

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

(12) A waste management plan that provides for:

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

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

iii. control of offensive odors.

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

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

A public comment sought to eliminate consideration of offensive odors as required in (b)(12)(iii) as not relevant with organic management. AWG does not concur and proposes that control of offensive odors be included in the Organic System Plan.

Origin of bivalve molluscs. In (c) the public commenter sought to eliminate the requirement that all seed be hatchery produced and proposed standards for natural spat collection. As a result of this comment and further consideration by AWG, (c) has been modified to allow wild collection under certain conditions for a limited time period. As developed in the *Supplement,* AWG has the burden to demonstrate that the proposed regulations for organic certification are for a highly managed system. Therefore, (c) now reads:

(c) 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).

A comment was received that (c)(2) be amended to allow triploidy. AWG responds that polyploidy is prohibited under § 205.251 Origin of aquaculture animals that controls this section for bivalve molluscs.

Bivalve mollusc forage production. Based upon private comments, AWG proposes that (d)(3) be amended to also provide for major pollution impacts.

(d) Bivalve mollusc forage production:

(1) Bivalves grown in onshore ponds, tanks, and other containers may be supplied organic aquatic plants produced under § 205.258 Farmed aquatic plants.

(2) 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.

(3) 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 (e) 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.

Contamination indicators: The public commenter seeks to exempt small farm sites and require sampling for only those sites that are larger than two acres. AWG recommends that the provisions of (e) apply to all farm sites seeking organic certification. In addition, the public commenter sought clarification of sampling procedures. AWG has amended (e) to further define and clarify sampling procedures, methods and criteria.

(e) Contamination indicators:

(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].

Animal health care practices: The public commenter sought to restrict (f) to hatchery seed to recognize their proposed allowance of wild set bivalves. AWG has modified (f) to read:

(f) Animal health care practices:

Hatchery bivalve seed must be certified to be

(1) 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.

Living conditions The public commenter sought to insert the words "owned or leased" in (g)(3)(ii). AWG believes the language is clear as written. Also sought was the allowance of certain unspecified chemicals. AWG points out that under § 205.601 or § 205.603, National List, it is possible to allow listed chemicals to be employed in organic production under certain conditions. AWG has modified (g) and (h) to now read:

(g) Living conditions:

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

(2) 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) 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) 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.

Bivalve growing facilities There were no comments received relative to facilities, and AWG has no changes to propose other then the addition of (6)(ii).

(h) Bivalve growing facilities:

(1) Bivalves may 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 (i)(4).

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

Harvesting bivalve shellfish The public commenter seeks to allow inter-tidal mechanical dredging. The amended (i) below allows inter-tidal harvesting under certain conditions. (i)(4) has been changed to specify sediment values found to be acceptable in scientific literature. A comment urged further consideration of harvesting Geoduck clams with the allowance of the use of hydraulic water jets for harvesting Geoduck clams. AWG has amended (i)(6) to allow use of

hydraulic jets for Geoduck clam harvesting.. After considerable review, various parts of (i) have been modified to allow harvesting of Geoduck clams consistent with the minimization of environmental disturbance. The public commenter and a private commenter sought the allowance of hand raking of clams. (i)(11) has been amended to allow for hand raking under certain conditions.

(i) Harvesting 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) The density of the sediment plume created during subtidal harvest operations cannot exceed 200 mg/liter dry weight of settable solids at any point ten meters away or greater.

(5) 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.

(6) The use of hydraulic water jets for harvesting of farmed Geoduck clams is allowed as long as requirements in (1) and (4) are met. The use of hydraulic water jets for intertidal harvesting of other burrowing molluscs is prohibited.

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

(8) 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.

(9) 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 held off the bottom by sled runners or other means to assure that the apparatus does not penetrate the substrate.

(10) 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 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. 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.

(11) Hand raking of clams is allowed, provided that the maximum density of the silt plume does not exceed 200 mg/liter dry weight of settable solids at any point ten meters away or greater.

Handling and transport of bivalve molluscs The public commenter questions the purpose of (j)(2). This provision eliminates a practice called soaking, a condition where bivalve meats after harvest add substantial mass and volume thereby changing the quality of this product. The public commenter also sought the elimination in the earlier draft of a proposed condition that the provisions of (j)(3) extend to retailers. AWG concurs that producers have little, or no, control of certified products once they reach the retail level and has removed this proposed condition.

(j) 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.