COMMENTS and PROPOSED REVISIONS
by the
Aquaculture Working Group
Pertaining to the Recommendations of the
USDA National Organic Standards Board
for Organic Aquaculture Standards

October 2010

The National Organic Program Aquaculture Working Group

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Special Thanks

to the following individuals for their contributions to the work of the Aquaculture Working Group in developing our comments and proposed revisions:

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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 wild fisheries working group was never appointed.

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 a variety of fish and shellfish, 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 and plants produced in aquaculture.

This report was deemed Interim since AWG was still 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 included oysters, clams, mussels and scallops.

At their Spring 2007 meeting, the NOSB adopted recommendations for aquaculture standards,[2] but withheld for further consideration sections pertaining to aquatic animal feed and facilities. Public comments were solicited and received concerning these two subjects, and at their Fall 2008 meeting, NOSB adopted recommendations for feed and facilities for inclusion in their recommended standards for aquaculture[3,4]. At their Spring 2010 meeting NOSB adopted recommendations for bivalve molluscs.[5] With this action, NOSB had completed a full set of Final Recommendations for NOP to consider for Final Rulemaking.

Since then, AWG has carefully reviewed the complete set of recommendations by NOSB and offers comments and proposed changes. Some proposed changes are simply editorial, others provide needed clarification, and other AWG recommendations are substantial and are required for successful organic production of aquatic animals and plants.

As before, our decisions have been guided by the Organic Food Production Act,[6] the Final Rule[7] (including its Preamble[8]), and comments of NOSB members during their deliberations at various meetings on aquaculture matters. AWG has performed our work through conference calls and email exchanges.

Aquaculture Working Group
George S. Lockwood, Chair
October 11, 2010

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[1] http://www.ams.usda.gov/nop/TaskForces/AATFInterimFinalReport.pdf
[2] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5056878
[3] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074508&acct=nosb
[4] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074509&acct=nosb
[5] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081491&acct=nosb
[6] http://agriculture.senate.gov/Legislation/Compilations/AgMisc/OGFP90.pdf
[7] http://www.ams.usda.gov/nop/NOP/standards.html
[8] http://www.ams.usda.gov/nop/NOP/standards/FullText.pdf

COMMENTS and PROPOSED REVISIONS

by the Aquaculture Working Group

Pertaining to the Recommendations of

the USDA National Organic Standards Board for Organic Aquaculture Standards

The Aquaculture Working Group offers the following comments and recommendations for changes to the set of Final Recommendations for organic aquaculture from the National Organic Standards Board to the USDA National Organic Program.

1. § 205.2 Terms Defined:

Replace

> 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.

with

> Bivalve molluscs. Molluscan shellfish species (Phylum *Mollusca*, Class *Pelecypoda* commonly called "bivalves") with two outer, hinged shells such as oysters, clams, mussels and scallops, but not including gastropods such as abalone and conch, and cephalopods, such as octopus and squid.

Replace

> Fish oil. Oil from rendering whole fish, fish cuttings, or cannery waste alone or in combination.

with

> Fish oil. Oil from rendering whole fish from forage fisheries, fish cuttings and other by-products, or cannery waste alone or in combination.

Add a new definition

> Forage fish. Wild fish harvested for the purpose of rendering fish meal and fish oil.

Add a new definition

> 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 systematic analysis and management of critical processing variables that impact upon the healthiness and safety of seafood products.

Change

> Livestock Any cattle, sheep, goat, swine, poultry, equine, or aquatic animals used for food or in the production of food, fiber, feed or other agricultural-based consumer products; wild or domesticated game; or other non-plant life, except such term shall not include bees for the production of food, fiber, feed, or other agricultural-based consumer products.

to read

Livestock Any cattle, sheep, goat, swine, poultry, equine, or aquatic animals used for food or in the production of food, fiber, feed or other agricultural-based consumer products; wild or domesticated game; or other non-plant life, except such term shall not include bees for the production of food, fiber, feed, or other agricultural-based consumer products. Regulations pertaining to aquatic animals are in §205.250 through §205.612, while regulations pertaining to terrestrial animals are in §205.236 through §205.239.

Change

Minimum nutritional requirements. Those that support optimum growth, health and reproduction in fish in all life stages of aquatic animals cultured in all types of rearing systems.

to read

Minimum nutritional requirements. Those requirements for proteins and amino acids, energy, lipids, carbohydrates, vitamins and minerals that support optimum growth, health and reproduction in fish in all life stages of aquatic animals cultured in all types of rearing systems.

Change

Natural assimilative capacity. The limitability of an aquatic ecosystem within and surrounding an aquaculture facility to assimilate and process effluents discharged from the facility without reduction in that ecosystem's ability to function and maintain life.

to read

Natural assimilative capacity. The limit of an aquatic ecosystem within and surrounding an aquaculture facility to assimilate and process effluents discharged from the facility without reduction in that ecosystem's ability to function and maintain life.

Add new definition:

Net pen (or cage). Any floating, suspended, or submerged enclosure located in public water that is used to hold and grow aquatic animals in fresh, brackish, or saltwater. The term net pen does not include nets employed in on-shore ponds and other containment vessels to separate fish.

Change

Persistent bioaccumulative toxins (PBT). Chemicals that resist breakdown and are persistent in the environment, bioaccumulate in food chains through consumption or uptake, and are a hazard to human health or wildlife. A term related to PBT is POP (persistent organic pollutant) and, for the purposes of these standards, the terms are interchangeable.

to read

Persistent bioaccumulative toxins (PBT). Chemicals that resist breakdown and are persistent in the environment, bioaccumulate in food chains through consumption or uptake, and are a hazard to human health or wildlife. Terms related to PBT include persistent organic pollutant (POP) and unavoidable residual envi-

ronmental contaminant (UREC). For the purposes of these standards, these terms are interchangeable.

Change

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*."

to read

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).

AWG recommends these changes and additions for improved clarity. In the case of the definition of Livestock, without the addition of the last sentence, the rules can be interpreted to mean that aquatic animals are under the jurisdiction of standards for Livestock as well as for Aquatic animals, where it is the intention to have different sections apply to each.

2. §205.201 Organic production and handling plan

As recommended by NOSB, this section would read:

(a) The producer or handler of a production or handling operation. …. must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic production and handling system plan must include:

(7) Regarding aquaculture operations, the organic system plan for aquaculture systems should include:

(i) A map of the production 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.

a. The location of all known point and non-point sources of prohibited substances and other potential contaminants must be included on the map.

b. Locations of water sampling stations must be identified on the site map.

(ii) A description of the materials used for all types of structures.

(iii) Documentation of environmental conditions in the growing area, including water quality and land use in contiguous watersheds.

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

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

a. 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.

(vi) List of animal and plant 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.

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

(viii) A waste management plan that provides for:

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

b. Composting or recycling of waste biological materials to the extent practicable.

c. Control of offensive odors.

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

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

(xi) An organic operation plan for an aquaculture operation using net pens must include the following:

a. Justification for the location of the net pens including a detailed description of how the location minimizes impact to surrounding environment, limits waste accumulation, and minimizes impact to the migratory and reproductive patterns of local wild fish populations, other local species like predators and birds and any other flora or fauna.

b. Nutrient management plan which describes waste management approaches, monitoring system for all nutrient inputs outputs and waste, and location of any and all farms or net pens in the vicinity that could impact, positively or negatively, the nutrient management process of the net pen seeking certification.

c. A description of anti-fouling practices.

AWG recommends that proposed § 205.201(a)(7), (a) through (x) be placed under § 205.250 Aquaculture general. This proposed regulation solely pertains to aquaculture, whereas this section § 205.201 pertains broadly to all of organic agriculture. Section § 205.201 is generic and non-specific, while § 205.250 pertains solely to aquaculture.

If this language is to remain in § 205.201, AWG recommends that (7) be changed to read: "The organic system plan for crops, livestock and aquaculture should include:"

AWG recommends that proposed § 205(a)(7)(xi) be placed in § 205.255 Aquaculture facilities as (k)(10) since this proposed language solely pertains to the use of net pens.

3. § 205.237 Livestock feed.

AWG recommends that the following be added

(a) The producer of an organic operation must not:

(7) Feed fish meal or fish oil from forage fish except as provided in § 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

AWG recommends that the same restrictions to conserve wild fish populations that are being applied to aquaculture also apply to terrestrial livestock. USDA allows use of fishmeal as a feed supplement for livestock, but this use of fishmeal is not now subject to the same restrictions as proposed for aquaculture

4. § 205.250 Aquaculture general.

In the Final Rule for agriculture, "organic system plan" appears sometimes with capital letters, and sometimes is not capitalized. AWG recommends "Organic System Plan" be used throughout aquaculture sections for consistency such as in:

(3) Metabolic products of one species are recognized as organic resources for one or more other species in an aquaculture production system. The Organic System Plan of facilities producing aquatic animals must consider measures to recycle or biologically process metabolic products. Where feasible, the Organic System Plan must include the polyculture of two or more different species grown in the same body of water, and the integration of additional species as water moves through the aquaculture facility or into adjoining discharge areas.

AWG recommends that § 205.250 (4) an (5) changed from

(4) The feasibility of using water discharges and filtered metabolic products as nutrients for vascular plants in agricultural crops and constructed wetlands must be considered in Organic System Plans. The quantities of such discharges and filtered products applied shall not exceed the requirements of targeted plants in the receiving area, and shall not be discharged into unplanned areas. Vascular agriculture crops using nutrients from certified organic aquaculture operations may be certified organic if in compliance with other regulations in this Subpart.

(5) Organic System Plans for aquaculture facilities must provided for the health and welfare of aquatic animals, preclude prohibited substances, and prevent contamination of aquaculture products from environmental sources.

to read

(4) The feasibility of using water discharges and filtered metabolic products as nutrients for vascular plants in agricultural crops and constructed wetlands must be considered in Organic System Plans. The quantities of such discharges and filtered products applied shall not exceed the requirements of targeted plants in the receiving area, and shall not be discharged into areas not included in the Organic System Plan. Vascular agriculture crops using nutrients from certified organic aquaculture operations may be certified organic if in compliance with other regulations in this Subpart.

(5) Organic System Plans for aquaculture facilities must include explanations of how the producer will provided for the health and welfare of aquatic animals, preclude the use of prohibited substances, and prevent contamination of aquaculture products from environmental sources.

AWG recommends that § 205.250 (10)(viii) be changed from

(viii) A Waste management plan that provides for:

To read

(viii) A Waste Management Plan that provides for:

As discussed above under § 205.201, AWG recommends that § 205.201(a)(7), (a) through (x) as proposed by NOSB be placed under this section § 205.250 *Aquaculture general*. The proposal of the NOSB solely pertains to aquaculture whereas this section § 205.201 pertains to all of organic agriculture. Section § 205.201 is generic and non-specific, while § 205.250 pertains solely to aquaculture.

If this proposed language is to remain in § 205.201, AWG recommends that (7) be changed to read: "The Organic System Plan for crops, livestock and aquaculture should include:" Without these proposed changes, regulations for aquaculture would involve considerably greater burdens for this form of organic production than for terrestrial agriculture.

AWG also recommends that proposed § 205.201(a)(7)(xi) be placed in § 205.255 *Aquaculture facilities* as (k)(10) since this paragraph solely pertains to the use of net pens. AWG believes that these conditions are considerably more specific and numerous for aquaculture than for crops and livestock.

Therefore, AWG proposes that §205.250 *Aquaculture general* be amended to include:

(10) The Organic System Plan for aquaculture systems should include where applicable:

(i) A map of the production 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 map should include:

a. The location of all known point and non-point sources of prohibited substances and other potential contaminants.

b. Locations of water sampling stations.

(ii) A description of the materials used for all structures.

(iii) Documentation of environmental conditions in the growing area, including water quality and land use in contiguous watersheds.

(iv) For open water systems and those discharging into the environment, a description of a water quality monitoring program that indicates parameters measured, frequency of measurement, and location of sampling stations.

(v) A description of measures that will minimize impacts of culture operations on aquatic ecosystems and wildlife, including:

a. 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 .

(vi) List of animal and plant 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.

(vii) A description of biosecurity practices that are designed to prevent to the occurrence and spread of diseases or parasites.

(viii) A waste management plan that provides for:

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

b. Composting or recycling of waste biological materials to the extent practicable.

c. Control of offensive odors.

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

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

AWG further recommends that § 205.255 *Aquaculture facilities* (discussed below) be amended to include:

(10) The Organic system plan for an aquaculture operation using open water net pens must include the following:

a. Justification for the location of the net pens including a detailed description of how the location minimizes impact to surrounding environment, limits waste accumulation, and minimizes impact to the migratory and reproductive patterns of local wild fish populations, other local species like predators and birds, and any other flora or fauna.

b. Nutrient management plan which describes waste management approaches, monitoring system for all nutrient inputs, outputs, and waste, and location of any and all farms or net pen operations in the vicinity that could impact, positively or negatively, the nutrient management process of the net pen operation seeking certification.

c. A description of anti-fouling practices.

5. § 205.251 Origin of aquaculture animals.

AWG recommends that this title be changed in order to be consistent to:

§ 205.251 Origin of aquatic animals.

AWG recommends that in (a), the last sentence be deleted that reads:

However, in either case, substances prohibited in § 205.610 and § 205.612 are not allowed during earlier life stages.

This subject was never discussed with AWG by NOSB and its Livestock committee. If the AWG had been given the opportunity to provide input, the AWG would have pointed out that hatchery and nursery facilities for a wide variety of aquatic animals and plants have unique complexities and necessities that vary substantially among species and therefore it is difficult to make general statements that apply fairly to the full range of candidate species. In addition, as with poultry, juvenile aquatic animals are often purchased for growout from hatcheries over which the organic producer has no control.

AWG recommends that (e) be changed from

(e) Production of triploid aquatic animals by any method including but not limited to

the application of temperature or pressure shock after fertilization and by crossing tetraploids with diploids is prohibited for fish to be sold as organic.

to read

(e) Production of triploid aquatic animals by any method including but not limited to the application of temperature or pressure shock after fertilization and by crossing tetraploids with diploids is prohibited for aquatic animals intended to be sold as organic.

6. § 205.252 Aquatic Animal feed.

AWG recommends, for purposes of clarification, that the following be changed from:

(e) Aquaculture feeds must be composed of feed ingredients that are certified organic, except that nonsynthetic substances and synthetic substances allowed by § 205.611 and § 205.612, may be used as feed additives and supplements.

to read:

(e) Aquaculture feeds must be composed of feed ingredients that are certified organic, except that nonsynthetic substances~~, synthetic substances allowed in § 205.611, and nonsynthetic substances allowed conditionally in § 205.612,~~ may be used as feed additives and supplements.

The proposed wording is confusing because some readers might infer that nonsynthetic substances could be allowed by § 205.611 and § 205.612, where there are no provisions for such listings.

AWG further recommends that (i) be changed from:

(i) Nutritional pigment compounds that or appear on § 205.611, or are organically produced and allowed by the U.S. Food and Drug Administration for inclusion in aquaculture feeds may be used.

to read:

(i) Nutritional pigment compounds that are nonsynthetic, <u>or are allowed under § 205.611</u>, or are organically produced<u>,</u> and allowed by the U.S. Food and Drug Administration for inclusion in aquaculture feeds, may be used.

These recommended changes, including the addition of a comma, provide clarification.

7. § 205.253 Aquatic animal health care.

AWG recommends that (a)(3) be changed from

(3) establishment of biosecurity measures known to reduce risk of entry of pathogens into the aquaculture production system or between the aquaculture production system and wild aquatic animals. These may include such measures as allowing only entry of broodstock tested and found free of reportable pathogens, animal vector control, and limited human entry by use of fences or barriers and locked entry points. In recirculating systems sanitation procedures must include scheduled removal of accumulated particulate organic matter. Culture water used in the system must be from a source tested and determined free of reportable pathogens and free of known vectors of diseases or disinfected to remove such infectious disease agents. In open water systems, if animals are potentially exposed to known infectious agents, this risk may be mitigated if approved vaccines and vaccination procedures are available. Biosecurity measures should not be used to justify growing conditions that compromise aquatic animal health from elevated stress and associated immunosupression;

to read

(3) establishment of biosecurity measures known to reduce risk of entry of pathogens into the aquaculture production system or between the aquaculture production system and wild aquatic animals. These may include such measures as allowing only entry of broodstock tested and found free of reportable pathogens, animal vector control, and limited human entry by use of fences or barriers and locked entry points. In recirculating systems sanitation procedures must include regular removal of accumulated particulate organic matter. Culture water used in the system must be from a source tested and determined free of reportable pathogens and free of known vectors of diseases or disinfected to remove such infectious disease agents. In open water systems, if animals are potentially exposed to known infectious agents, this risk may be mitigated if approved vaccines and vaccination procedures are available. Biosecurity measures should not be used to justify growing conditions that compromise aquatic animal health from elevated stress and associated immunosupression;

AWG recommends that (a)(5) be changed from

(5) medication records must be kept indicating materials used, rates and methods of application , and applications dates. Records need to identify all lots of aquatic animals treated. Records of medical treatment are required for all treatments and are not limited to substances in compliance with §205.611; and

to read

(5) keeping medication records indicating materials used, rates and methods of application , and applications dates. Records need to identify all lots of aquatic animals treated. Records of medical treatment are required for all treatments and are not limited to substances in compliance with §205.611; and

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AWG recommends that (a)(6) as proposed be deleted

(6) use of multiple species of plants and animals to reduce disease problems (including but not limited to cleaner fish that "groom" other fish), fowling [sic] (including but not limited to growing species of algae that can use the nutrient runoff from the new pen) is encouraged.

and replaced with:

(6) Implementation of practices that break the life-cycle of pathogens. These may include but are not limited to site fallowing and co-stocking cleaner fish to remove parasites.

AWG believes that NOSB did not intend to recommend the use of birds ("fowling") as a method to reduce disease problems. This section deals with animal health provisions and AWG suggests that the suggested language achieves this objective better than the language proposed by the NOSB. For example, the use of algae to remove nutrients is not demonstrated to reduce the risk of disease outbreaks.

AWG recommends that the following (c)(7) be deleted:

(7) Whether or not diseased fish are treated, they may not be sold as organic.

and replace with:

(7) sell as organic any clinically diseased fish as diagnosed by a veterinary or other fish health specialist.

and that a new paragraph (d) be added that provides:

> (d) The producer of organic aquaculture products must:
>
> (1) record and retain records of any unexplained or unexpected mortality events or other evidence of disease or parasitism;
>
> (2) refer unexplained or unexpected morbidity or mortality events to a veterinary or other fish health professional.

This provision (c)(7) was proposed by the NOSB without discussion with the AWG and without the opportunity for public comment. As written it is ambiguous because elsewhere it is required that treatment not be withheld from diseased animals in order to retain the potential for certification. AWG suggests that the proposed replacement and additional text accomplishes what it believes to be the objective of the NOSB in including this provision. An equivalent requirement is not included for livestock or crops.

8. § 205.254 Aquaculture living conditions.

AWG recommends that the period at the end of (a)(2)(ii) be removed to read:

> (ii) minimal potential for injury, and

AWG suggests that (2)(iii) be changed from

> (iii) appropriate population or biomass densities, appropriate for the particular aquatic animal and culture conditions, and that promote natural behaviors and limits aggressive and dominant behaviors from other aquatic animals
>
> to read
>
> (iii) population or biomass densities that are appropriate for the particular aquatic animal and culture conditions, and that promote natural behaviors and limits aggressive and dominant behaviors from other aquatic animals

AWG further suggests that (b) be changed from:

> (b) A comprehensive integrated predator management plan, which employs nonlethal deterrents as a first course of action, shall be developed and implemented as part of the Organic system plan. Any encounter with predators must be noted and reported to the ACA and inspector

to read:

> (b) A comprehensive Integrated Predator Management Plan, which employs nonlethal deterrents as a first course of action, shall be developed and implemented as part of the Organic System Plan. Any encounter with predators must be noted and reported to the <u>accredited certifying agent</u> and inspector.

AWG recommends that ACA be spelled out for clarity.

AWG recommends that (3) be changed from:

> (3) Lethal measures may be taken only when predators threaten human safety or are necessary for predator welfare and must include appropriate documentation. Lethal measures must be in compliance with local laws and the laws of the Unit-

ed States. There is an absolute prohibition on predator mortality if the species is listed nationally or globally as vulnerable, endangered, or critically endangered (i.e. present on the International Union of Conservation in Nature (IUCN) red list)

to read:

(3) Lethal measures may be taken only when individual predators are a direct and immediate threat to human safety or are necessary to relieve pain and suffering of predators with serious injury or disease. Any killing of predators must by documented and include an explanation of why lethal measures were appropriate. Lethal measures must be in compliance with local laws and the laws of the United States.

The second sentence was added by the NOSB without discussion and input from AWG or the public. There are documented cases where lethal measures have been required when animals dangerous to humans enter aquaculture facilities. An employer has a firm obligation under federal laws to provide a safe workplace for employees. To allow a wild animal to present a significant threat to worker safety would be a violation of good management practices, and in many places in the world it would be illegal, including in the United States. We therefore suggest any tradeoffs that must be made between human safety, animal welfare and conservation be made in manner consistent with US federal law and laws applicable to the farm location. The AWG acknowledges the concern of the NOSB regarding threatened and endangered species but believes that the absolute prohibition on lethal control of predators that are threatened or endangered proposed by the NOSB is an extreme position and does not consider the trade-offs with worker safety and the welfare of cultured animals.

AWG recommends that (b)(4) be changed from.

(4) Underwater acoustic harassment devices (AHD's) of any kind shall not be permitted.

to read.

(4) Underwater acoustic harassment devices of any kind shall not be permitted.

9. § 205.255 Aquaculture facilities.

Paragraph (g) as proposed by the NOSB reads:

(g) Potentially adverse environmental impacts from aquaculture production must be minimized. For the purpose of this paragraph, the "site" described in the Organic system plan is an identified area of land or a water body owned or licensed or leased and managed as certified organic by the facility operator. (1) The aquaculture facility must include a suitable waste management approach which that must:

i. Meet a performance target of recycling a minimum of 50% of nutrients (Nitrogen and Phosphorus).

ii. Have discharge levels that meet all local, state, federal or territorial requirements for nutrient discharge into receiving water ways to minimize or even improve the immediate or surrounding environment.

AWG submits that while the proposed target of 50% might be met by recirculating systems or freshwater raceway systems that use effluent to irrigate terrestrial crops during warm months or have

good opportunities to collect waste solids, many farm systems, including many pond systems, and many marine systems, could not meet this requirement. AWG members are unaware of any existing systems that currently meet this requirements. In summary, the requirement to recycle 50% of nutrients would unduly restrict organic aquaculture production to a limited number of production systems, and species.. This provision was inserted by the NOSB without AWG input or public comment.

AWG recommends that the NOSB proposal for (g) be replaced with:

> (g) Potentially adverse environmental impacts from aquaculture production must be minimized. The effluent discharge must not exceed the natural assimilative capacity of an area within 25 meters of the site boundary. For the purpose of this paragraph, the "site" described in the Organic system plan is an identified area of land or a water body owned or licensed or leased and managed as certified organic by the facility operator.
>
> (1) The aquaculture facility must develop and implement a suitable Waste Management Plan that must:
>
> i. Include and meet performance targets for maximizing the utilization and recycling of nutrients as referenced by nutrient inputs (*i.e.*, in feed) including the nutrients contributing to the growth of the aquatic animal. Such targets must be appropriate for the species being grown and the growing system employed.
>
> ii. Include and establish performance targets for minimizing the discharge of any feed nutrient (particularly nitrogen and phosphorous) that is limiting primary productivity in adjoining aquatic ecosystems, except this provision does not apply to bivalve molluscs grown in compliance with § 205.257 Bivalve molluscs.
>
> iii. Be reviewed at least annually to delineate improvements in nutrient recycling when possible. In the event that improvement is not technically feasible, the producer shall prepare a detailed explanation for the accredited certifying agent.
>
> (2) Appropriate methods for accomplishing (1) i. and (1) ii. include use of aquaculture discharge waters for irrigation of terrestrial crops, integrated aquaculture with molluscs and aquatic plants, filter feeding or scavenger fish, or in combination; constructed wetlands; and assimilation of nutrients by organisms retained in the facility. Recycling methods may include use of aquaculture discharge waters or recovered solids for fertilizing terrestrial crops; integrated aquaculture with molluscs and aquatic plants; constructed wetlands; and assimilation of nutrients by organisms retained in the system. Algae, vascular plants, molluscs, filter feeding aquatic animals or scavenger aquatic animals, or a combination, can be grown in or adjacent to the facility. Other biological means for recycling nutrients also may be employed.
>
> (3) The aquaculture facility must implement a waste management plan for discharges into public water that includes:
>
> i. documentation of peak nutrient discharges during a crop cycle considering such factors as maximum biomass and feeding rates.
>
> ii. a determination of which nutrient or nutrients are limiting primary productivity in adjoining aquatic ecosystems.
>
> iii. a determination if, and under what circumstances, the limiting nutrient or

nutrients in facility discharges would make a significant contribution to eutrophication in adjoining aquatic ecosystems.

iv. a provision that if a significant contribution to eutrophication is possible, the Waste Management Plan shall include specific protocols to prevent discharge of the nutrient at levels that would elevate the risks of eutrophication. These may included reducing feeding rates and biomass levels, collection and recycling animal metabolites and waste feed, including other cultured organisms that utilize the nutrient in the facility, and relocation of the facility to another site.

AWG recommends that this language be substituted since it is not prohibitive and accomplishes the goal of maximum recycling with minimum environmental effects. The proposed language addresses the concerns of the NOSB about the impacts of waste nutrients on adjacent ecosystems and minimizing environmental impacts of those discharges, in part through nutrient recycling.

AWG recommends that "Nutrient Management Plan" in (h) be changed to read:

(h) Every organic aquaculture facility must develop a Nutrient Management Plan that evaluates the technical and economic feasibility of options appropriate for the culture system to recover solid and dissolved waste nutrients in other plant and animal crops. Options may include using settled solids as a soil amendment, suspended solids to grow filter-feeding aquatic animals, and dissolved nutrients as a nutrient source for terrestrial crops or aquatic plants.

AWG also recommends that (i) be changed from:

(i) Construction and operation of aquaculture facilities shall not impair water quality to require a change in the designated use of receiving waters and must not salinize or otherwise contaminate soils.

to read:

(i) Construction and operation of aquaculture facilities shall not impair water quality to require a change in the designated use of receiving waters and must not salinate or otherwise contaminate soils.

It is recommended that (k) be changed from:

(k) Open water net-pens and enclosures are permitted in situations where water depth, current velocities and direction, stocking densities, and other factors act to adequately disperse metabolic products in order to minimize any negative impacts on the environment in areas surrounding the pen location(s). Monitoring shall be employed to ensure that the natural assimilative capacity at the site is not overburdened and that performance standards and targets are met. An organic conversion period of at least one year, or one production cycle, whichever is less, shall be required.

to read:

(k) Net-pens and enclosures in public water are permitted in situations where water depth, current velocities and direction, stocking densities, and other factors act to adequately disperse metabolic products in order to minimize any negative im-

> pacts on the environment in areas surrounding the pen location(s). Monitoring shall be employed to ensure that the natural assimilative capacity at the site is not overburdened and that performance standards and targets are met. An organic conversion period of at least one year, or one production cycle, whichever is less, shall be required.

AWG believes that "Net-pens and enclosures in public water" better describes the structures in this section. The addition of "public waters" is consistent with the proposed definition of net pens.

AWG suggests that (k)(1) be changed from:

> (1) The net pens must be situated in such manner that avoid migratory routes of native species and do not disturb reproductive patterns of local wild fish populations, as well as the habits of other local species like predators and birds and any other flora or fauna.

to read:

> (1) The net pens must be situated in such manner that avoid migratory routes of native species and do not disturb reproductive patterns of local wild fish populations and that of other local species like predators and birds or other flora or fauna.

The purpose of this suggested change is to clarify ambiguous language while preserving the intent of the NOSB.

AWG recommends that (k)(2) be changed from:

> (2) Only native fish of local genotype shall be cultured. Non-native species or native species with significant genetic divergence compared to wild stock (*i.e.*, due to selective breeding or other processes), may not be certified as organic if produced in net pens. Operations with escapes greater than 0.5% of cultured stock (within any containment device) over the course of a grow out season shall have their organic status revoked.

to read:

> (2) The aquatic animals cultivated in net pens in public water must be strains of native species or naturally reproducing species that have been established in the local environment for at least twenty (20) years. The organic system plan must include containment management.

This proposed allowed level of 0.5% appears to AWG to be unreasonably extreme. It is substantially below detection limits in practical aquaculture management. In addition, the penalty of revocation of organic status appears to AWG to be unreasonably harsh. Revocation actions are usually limited to cases of deliberate acts, such as fraud. This important condition was never open to public comment or discussion with AWG.

In addition, the adoption of this proposed section in the Final Rule would prevent the net-pen culture of tilapia, a major fish that is farmed around the world at most locations other than the Near East where it is native.

AWG recommends that (k)(3) be changed for clarity and consistency to read:

(3) Producers employing net pens in public water shall implement all practicable measures stated in § 205.253. Producers must implement measures to prevent transmission of diseases and parasites between cultured and wild aquatic animals and must:

For (k)(3) i, AWG suggests adding "seek to" to read as follows:

i. Site net pens in such a manner as to <u>seek to</u> prevent contamination and disease from conventional fish pens or native fish populations taking into account factors like current and seasonal changes.

It is impossible with absolute certainty to prevent any contamination or disease transfer as required by the provision recommended by the NOSB. However, the AWG agrees that it is a very worthy objective to use any and all means that seek to prevent contamination and disease transfer.

AWG recommends deletion of (k)(3) iii "In salt water systems, keep records indicating salinity levels on a weekly basis." because this requirement has no relevance to organic aquaculture. With this change (3) iv must be renumbered to (3) iii.

For consistency, (k)(4) should be changed to read "Producers <u>employing net pens</u> shall implement all practicable measures stated in § 205.254.

AWG recommends changing:

(k)(6) Net pen anti-fouling practices.

i. Most anti-fouling on the nets should be a physical or biological control, or if it is chemical then it has to be listed on the national list of allowed materials specifically for that use.

to read:

i. Except as provided in ii. below, control of fouling on nets must be by physical or biological means.

AWG offers the alternative language because it more clearly indicates the preference for physical or biological methods of fouling control.

AWG recommends changing (k)(7) from:

(7) Use of multiple species of aquatic plants and animals for recycling nutrients is encouraged along with pen rotation to allow for site regeneration.

to read:

(7) Use of multiple species of aquatic plants <u>and/or</u> animals for recycling nutrients is <u>required</u> along with pen rotation to allow for site regeneration.

The addition of "and/or" is for purposes of clarification. AWG suggests that "required" in place of "encouraged" is consistent with the intent of this proposed rule and organic principles.

AWG also recommends that (7)(i) be changed from:

> i**.** If species of aquatic plants and animals are used they must be native species or local genotypes.

to read:

> i. Species of aquatic plants and animals placed outside of and adjacent to net pens for the purpose of recycling nutrients are encouraged to be native species or local genotypes when available.

The use of multiple species is encouraged in this section for purposes of recycling nutrients. AWG proposes that non-native species be allowed in this instance to provide more flexibility to producers to recycle nutrients.

AWG recommends that (k)(9) be amended with the addition of "in public waters" to read:

> (9) In all cases, benthic habitats surrounding net pens <u>in public waters</u> must be shown to not have significant measurable changes in chemistry and biodiversity.

AWG recommends that the following language be inserted here in § 205.255 Aquaculture facilities, (k)(10) and not in § 205.201 (a)(7) as NOSB proposes. This language is specific for aquaculture net pens in public waters and does not pertain in any manner to terrestrial agriculture.

> (10) The Organic System Plan for an aquaculture operation using net pens in public waters must include the following:
>
> a. Justification for the location of the net pens including a detailed description of how the location minimizes impact to surrounding environment, limits waste accumulation, and minimizes the impact to the migratory and reproductive patterns of local wild fish populations, other local species like predators and birds, and any other flora or fauna.
>
> b. Nutrient management plan that describes waste management approaches, monitoring system for all nutrient inputs, outputs, and waste, and location of any and all farms or net pen operations in the vicinity that could impact, positively or negatively, the nutrient management process of the net pen operation seeking certification.
>
> c. A containment plan to assure that fish do not escape into public waters.
>
> d. A description of anti-fouling practices.

10. § 205.257 Bivalve Molluscs

AWG recommends that (a)(1) be corrected to reference the new National List sections for aquaculture to read:

> (1) Except as otherwise provided, all provisions of § 205.250 through § 205.259, Aquaculture, and <u>§ 205.609 through § 205.612,</u> ~~§ 205.600 through § 205.604~~ National List, in this subsection apply to bivalves.

AWG also recommends that the following clause be stricken from (d)(1)(i) to read:

> (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:

In (f)(7), after Mussel Watch Program "of the US National Oceanic and Atmospheric Administration [http:/ccma.nos.noaa.gov/abpout/coast/nsandt/musselwatch.html]" should be added to read

> (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/abpout/coast/nsandt/musselwatch.html] that are collected within the establish site boundaries …

Under (i)(4), the National List reference should be corrected to read:

> (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 § 205.6~~04~~12, except as provided in § 205.6~~03~~11.

11. § 205.258 Farmed aquatic plants.

AWG recommends that the introductory paragraph be changed from:

> Aquatic plants that are intended to be sold, labeled, or represented as organic must be managed according to all applicable rules stated in **Subpart C – Organic Production and Handling Requirements** of the National Rule, from § 205.200 up to and including § 205.207,*Except*,

to read:

> Aquatic plants that are intended to be sold, labeled, or represented as organic must be managed according to all applicable rules stated § 205.200 and § 205.201 of the National Rule *Except*,

---

AWG suggests that the following sections that deal with terrestrial crop agriculture are not practical for aquatic systems and should not apply:

> 202 Land requirements
> 203 Soil fertility
> 204 Seeds and planting stock
> 205 Crop rotation
> 206 Crop pest, weed, and disease

Including these provisions here contradicts § 205.250(1) that specifically exempts these from applying to aquaculture. These requirements for terrestrial plants simply do not apply to aquatic plants.

AWG suggests that (a)(2) be corrected to reference the new National List sections for aquaculture and not agriculture to read

> 2) aquatic plants may be provided dissolved macro-nutrients and micro-nutrients, including trace minerals, chelating compounds, and vitamins listed in §205.609~~1~~; however, the dissolved amounts shall not exceed those necessary for health growth of the plants, and such culture media shall be disposed of in a manner that does not adversely impact the environment; and

---

AWG recommends that (b) and (b)(1) be changed from

> (b) Aquatic plants may be grown in ~~open water~~ organic systems provided that:
>
> (1) That, manure from terrestrial animals, in any form, may not be used to fertilize open water aquatic plants.

to read

> (b) Aquatic plants may be grown in organic systems in public water provided that:
>
> (1) manure from terrestrial animals, in any form, may not be used to fertilize aquatic plants in public water.

These changes are to maintain consistency in language throughout the document.

AWG recommends addition of the following:

> (c) The producer must use organically grown starter culture and planting stock, except nonorganically produced starter culture and planting stock may be used to produce an organic crop when an equivalent organically produced culture or stock is not commercially available.
>
> (d) Aquatic plants must be under continuous organic management beginning no later than when 5% of total harvest weight has been achieved. However, when initially grown with synthetic substances not allowed in § 205, the plants must we washed to remove inorganic growth media prior to being placed under organic management. If separating media from the plants is not possible, then the producer must take steps to minimize transfer of media with the plant when inoculating the organic production culture.

Provisions for starter culture and planting stock were not considered in the early recommendations by AWG to NOSB, and were not developed in the NOSB recommendations. This would correct those oversights.

12. § 205.301 Product composition.

AWG recommends the following addition as (b)(2)

> (2) Livestock (and their products) that have been fed environmentally responsible wild caught fish meal or oil as a feed supplement pursuant to 205.612, and that are used as ingredients, must indicate (Fed environmentally responsible wild caught fish) next to the name of the livestock or livestock product.

The NOSB recommendations mandate this label for aquatic animals and their products in order to conserve wild fish resources from which fish meal is produced. AWG suggests that producers of terrestrial animals such as poultry that are fed fish meal must also be required to post this label.

13. § 205.303 Packaged products labeled "100 percent organic" or "organic.

AWG recommends the following be added as (b)(1)(ii)

> (ii) For livestock fed wild caught fish meal or oil as a feed supplement pursuant to § 205.612 must indicate (Fed environmentally responsible wild caught fish) on the label directly beneath or next to the name of the livestock or livestock product.

The NOSB recommendations mandate this label for aquatic animals and their products in order to conserve wild fish resources from which fish meal is produced. For consistency, the AWG suggests that producers of terrestrial animals that are fed fish meal must also be required to post this label.

14. § 205.306 Labeling of livestock feed.

AWG recommends adding "and aquatic animal" to (a) to read

> (a) Livestock and aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) may display on any package panel the following terms:

and to include this same clause in (c) to read

> (c) Livestock and aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) must:

15. § 205.308 Agricultural in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

AWG recommends adding (a)(2) to read

> (2) If livestock or livestock products are labeled as "organic" and the livestock are fed wild caught fish meal or oil as a feed supplement pursuant to § 205.612, the label, display and display containers must indicate ("Fed environmentally responsible wild caught fish") directly beneath or next to the name of the livestock or livestock product.

As included above, AWG recommends that livestock that consume fish meal and their products must carry the same labeling requirements as are proposed for aquatic animals and their produces.

Appendix A

AQUACULTURE

FINAL RECOMMENDATIONS OF THE

NATIONAL ORGANIC STANDARDS BOARD

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

(a) Synthetic substances and ingredients, except as provided in §205.601, §205.603, §205.609 or §205.611;

(b) Nonsynthetic substances prohibited in §205.602, §205.604, §205.610 or §205.612;

§ 205.2 Terms defined.

The following definitions shall be added to § 205.2 Terms defined.

Aquaculture. The propagation and rearing of aquatic animals and plants.

Aquaculture facility. Any land, structure, or other appurtenance used for aquaculture. Such term includes but is not limited to any laboratory, hatchery, rearing pond, tank, raceway, net pen, cage, raft, longline, geographically defined seafloor, or other structure or defined boundary used in aquaculture.

Aquaculture product. Any product of aquaculture, including but not limited to whole alive or dead aquatic animals, gutted fish, fillets and other forms of raw or processed meat, eggs for human consumption, eggs for reproduction, skin and other animal parts, and alive, fresh and dehydrated aquatic plants, either whole or processed. By-products from aquatic animals grown in aquaculture, such as fish meal, oil, silage, and hydrolyzed offal, are included.

Aquatic animal. Any finfish, mollusc, crustacean, or other aquatic vertebrate or invertebrate grown in fresh, brackish or saltwater, except amphibians, reptiles, birds and mammals.

Aquatic animal broodstock. Sexually mature aquatic animals used to produce progeny that may be incorporated into an organic aquaculture production system.

Aquatic plant. Any plant grown in an aquaculture facility, including microscopic or macroscopic algae, and excluding vascular aquatic plants such as watercress, rice, water hyacinth, and hydroponically produced vascular plant crops.

Aquaculture production system. A process for growing aquatic animals and plants in an aquaculture facility.

Bivalve molluscs. Molluscan shellfish species (Phylum *Mollusca,* Class *Pelecypoda* commonly called "bivalves") with two outer, hinged shells such as oysters, clams, mussels and scallops, but not including gastropods such as abalone and conch, and cephalopods, such as octopus and squid.

Coldwater finfish. Salmonids, cod, marine flatfish and other species not considered in this section as warmwater finfish.

Fish meal. Dried ground tissue of undecomposed whole fish or fish cuttings, either or

both, with or without the extraction of part of the oil.

Fish oil. Oil from rendering whole fish, fish cuttings, or cannery waste alone or in combination.

Fish silage. A mixture of solids and liquids obtained by the breakdown of fish tissue using natural enzymes with or without addition of acids or bases to control spoilage and to enhance enzyme activity.

Finfish. Aquatic vertebrate animals consisting of bony fish (*Telestomi*), not including mammals, birds, amphibians and reptiles. In this section, coldwater finfish include salmonids, cod, marine flatfish not considered warmwater finfish. Warmwater finfish have optimum temperatures for growth between 25 and 30°C. Examples include catfish, tilapia, and paddlefish.

Forage fisheries. Wild fish harvested for the purpose of rendering fish meal and fish oil.

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.

Livestock Any cattle, sheep, goat, swine, poultry, equine, or aquatic animals used for food or in the production of food, fiber, feed or other agricultural-based consumer products; wild or domesticated game; or other non-plant life, except such term shall not include bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Metabolic products of aquatic animals. Solid and dissolved compounds released by aquatic animals during growth in an aquaculture production system.

Minimum nutritional requirements. Those that support optimum growth, health and reproduction in fish in all life stages of aquatic animals cultured in all types of rearing systems.

Monosex stocks. Populations of aquatic animals of one sex obtained by artificially induced or natural processes, or by manual selection.

Natural assimilative capacity. The ability of an aquatic ecosystem within and surrounding an aquaculture facility to assimilate and process effluents discharged from the facility without reduction in that ecosystem's ability to function and maintain life.

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

Open water net pen. A structure in an ocean, lake, or other waterway containing nets configured to form enclosed pens for containing aquatic animals where water freely flows into and out of the pens.

Persistent bioaccumulative toxins (PBT). Chemicals that resist breakdown and are persistent in the environment, bioaccumulate in food chains through consumption or uptake, and are a hazard to human health or wildlife. A term related to PBT is POP (persistent organic pollutant) and, for the purposes of these standards, the terms are interchangeable.

Polyploid. Aquatic animals with more than two sets of homologous chromosomes. Most

aquatic animals are naturally diploid (2n). Triploid aquatic animals are typically sterile (non-reproductive) and tend to grow faster than diploid aquatic animals.

Reportable pathogens. Pathogens of aquatic animals whose diagnosis must be reported, by law, to pertinent state or federal authorities. Included are pathogens listed as Reportable by the Office Internationale Epitozooties.

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.

Shellfish. Aquatic invertebrate animals including molluscs and crustaceans.

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.

Sustainability. Meeting the needs of the present without compromising the ability of future generations to meet their own needs (1987 Brundtland Report). Sustainably managed resources are those where long-term productivity is maintained to meet human needs while simultaneously conserving biodiversity, environmental quality, and ecosystem services. Ecosystem services are functions provided by ecosystems such as nutrient cycling, flood control, and more. Their importance was highlighted in the 2005 Millennium Ecosystem Assessment report, which was the result of a major international effort involving a number of agencies.

Wild fish. Any species of fish or shellfish, raw or processed, harvested from wild sources used for human food or in animal feeds, including feeds for aquatic animals.

§205.201 Organic production and handling plan

(a) The producer or handler of a …. An organic production and handling system plan must include:

(b) A producer may substitute …. Requirements of this subpart.

(c) 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.

§ 205.237 Livestock feed.

(b) **…**

(c) The producer of an organic operation must not:

(7) Feed fish meal or fish oil from forage fish except as provided in § 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

§ 205.250 Aquaculture general.

(1) Aquatic animals, aquatic animal products, aquatic plants, and aquatic plant products to be sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," must be produced and handled in accordance with this section: Except that the requirements of Sections § 205.236 through § 205.239 shall not apply to the production of aquatic animals or aquatic animal products and the requirements of Sections § 205.202 through § 205.206 shall not apply to the production of aquatic plant or aquatic plant products.

(2) Metabolic products of aquaculture species are not considered animal manure under § 205.2 Terms Defined, Manure, and § 205.239 (c) Livestock Living Conditions.

(3) Metabolic products of one species are recognized as organic resources for one or more other species in an aquaculture production system. The Organic System Plan of facilities producing aquatic animals must consider measures to recycle or biologically process metabolic products. Where feasible, the Organic System plan must include the polyculture of two or more different species grown in the same body of water, and the integration of additional species as water moves through the aquaculture facility or into adjoining discharge areas.

(4) The feasibility of using water discharges and filtered metabolic products as nutrients for vascular plants in agricultural crops and constructed wetlands must be considered in Organic System Plans. The quantities of such discharges and filtered products applied shall not exceed the requirements of targeted plants in the receiving area, and shall not be discharged into unplanned areas. Vascular agriculture crops using nutrients from certified organic aquaculture operations may be certified organic if in compliance with other regulations in this Subpart.

(5) Organic System Plans for aquaculture facilities must provided for the health and welfare of aquatic animals, preclude prohibited substances, and prevent contamination of aquaculture products from environmental sources.

(6) Biodiversity of natural aquatic ecosystems, functional integrity of aquatic environments, and the quality of adjoining aquatic and terrestrial ecosystems must be protected. All aquatic animals possessed and grown at an aquaculture facility must be in compliance with all applicable laws.

(7) Measures shall be taken to prevent escapes of cultivated animals and plants from the aquaculture facility and to document any that do occur. These measures shall be documented in the Organic System Plan.

(8) By-products from the production of aquatic animals, such as fish meal, fish oil, silage and hydrolyzed offal, produced in an organic aquaculture production system, and handled in accordance with organic handling requirements, may be labeled organic.

(9) Aquaculture facilities shall be designed, operated and managed in a manner that seeks to maximize the welfare of cultured aquatic animals, minimizes the stress on those animals, and prevents the spread of disease within the facility and to all adjoining ecosystems and native fish species.

(10) The organic system plan for aquaculture systems should include:

(i) A map of the production 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 map should include:

a. The location of all known point and non-point sources of prohibited substances and other potential contaminants.

b. Locations of water sampling stations.

(ii) A description of the materials used for all structures.

(iii) Documentation of environmental conditions in the growing area, including water quality and land use in contiguous watersheds.

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

(v) A description of measures that will minimize impacts of culture operations on aquatic ecosystems and wildlife, including:

a. 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.

(vi) List of animal and plant 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.

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

(viii) A waste management plan that provides for:

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

b. Composting or recycling of waste biological materials to the extent practicable.

c. Control of offensive odors.

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

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

(xi) The organic system plan for an aquaculture operation using open water net pens must include the following:

a. Justification for the location of the net pens including a detailed description of how the location minimizes impact to surrounding environment, limits waste accumulation, and minimizes impact to the migratory and reproductive patterns of local wild fish populations, other local species like predators and birds, and any other flora or fauna.

b. Nutrient management plan which describes waste management approaches, monitoring system for all nutrient inputs, outputs, and waste, and location of any and all farms or net pen operations in the vicinity that could impact, positively or negatively, the nutrient management process of the net pen operation seeking certification.

c. A description of anti-fouling practices.

§ 205.251 Origin of aquaculture animals.

(a) Aquatic animals grown in aquaculture to be sold as organic must have been under continuous organic management beginning no later than the second day after final larval metamorphosis and the beginning of exogenous feeding, where applicable by species, or beginning no later than when 5% of total market weight has been achieved, whichever is greater. However, in either case, substances prohibited in § 205.610 and § 205.612 are not allowed during earlier life stages.

(b) Aquatic animals that are removed from an organic production system and subsequently managed on a non-organic facility may not be sold, labeled, or represented as organically produced.

(c) Broodstock that has not been under continuous organic management may not be sold, labeled, or represented as organic slaughter stock.

(d) The producer of an organic aquaculture facility must maintain records sufficient to preserve the identity of all organically managed animals (by lot) and edible and nonedible animal products to assure reliable traceability from farm to market.

(e) Production of triploid aquatic animals by any method including but not limited to the application of temperature or pressure shock after fertilization and by crossing tetraploids with diploids is prohibited for fish to be sold as organic.

(f) Culture of monosex stocks of aquatic animals obtained by direct treatment with steroidal or other hormones (including methyl-testosterone) or by other direct-treatment artificial induction methods, including use of excluded methods, is prohibited.

(g) Cultivation of any genetically modified aquatic animal or an organism produced by any other excluded method provided in § 205.2 Terms defined, is prohibited.

(h) In cases where hatchery progeny of aquatic animals are not commercially available, boodstock may be collected from the wild provided that they are collected in a sustainable manner, as documented in the Organic System Plan, and where appropriate, in compliance with all federal and state regulations, and in collaboration with government agencies, to assure that natural populations and the collected individuals are protected and that biodiversity in the ecosystem is supported.

§ 205.252 Aquatic Animal feed.

(a) Feeds and feeding practices must meet the minimum nutritional requirements of the aquatic animal.

(b) Use of aquatic animal feeds must minimize the environmental impact of released nutrients on receiving waters and adjoining ecosystems as documented in the Organic System Plan.

(c) Aquatic animals must be provided with their natural nutrients consistent with the need to optimize health and growth of the aquatic animal. This includes live foods and the sources of ingredients in formulated feeds as allowed in the rule.

(d) Feeds for aquaculture products for human consumption must contain lipids from fish oil or other omega-3 sources produced by microorganisms or organic plants to meet the nutritional requirement of specific lipids for the particular aquatic species, except that other lipids from organic sources may be provided in feeds for aquatic animals that have a specific dietary requirements for such ingredients to the extent necessary to meet the minimum requirement for that lipid in that aquatic animal.

(e) Aquaculture feeds must be composed of feed ingredients that are certified organic, except that nonsynthetic substances, and synthetic substances allowed by § 205.611 and § 205.612, may be used as feed additives and supplements.

(f) Aquaculture feeds may include fish meal and fish oil derived from organically raised aquatic animals or algae according to an Organic System Plan, providing the meal and oil is produced from aquatic animals of a different family than the aquatic animal being fed.

(g) Silage and lipids produced from organic fish that is enzyme-processed, or produced with acids and bases that are organically certified or approved in § 205.611 for fish emulsion or other purposes, may be certified organic and incorporated into organic aquaculture feeds without limitation.

(h) Organic aquaculture feeds may include meals and oils containing essential fatty acids produced by processes allowed in organic production.

(i) Nutritional pigment compounds that are nonsynthetic, or appear on 205.611, or are organically produced, and allowed by the U.S. Food and Drug Administration for inclusion in aquaculture feeds, may be used.

(j) The producer of organic aquatic animals shall not:

(1) incorporate or introduce any type of antibiotic or hormone in feeds, the water supply, or the environment;

(2) provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance of the species at its specific stage of life;

(3) feed mammalian or poultry slaughter products to aquatic animals;

(4) use feedstuffs extracted with synthetic solvents not approved on 205.611;

(5) use feed, feed additives, and feed supplements in violation of the U.S. Federal Food, Drug, and Cosmetic Act; or

(6) use any genetically modified organism, or any organism produced by any other excluded method provided in § 205.2 Terms defined, or product thereof, as a feed ingredient.

(k) Fish meal or fish oil may not be sourced from any fishery classified by relevant state/provincial, national, or international fisheries authorities as follows: “at risk of reduced reproductive capacity;” “suffering reduced reproductive capacity;” “harvested outside precautionary limits;” “over-exploited;” “depleted;” “overfished;” “overfishing is occurring;” or any other comparable classification, or at significant risk of those conditions within the next recruitment cycle.

(l) For fish meal and fish oil from wild fish used in organic feeds, levels of unavoidable residual environmental contaminants, including persistent bioaccumulative toxins (PBTs) and mercury, cadmium, lead, arsenic and tin must be less than or equal to the lowest levels found in commercially available fish meal and fish oil, provided, however, that the comparable products are classes of fish meal and fish oil allowed in this section, and do not include those produced with volatile organic solvents not allowed under § 205.611. Fish oil must be treated with activated carbon, which may include synthetic activated carbon, or any process using water as a solvent, for removal of contaminants.

(m) Supplementation of fish meal and fish oil from other non-organic aquatic feed products not specifically allowed in this section is prohibited.

§ 205.253 Aquatic Animals health care.

(a) The aquaculture producer must establish and maintain preventive health care practices that optimize animal welfare and minimize animal stress and pain by implementing the following procedures and practices:

(1) provision of a source of nutrition inclusive of live and formulated feeds sufficient to meet minimum nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy and other necessary dietary or nutritional components in compliance with §205.611 and §205.612;

(2) maintenance of life-supporting water rearing conditions, including control of potentially toxic metabolic compounds (ammonia and carbon dioxide) within known physiological tolerance ranges for the species, and the maintenance of water temperature, oxygen concentration, and pH within known life-supporting values for the species and the prevention of extended excursions to stressful extremes. Efforts to maintain such conditions must be documented by a monitoring and record-keeping program for these and other species specific key water quality parameters that affect health. The frequency of such monitoring shall depend on the culture system, site, species, life stage, and environmental characteristics;

(3) establishment of biosecurity measures known to reduce risk of entry of pathogens into the aquaculture production system or between the aquaculture production system and wild aquatic animals. These may include such measures as allowing only entry of broodstock tested and found free of reportable pathogens, animal vector control, and limited human entry by use of fences or barriers and locked entry points. In recirculating systems sanitation procedures must include scheduled removal of accumulated particulate organic matter. Culture water used in the system must be from a source tested and determined free of reportable pathogens and free of known vectors of diseases or disinfected to remove such infectious disease agents. In open water systems, if animals are potentially exposed to known infectious agents, this risk may be mitigated if approved vaccines and vaccination procedures are available. Biosecurity measures should not be used to justify growing conditions that compromise aquatic animal health from elevated stress and associated immunosupression;

(4) administration of vaccines, other veterinary biologics, and approved natural supplements, such as supplementation or treatment of healthy animals with beneficial bacteria, appropriate to the species and location in compliance with §205.611 and §205.612;

(5) medication records must be kept indicating materials used, rates and methods of application , and applications dates. Records need to identify all lots of aquatic animals treated. Records of medical treatment are required for all treatments and are not limited to substances in compliance with §205.611; and

(6) use of multiple species of plants and animals to reduce disease problems (including but not limited to cleaner fish that "groom" other fish), fouling (including but not limited to growing species of algae that can use the nutrient run-off from the net pen) is encouraged.

(b) When preventive practices and veterinary biologics are inadequate to prevent disease, a producer may administer synthetic medications, provided that such medications are allowed under § 205.611. (1) parasiticides allowed under § 205.611 may be used on aquatic broodstock, but none that are to be sold, labeled, or represented as organically produced.

(c) The producer of organic aquaculture products must not:

(1) sell, label, or represent as organic any aquatic animal or edible product derived from any aquatic animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.611, or any substance that contains a nonsynthetic substance prohibited in § 205.612;

(2) administer any type of animal medication or therapy, other than vaccination, in the absence of illness;

(3) administer hormones for growth promotion, prevention of reproductive maturation, and sex reversal;

(4) administer synthetic parasiticides except as allowed under § 205.611;

(5) administer animal drugs in violation of the U.S. Food and Drug Administration regulations, and vaccines in violation of U.S. Department of Agriculture regulations; and

(6)withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Lots of aquatic animals treated with a prohibited substance must be clearly identified by lot number and shall not be sold, labeled, or represented as organically produced. Except for earthen ponds not lined with impervious barriers, facilities containing aquatic animals during medical treatment are not required to undergo conversion periods specified in paragraphs (l) and (m)of § 205.255 Aquaculture facilities.

(7) Whether or not diseased fish are treated, they may not be sold as organic.

§ 205.254 Aquaculture living conditions.

(a) Aquaculture systems must establish and maintain living conditions as documented in the Organic System Plan that accommodates the health and natural behavior of the aquatic animals, including:

(1) an environment operated within the tolerance limits characteristic of the aquatic animal and stage of development by monitoring and maintaining water quality appropriate for the production system and species, including temperature, pH, salinity, pho-

toperiod, dissolved oxygen, ammonia, and nitrite concentrations, without sudden changes or prolonged exposure to extremes; and

(2) containment that allows the animals:

(i) to exercise swimming behavior within the culture unit;

(ii) minimal potential for injury, and

(iii) appropriate population or biomass densities, as recommended by species, that promote natural behaviors and limits aggressive and dominant behaviors from other aquatic animals.

(b) A comprehensive integrated predator management plan, which employs non-lethal deterrents as a first course of action, shall be developed and implemented as part of the organic system plan. Any encounter with predators must be noted and reported to the accredited certifying agent and inspector.

(1) The culture system must be managed to minimize the risk of losses of cultured stock, stress to cultured aquatic animals caused by predators, and harm to predators.

(2) Organic aquaculture facilities must develop an integrated Predator Deterrence Plan as described in the Organic System Plan that identifies potential predators, appropriate deterrence methods, how predator behavior will be modified by application of deterrence methods, documentation of control methods and effects, contingencies for failure to achieve objectives, and how plan implementation conserves biodiversity in the ecosystem adjacent to and including the aquaculture facility. Examples of such control measures include but not limited to site selection, physical barriers, repellents, and legal predator deterrence methods.

(3) Lethal measures may be taken only when predators threaten human safety or are necessary for predator welfare and must include appropriate documentation. Lethal measures must be in compliance with local laws and the laws of the United States. There is an absolute prohibition on predator mortality if the species is listed nationally or globally as vulnerable, endangered, or critically endangered (*i.e.*, present on the International Union of Conservation in Nature (IUCN) red list)

(4) Underwater acoustic deterrent devices of any kind shall not be permitted

(c) Non-organic aquatic animals may be used in aquaculture production systems for controlling pests, such as weeds, snails, algae, and parasites. Triploid animals may be employed provided that the animals are legal to culture, not labeled organic, and readily separated at harvest from the aquatic animals under organic management.

§ 205.255 Aquaculture facilities.

(a) Aquaculture facilities shall be designed, operated and managed in a manner that seeks to maximize the welfare and minimize the stress of cultured aquatic animals, and prevents the spread of disease within the facility and to all adjoining ecosystems and native fish species.

(b) Construction and operation of organic aquaculture facilities shall not compromise the structure and function of adjoining aquatic and terrestrial ecosystems as described in the Organic System Plan.

(c) Water sources for aquaculture facilities must be selected carefully and managed to avoid environmental contaminants that can harm human health.

(d) Facility boundaries shall be identified clearly.

(e) Organic aquaculture facilities shall provide buffers from potential contamination sources including pesticide drift and other possible contaminants from conventional aquaculture as documented in the Organic System Plan.

(f) Pond berms and tank tops shall be designed and constructed to prevent contamination from the environment during a 100-year flood event.

(g) Potentially adverse environmental impacts from aquaculture production must be minimized. The rate of effluent discharge must not exceed the natural assimilative capacity of an area within 25 meters of the site boundary. For the purpose of this paragraph, the "site" described in the Organic System Plan is an identified area of land or a water body owned or licensed or leased and managed as certified organic by the facility operator.

(1) The aquaculture facility must include a suitable waste management approach that must:

i. Meet a performance target of recycling a minimum of 50% of nutrients (Nitrogen and Phosphorus).

ii. Have discharge levels that meet all local, state, federal or territorial requirements for nutrient discharge into receiving waterways to minimize or even improve the immediate or surrounding environment.

(h) Every organic aquaculture facility must develop a Nutrient Management Plan that evaluates the technical and economic feasibility of options appropriate for the culture system to recover solid and dissolved waste nutrients in other plant and animal crops. Options may include using settled solids as a soil amendment, suspended solids to grow filter-feeding aquatic animals, and dissolved nutrients as a nutrient source for terrestrial crops or aquatic plants.

(i) Construction and operation of aquaculture facilities shall not impair water quality to require a change in the designated use of receiving waters and must not salinize or otherwise contaminate soils.

(1) Structures used in aquaculture production must not contain or be treated with prohibited materials, except as provided § 205.611 or § 205.612.

(j) Aquaculture facilities must be managed with all reasonable security measures (mechanical, physical, and biological barriers) with the goal of eliminating escapes caused by predators, adverse weather conditions (including floods), facility malfunction, facility damage, or other causes. Facilities must be operated with preventative measures against possible escapes into the natural environment of the aquatic animals in production. The Organic System Plan must describe measures to prevent escape, procedures to detect and document escapes should they occur, and actions to be undertaken in the event of escape.

(k) Open water net-pens and enclosures are permitted in situations where water depth, current velocities and direction, stocking densities, and other factors act to adequately disperse metabolic products in order to minimize any negative impacts on the environment in areas surrounding the pen location(s). Monitoring shall be employed to ensure that the natural assimilative capacity at the site is not overburdened and that performance

standards and targets are met. An organic conversion period of at least one year, or one production cycle, whichever is less, shall be required.

(1) The net pens must be situated in such manner that avoid migratory routes of native species and do not disturb reproductive patterns of local wild fish populations, as well as the habits of other local species like predators and birds and any other flora or fauna.

(2) Only native fish of local genotype shall be cultured. Non-native species or native species with significant genetic divergence compared to wild stock (*i.e.*, due to selective breeding or other processes), may not be certified as organic if produced in net pens. Operations with escapes greater than 0.5% of cultured stock (within any containment device) over the course of a grow out season shall have their organic status revoked.

(3) Net pen producers shall implement all practicable measures stated in § 205.253. Producers must implement measures to prevent transmission of diseases and parasites between cultured and wild aquatic animals and must:

i. Site net pens in such a manner as to prevent contamination and disease from conventional fish pens or native fish populations taking into account factors like current and seasonal changes.

ii. Consider buffer zones for other potential sources of contamination by any substances not allowed in organic production.

iii. In salt water systems, keep records indicating salinity levels on a weekly basis.

iv. Keep medication records indicating materials used, rates and methods of application, and application dates.

(4) Net pen producers shall implement all practicable measures stated in § 205.254

(5) Facility managers shall implement all practicable measures to minimize escapes and must have in place a protocol for monitoring and reporting on escapes.

(6) Net pen anti-fouling practices.

i. Except as provided in ii. below, control of fouling on nets must be by physical or biological means.

ii. Except as may be provided in § 205.609 through § 205.612, chemical treatment of bio-fouling organisms on nets is not allowed.

iii. Copper based anti-fouling materials are prohibited.

(7) Use of multiple species of aquatic plants and animals for recycling nutrients is encouraged along with pen rotation to allow for site regeneration. i**.** If species of aquatic plants and animals are used they must be native species or local genotypes.

(8) Farm level effluents and the potential influence of other aquatic farms must be shown not to exceed the natural assimilative capacity of the surrounding ecosystem.

(9) In all cases, benthic habitats surrounding net pens must be shown to not have significant measurable changes in chemistry and biodiversity.

(l) Production systems with direct soil-water contact are allowed, provided that a conversion period of 36 months occurs between the date of the last application of prohibited

substances and the harvest of aquatic animals under organic management and intended to be certified organic.

(m) Production systems with containment units of plastic, fiberglass, metal, concrete or other cleanable surfaces able to hold water are allowed, provided that the unit is filled with water to its capacity and then drained and cleaned before production can be certified organic.

(n) Recirculating systems are permitted if the system supports the health, growth, and well-being of the species, including:

(1) stocking or biomass density appropriate for the particular species being produced to ensure animal health and overall well-being, including the natural behavioral characteristics of the species; and

(2) the provision of emergency life support systems to provide appropriate maintenance of water quality, especially dissolved oxygen levels, in the event that primary life support systems fail.

§ 205.256 Aquaculture additional [Reserved].

§ 205.257 Bivalve Molluscs

(a) Bivalve molluscs general:

(1) Except as otherwise provided, all provisions of § 205.250 through § 205.259, Aquaculture, and § 205.609 through § 205.612, 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 indi-

cate 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,” “approved,” or “conditionally approved” subject to specific provisions of these standards. Bivalves grown at locations that are not classified, or classified as ,” “restricted,” “conditional-

ly 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/abpout/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 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 205.612, except as provided in 205.611.

(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.

(11) 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.

§ 205.258 Farmed aquatic plants.

Aquatic plants that are intended to be sold, labeled, or represented as organic must be managed according to all applicable rules stated in § 205.200 and § 205.201 of the National Rule , *Except*,

(a) Aquatic plants may be grown in closed containment organic systems provided that:

(1) any pond with soil from which aquatic plants are intended to be represented as organic must have had no prohibited substances, as listed in §205.201, applied for 36 months immediately preceding harvest of the crop, and containment vessels must have organic approved clean-out procedures prior to use to prevent contact or contamination with prohibited materials;

(2) aquatic plants may be provided dissolved macro-nutrients and micro-nutrients, including trace minerals, chelating compounds, and vitamins listed in §205.609; however, the dissolved amounts shall not exceed those necessary for health growth of the plants, and such culture media shall be disposed of in a manner that does not adversely impact the environment; and

(3) the pond or containment vessel has berm elevations with distinct defined boundaries and buffer zones with runoff diversions to prevent the unintended application of a prohibited substance into the pond or containment vessel, or allowed contact with a prohibited substance applied to adjoining land that is not under organic management.

(4) pond drainage must be done in a manner that prevents any and all sediment materials and nutrients from being discharged into waterways, such that:

(i) the pond discharge water meets quality standards based on the Total Maximum Daily Load (TMDL) for the receiving waterway as provided on the current state code pond permit process

(ii)in cases where TMDL metrics are unavailable, discharge water must meet a minimum standard of secondary treatment, which is defined as less than 30 mg/l BOD total suspended solids where an 85% removal of BOD is attained [EPA Guidelines Ref. QAC 252:606-1-5…(i)A]

(5) Manure from terrestrial animals may be used to fertilize aquatic plants intended to feed organic fish, in aquaculture ponds for organic production systems, provided:

(i) the manure is composted in compliance with § 205.203,

(b) Aquatic plants may be grown in open water organic systems provided that:

(1) That, manure from terrestrial animals, in any form, may not be used to fertilize open water aquatic plants.

§ 205.259 Harvest, transport, post harvest handling, and slaughter of aquatic animals.

(a) Handling of stock during harvesting, transport, and slaughtering operations must be carried out with minimal disturbance and stress to the aquatic animal.

(b) Adverse environmental impacts associated with harvest operations must be minimized.

(c) Aquatic animals transported to slaughter and processing facilities, or to live haul markets, shall be transported under conditions appropriate to the species and in such manner to minimize the adverse effects of:

(1) water quality;

(2) time spent in transport;

(3) animal density;

(4) metabolic substances; and

(5) escape.

(d) Fish should be held in high quality water for the duration of food deprivation prior to transport and slaughter for a period not to exceed the time necessary to allow clearance of stomach and intestine contents.

(e) Just prior to slaughter and before or immediately after they are removed from water, finfish must be stunned by a method that renders them instantly insentient and maintains insentience until death.

(1) Permitted procedures include:

(i) concussion to the head promptly followed by prompt severing of the gill arches or decapitation;

(ii) electrical stunning sufficient to achieve insentience immediately followed by severing of the gill arches or decapitation;

(iii) electrocution with electric current sufficient to achieve insentience; or

(iv) ice slurry for warmwater marine finfish; provided that this method will be on-

ly permitted for five years after the date when organic standards for farmed aquatic animals are promulgated as an amendment to the Final Rule.

(2) Prohibited slaughtering methods for finfish include those that use:

(i) ice or ice slurry except as provided in (iv) above;

(ii) carbon dioxide;

(iii) synthetic anesthetics, including MS-222;

(iv) natural plant anesthetics not approved by the U.S. Food and Drug Administration for this purpose, including clove oil;

(v) suffocation or asphyxiation (leaving fish to die in air); or

(vi) exsanguination (bleeding) without stunning.

(f) Slaughter using ice or ice slurry is allowed for crustaceans, molluscs, and other aquatic animals that are non-sentient.

(g) The disposal of harvest water, blood water, viscera and disinfectant should pose no threat to wild or farmed fish or the environment and comply with existing laws.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as "100 percent organic."* A raw or processed aquaculture product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to §205.303.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed aquaculture product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303.

(1) Aquatic animals (and their products) that have been fed environmentally responsible wild caught fish meal or oil as a feed supplement pursuant to 205.612, and that are used as ingredients, must indicate (Fed environmentally responsible wild caught fish) next to the name of the fish.

(2) Livestock (and their products) that have been fed environmentally responsible wild caught fish meal or oil as a feed supplement pursuant to 205.612, and that are used as ingredients, must indicate (Fed environmentally responsible wild caught fish) next to the name of the fish.

(e) Livestock feed.

(1) A raw or processed aquatic animal feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed aquatic animal feed product sold, labeled, or represented as "organic" must be produced in conformance with §205.237.

(3) A raw or processed aquatic animal feed product sold, labeled, or represented as "organic" must be produced in conformance with §205.252.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(b) Aquaculture products in packages described in §205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(i) For aquatic animals fed wild caught fish meal or oil as a feed supplement pursuant to 205.612 must indicate (Fed environmentally responsible wild caught fish) on the label directly beneath or next to the name of the fish.

§ 205.306 Labeling of livestock feed.

(a) Aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) may display on any package panel the following terms:

(1) The statement, "100 percent organic" or "organic," as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, Provided, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(c) Aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) must:

(i) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by...," or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(ii) Comply with other Federal agency or State feed labeling requirements as applicable.

§ 205.308 Aquaculture products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Aquaculture products in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided,* That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.

(1) If fish is labeled as "organic" and fed wild caught fish meal or oil as a feed supplement pursuant to 205.612, the label, display and display containers must indicate ("Fed environmentally responsible wild caught fish") directly beneath or next to the name of the fish.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.609 Synthetic substances allowed for use in organic aquatic plant production. [Reserved]

§ 205.610 Nonsynthetic substances prohibited for use in organic aquatic plant production. [Reserved]

§ 205.611 – Synthetic substances allowed for use in organic aquatic animal production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic aquatic animal production**:**

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(c) As feed supplements—None.

(d) As feed additives.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

§ 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

The following nonsynthetic substances may not be used in organic aquatic animal production:

(a) Fish meal and fish oil from wild caught fish and other wild aquatic animals, ***Except*** if produced from environmentally responsible food grade wild caught fisheries and fed in the following step-wise levels: a maximum combined total of 25% during year 1 through 5 after this regulation is implemented, a maximum combined total of 15% during year 6 through 8, and a maximum combined total of 10% during year 9 through year 10, and a maximum combined total of 5% during year 11 and 12, with the percentages by weight of feed being averages over the production cycle of the aquatic animal.

(1) fish meal and fish oil may not be stabilized with synthetic stabilizers unless allowed on §205.611

(b) Feed from forage fisheries.

(c) –(z) [Reserved]

Appendix B

AQUACULTURE WORKING GROUP
Text Including Proposed Changes by the AWG to the
Final Recommendations of The
National Organic Standards Board

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

(a) Synthetic substances and ingredients, except as provided in §205.601, §205.603, §205.609 or §205.611;

(b) Nonsynthetic substances prohibited in §205.602, §205.604, §205.610 or §205.612;

§ 205.2 Terms defined.

The following definitions shall be added to § 205.2 Terms defined.

Aquaculture. The propagation and rearing of aquatic animals and plants.

Aquaculture facility. Any land, structure, or other appurtenance used for aquaculture. Such term includes but is not limited to any laboratory, hatchery, rearing pond, tank, raceway, net pen, cage, raft, longline, geographically defined seafloor, or other structure or defined boundary used in aquaculture.

Aquaculture product. Any product of aquaculture, including but not limited to whole alive or dead aquatic animals, gutted fish, fillets and other forms of raw or processed meat, eggs for human consumption, eggs for reproduction, skin and other animal parts, and alive, fresh and dehydrated aquatic plants, either whole or processed. By-products from aquatic animals grown in aquaculture, such as fish meal, oil, silage, and hydrolyzed offal, are included.

Aquatic animal. Any finfish, mollusc, crustacean, or other aquatic vertebrate or invertebrate grown in fresh, brackish or saltwater, except amphibians, reptiles, birds and mammals.

Aquatic animal broodstock. Sexually mature aquatic animals used to produce progeny that may be incorporated into an organic aquaculture production system.

Aquatic plant. Any plant grown in an aquaculture facility, including microscopic or macroscopic algae, and excluding vascular aquatic plants such as watercress, rice, water hyacinth, and hydroponically produced vascular plant crops.

Aquaculture production system. A process for growing aquatic animals and plants in an aquaculture facility.

Bivalve molluscs. Molluscan shellfish species (Phylum *Mollusca*, Class *Pelecypoda* commonly called “bivalves”) with two outer, hinged shells such as oysters, clams, mussels and scallops, but not including gastropods such as abalone and conch, and cephalopods, such as octopus and squid.

Coldwater finfish. Salmonids, cod, marine flatfish and other species not considered in this section as warmwater finfish.

Fish meal. Dried ground tissue of undecomposed whole fish or fish cuttings, either or both, with or without the extraction of part of the oil.

Fish oil. Oil from rendering whole fish from forage fisheries, fish cuttings and other by-products, or cannery waste alone or in combination.

Fish silage. A mixture of solids and liquids obtained by the breakdown of fish tissue using natural enzymes with or without addition of acids or bases to control spoilage and to enhance enzyme activity.

Finfish. Aquatic vertebrate animals consisting of bony fish (*Telestomi*), not including mammals, birds, amphibians and reptiles. In this section, coldwater finfish include salmonids, cod, marine flatfish not considered warmwater finfish. Warmwater finfish have optimum temperatures for growth between 25 and 30°C. Examples include catfish, tilapia, and paddlefish.

Forage fish. Wild fish harvested for the purpose of rendering fish meal and fish oil.

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 systematic analysis and management of critical processing variables that impact upon the healthiness and safety of seafood products.

Livestock Any cattle, sheep, goat, swine, poultry, equine, or aquatic animals used for food or in the production of food, fiber, feed or other agricultural-based consumer products; wild or domesticated game; or other non-plant life, except such term shall not include bees for the production of food, fiber, feed, or other agricultural-based consumer products. Regulations pertaining to aquatic animals are in §205.250 through §205.612, while regulations pertaining to terrestrial animals are in §205.236 through §205.239.

Metabolic products of aquatic animals. Solid and dissolved compounds released by aquatic animals during growth in an aquaculture production system.

Minimum nutritional requirements. Those requirements for proteins and amino acids, energy, lipids, carbohydrates, vitamins and minerals that support optimum growth, health and reproduction in fish in all life stages of aquatic animals cultured in all types of rearing systems.

Monosex stocks. Populations of aquatic animals of one sex obtained by artificially induced or natural processes, or by manual selection.

Natural assimilative capacity. The limit of an aquatic ecosystem within and surrounding an aquaculture facility to assimilate and process effluents discharged from the facility without reduction in that ecosystem's ability to function and maintain life.

Net pen (or cage). Any floating, suspended, or submerged enclosure located in public water that is used to hold and grow aquatic animals in fresh, brackish, or saltwater. The term net pen does not include nets employed in on-shore ponds and other containment vessels to separate fish.

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

Persistent bioaccumulative toxins (PBT). Chemicals that resist breakdown and are persistent in the environment, bioaccumulate in food chains through consumption or uptake, and are a hazard to human health or wildlife. Terms related to PBT include persistent organic pollutant (POP) and unavoidable residual environmental contaminant (UREC). For the purposes of these standards, these terms are interchangeable.

Polyploid. Aquatic animals with more than two sets of homologous chromosomes. Most aquatic animals are naturally diploid (2n). Triploid aquatic animals are typically sterile (non-reproductive) and tend to grow faster than diploid aquatic animals.

Reportable pathogens. Pathogens of aquatic animals whose diagnosis must be reported, by law, to pertinent state or federal authorities. Included are pathogens listed as Reportable by the Office Internationale Epitozooties.

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).

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

Shellfish. Aquatic invertebrate animals including molluscs and crustaceans.

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.

Sustainability. Meeting the needs of the present without compromising the ability of future generations to meet their own needs (1987 Brundtland Report). Sustainably managed resources are those where long-term productivity is maintained to meet human needs while simultaneously conserving biodiversity, environmental quality, and ecosystem services. Ecosystem services are functions provided by ecosystems such as nutrient cycling, flood control, and more. Their importance was highlighted in the 2005 Millennium Ecosystem Assessment report, which was the result of a major international effort involving a number of agencies.

Wild fish. Any species of fish or shellfish, raw or processed, harvested from wild sources used for human food or in animal feeds, including feeds for aquatic animals.

§205.201 Organic production and handling plan

(a) The producer or handler of a …. An organic production and handling system plan must include:

(b) A producer may substitute …. Requirements of this subpart.

(c) 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.

§ 205.237 Livestock feed.

(d) **…**

(e) The producer of an organic operation must not:

(7) Feed fish meal or fish oil from forage fish except as provided in § 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

§ 205.250 Aquaculture general.

(1) Aquatic animals, aquatic animal products, aquatic plants, and aquatic plant products to be sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," must be produced and handled in accordance with this section: Except that the requirements of Sections § 205.236 through § 205.239 shall not apply to the production of aquatic animals or aquatic animal products and the requirements of Sections § 205.202 through § 205.206 shall not apply to the production of aquatic plant or aquatic plant products.

(2) Metabolic products of aquaculture species are not considered animal manure under § 205.2 Terms Defined, Manure, and § 205.239 (c) Livestock Living Conditions.

(3) Metabolic products of one species are recognized as organic resources for one or more other species in an aquaculture production system. The Organic System Plan of facilities producing aquatic animals must consider measures to recycle or biologically process metabolic products. Where feasible, the Organic System Plan must include the polyculture of two or more different species grown in the same body of water, and the integration of additional species as water moves through the aquaculture facility or into adjoining discharge areas.

(4) The feasibility of using water discharges and filtered metabolic products as nutrients for vascular plants in agricultural crops and constructed wetlands must be considered in Organic System Plans. The quantities of such discharges and filtered products applied shall not exceed the requirements of targeted plants in the receiving area, and shall not be discharged into areas not included in the Organic System Plan. Vascular agriculture crops using nutrients from certified organic aquaculture operations may be certified organic if in compliance with other regulations in this Subpart.

(5) Organic System Plans for aquaculture facilities must include explanations of how the producer will provided for the health and welfare of aquatic animals, preclude the use of prohibited substances, and prevent contamination of aquaculture products from environmental sources.

(6) Biodiversity of natural aquatic ecosystems, functional integrity of aquatic environments, and the quality of adjoining aquatic and terrestrial ecosystems must be protected. All aquatic animals possessed and grown at an aquaculture facility must be in compliance with all applicable laws.

(7) Measures shall be taken to prevent escapes of cultivated animals and plants from the aquaculture facility and to document any that do occur. These measures shall be documented in the Organic System Plan.

(8) By-products from the production of aquatic animals, such as fish meal, fish oil, silage and hydrolyzed offal, produced in an organic aquaculture production system, and handled

in accordance with organic handling requirements, may be labeled organic.

(9) Aquaculture facilities shall be designed, operated and managed in a manner that seeks to maximize the welfare of cultured aquatic animals, minimizes the stress on those animals, and seeks to prevent the spread of disease within the facility and to all adjoining ecosystems and native fish species.

(10) The Organic System Plan for aquaculture systems should include where applicable:

(i) A map of the production 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 map should include:

a. The location of all known point and non-point sources of prohibited substances and other potential contaminants.

b. Locations of water sampling stations.

(ii) A description of the materials used for all structures.

(iii) Documentation of environmental conditions in the growing area, including water quality and land use in contiguous watersheds.

(iv) For open water systems and those discharging into the environment, a description of a water quality monitoring program that indicates parameters measured, frequency of measurement, and location of sampling stations.

(v) A description of measures that will minimize impacts of culture operations on aquatic ecosystems and wildlife, including:

a. 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 .

(vi) List of animal and plant 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.

(vii) A description of biosecurity practices that are designed to prevent to the occurrence and spread of diseases or parasites.

(viii) A Waste Management Plan that provides for:

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

b. Composting or recycling of waste biological materials to the extent practicable.

c. Control of offensive odors.

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

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

§ 205.251 Origin of aquatic animals.

(a) Aquatic animals grown in aquaculture to be sold as organic must have been under continuous organic management beginning no later than the second day after final larval metamorphosis and the beginning of exogenous feeding, where applicable by species, or beginning no later than when 5% of total market weight has been achieved, whichever is greater.

(b) Aquatic animals that are removed from an organic production system and subsequently managed on a non-organic facility may not be sold, labeled, or represented as organically produced.

(c) Broodstock that has not been under continuous organic management may not be sold, labeled, or represented as organic slaughter stock.

(d) The producer of an organic aquaculture facility must maintain records sufficient to preserve the identity of all organically managed animals (by lot) and edible and nonedible animal products to assure reliable traceability from farm to market.

(e) Production of triploid aquatic animals by any method including but not limited to the application of temperature or pressure shock after fertilization and by crossing tetraploids with diploids is prohibited for aquatic animals intended to be sold as organic.

(f) Culture of monosex stocks of aquatic animals obtained by direct treatment with steroidal or other hormones (including methyl-testosterone) or by other direct-treatment artificial induction methods, including use of excluded methods, is prohibited.

(g) Cultivation of any genetically modified aquatic animal or an organism produced by any other excluded method provided in § 205.2 Terms defined, is prohibited.

(h) In cases where hatchery progeny of aquatic animals are not commercially available, broodstock may be collected from the wild provided that they are collected in a sustainable manner, as documented in the Organic System Plan, and where appropriate, in compliance with all federal and state regulations, and in collaboration with government agencies, to assure that natural populations and the collected individuals are protected and that biodiversity in the ecosystem is supported.

§ 205.252 Aquatic Animal feed.

(a) Feeds and feeding practices must meet the minimum nutritional requirements of the aquatic animal.

(b) Use of aquatic animal feeds must minimize the environmental impact of released nutrients on receiving waters and adjoining ecosystems as documented in the Organic System Plan.

(c) Aquatic animals must be provided with their natural nutrients consistent with the need to optimize health and growth of the aquatic animal. This includes live foods and the sources of ingredients in formulated feeds as allowed in the rule.

(d) Feeds for aquaculture products for human consumption must contain lipids from fish oil or other omega-3 sources produced by microorganisms or organic plants to meet the nutritional requirement of specific lipids for the particular aquatic species, except that other lipids from organic sources may be provided in feeds for aquatic animals that have

a specific dietary requirements for such ingredients to the extent necessary to meet the minimum requirement for that lipid in that aquatic animal.

(e) Aquaculture feeds must be composed of feed ingredients that are certified organic, except that nonsynthetic substances may be used as feed additives and supplements.

(f) Aquaculture feeds may include fish meal and fish oil derived from organically raised aquatic animals or algae according to an Organic System Plan, providing the meal and oil is produced from aquatic animals of a different family than the aquatic animal being fed.

(g) Silage and lipids produced from organic fish that is enzyme-processed, or produced with acids and bases that are organically certified or approved in § 205.611 for fish emulsion or other purposes, may be certified organic and incorporated into organic aquaculture feeds without limitation.

(h) Organic aquaculture feeds may include meals and oils containing essential fatty acids produced by processes allowed in organic production.

(i) Nutritional pigment compounds that are nonsynthetic, or are allowed under § 205.611, or are organically produced, and allowed by the U.S. Food and Drug Administration for inclusion in aquaculture feeds, may be used.

(j) The producer of organic aquatic animals shall not:

(1) incorporate or introduce any type of antibiotic or hormone in feeds, the water supply, or the environment;

(2) provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance of the species at its specific stage of life;

(3) feed mammalian or poultry slaughter products to aquatic animals;

(4) use feedstuffs extracted with synthetic solvents not approved on 205.611;

(5) use feed, feed additives, and feed supplements in violation of the U.S. Federal Food, Drug, and Cosmetic Act; or

(6) use any genetically modified organism, or any organism produced by any other excluded method provided in § 205.2 Terms defined, or product thereof, as a feed ingredient.

(k) Fish meal or fish oil may not be sourced from any fishery classified by relevant state/provincial, national, or international fisheries authorities as follows: “at risk of reduced reproductive capacity;” “suffering reduced reproductive capacity;” “harvested outside precautionary limits;” “over-exploited;” “depleted;” “overfished;” “overfishing is occurring;” or any other comparable classification, or at significant risk of those conditions within the next recruitment cycle.

(l) For fish meal and fish oil from wild fish used in organic feeds, levels of unavoidable residual environmental contaminants, including persistent bioaccumulative toxins (PBTs) and mercury, cadmium, lead, arsenic and tin must be less than or equal to the lowest levels found in commercially available fish meal and fish oil, provided, however, that the comparable products are classes of fish meal and fish oil allowed in this section, and do not include those produced with volatile organic solvents not allowed under § 205.611. Fish oil must be treated with activated carbon, which may include synthetic activated carbon, or any process using water as a solvent, for removal of contaminants.

(m) Supplementation of fish meal and fish oil from other non-organic aquatic feed products not specifically allowed in this section is prohibited.

§ 205.253 Aquatic animal health care.

(a) The aquaculture producer must establish and maintain preventive health care practices that optimize animal welfare and minimize animal stress and pain by implementing the following procedures and practices:

(1) provision of a source of nutrition inclusive of live and formulated feeds sufficient to meet minimum nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy and other necessary dietary or nutritional components in compliance, where appropriate with §205.611 and §205.612;

(2) maintenance of life-supporting water rearing conditions, including control of potentially toxic metabolic compounds (ammonia and carbon dioxide) within known physiological tolerance ranges for the species, and the maintenance of water temperature, oxygen concentration, and pH within known life-supporting values for the species and the prevention of extended excursions to stressful extremes. Efforts to maintain such conditions must be documented by a monitoring and record-keeping program for these and other species specific key water quality parameters that affect health. The frequency of such monitoring shall depend on the culture system, site, species, life stage, and environmental characteristics;

(3) establishment of biosecurity measures known to reduce risk of entry of pathogens into the aquaculture production system or between the aquaculture production system and wild aquatic animals. These may include such measures as allowing only entry of broodstock tested and found free of reportable pathogens, animal vector control, and limited human entry by use of fences or barriers and locked entry points. In recirculating systems sanitation procedures must include regular removal of accumulated particulate organic matter. Culture water used in the system must be from a source tested and determined free of reportable pathogens and free of known vectors of diseases or disinfected to remove such infectious disease agents. In open water systems, if animals are potentially exposed to known infectious agents, this risk may be mitigated if approved vaccines and vaccination procedures are available. Biosecurity measures should not be used to justify growing conditions that compromise aquatic animal health from elevated stress and associated immunosupression;

(4) administration of vaccines, other veterinary biologics, and approved natural supplements, such as supplementation or treatment of healthy animals with beneficial bacteria, appropriate to the species and location in compliance, where appropriate, with §205.611 and §205.612;

(5) keeping medication records indicating materials used, rates and methods of application , and applications dates. Records need to identify all lots of aquatic animals treated. Records of medical treatment are required for all treatments and are not limited to substances in compliance with §205.611; and

(6) implementation of practices that break the life-cycle of pathogens. These may include but are not limited to site fallowing and co-stocking cleaner fish to remove parasites.

(b) When preventive practices and veterinary biologics are inadequate to prevent disease, a producer may administer synthetic medications, provided that such medications are allowed under § 205.611. Parasiticides allowed under § 205.611 may be used on aquatic broodstock, but none that are to be sold, labeled, or represented as organically produced.

(c) The producer of organic aquaculture products must not:

(1) sell, label, or represent as organic any aquatic animal or edible product derived from any aquatic animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.611, or any substance that contains a nonsynthetic substance prohibited in § 205.612;

(2) administer any type of animal medication or therapy, other than vaccination, in the absence of illness;

(3) administer hormones for growth promotion, prevention of reproductive maturation, and sex reversal;

(4) administer synthetic parasiticides except as consistent with (b)(1);

(5) administer animal drugs in violation of the U.S. Food and Drug Administration regulations, and vaccines in violation of U.S. Department of Agriculture regulations;

(6) withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Lots of aquatic animals treated with a prohibited substance must be clearly identified by lot number and shall not be sold, labeled, or represented as organically produced. Except for earthen ponds not lined with impervious barriers, facilities containing aquatic animals during medical treatment are not required to undergo conversion periods specified in paragraphs (l) and (m)of § 205.255 Aquaculture facilities, and

(7) sell as organic any clinically diseased fish as diagnosed by a veterinary or other fish health specialist.

(d) The producer of organic aquaculture products must:

(1) record and retain records of any unexplained or unexpected mortality events or other evidence of disease or parasitism;

(2) refer unexplained or unexpected morbidity or mortality events to a veterinary or other fish health professional.

§ 205.254 Aquaculture living conditions.

(a) Aquaculture systems must establish and maintain living conditions as documented in the Organic System Plan that accommodates the health and natural behavior of the aquatic animals, including:

(1) an environment operated within the tolerance limits characteristic of the aquatic animal and stage of development by monitoring and maintaining water quality appropriate for the production system and species, including temperature, pH, salinity, photoperiod, dissolved oxygen, ammonia, and nitrite concentrations, without sudden changes or prolonged exposure to extremes; and

(2) containment that allows the animals:

(i) to exercise swimming behavior within the culture unit;

(ii) minimal potential for injury, and

(iii) population or biomass densities that are appropriate for the particular aquatic animal and culture conditions, and that promote natural behaviors and limits aggressive and dominant behaviors from other aquatic animals.

(b) A comprehensive Integrated Predator Management Plan, that employs non-lethal deterrents as a first course of action, shall be developed and implemented as part of the Organic System Plan. Any encounter with predators must be noted and reported to the accredited certifying agent and inspector.

(1) The culture system must be managed to minimize the risk of losses of cultured stock, stress to cultured aquatic animals caused by predators, and harm to predators.

(2) The Integrated Predator Deterrence Plan as described in the Organic System Plan must identify potential predators, appropriate deterrence methods, how predator behavior will be modified by application of deterrence methods, documentation of control methods and effects, contingencies for failure to achieve objectives, and how plan implementation conserves biodiversity in the ecosystem adjacent to and including the aquaculture facility. Examples of such control measures include but not limited to site selection, physical barriers, repellents, and legal predator deterrence methods.

(3) Lethal measures may be taken only when individual predators are a direct and immediate threat to human safety or are necessary to relieve pain and suffering of predators with serious injury or disease. Any killing of predators must by documented and include an explanation of why lethal measures were appropriate. Lethal measures must be in compliance with local laws and the laws of the United States.

(4) Underwater acoustic harassment devices of any kind shall not be permitted.

(c) Non-organic aquatic animals may be used in aquaculture production systems for controlling pests, such as weeds, snails, algae, and parasites. Triploid animals may be employed provided that the animals are legal to culture, not labeled organic, and readily separated at harvest from the aquatic animals under organic management.

§ 205.255 Aquaculture facilities.

(a) Aquaculture facilities shall be designed, operated and managed in a manner that seeks to maximize the welfare and minimize the stress experienced by cultured aquatic animals, and seeks to prevent the spread of pathogens within the facility and to all adjoining ecosystems and native aquatic animals.

(b) Construction and operation of organic aquaculture facilities shall not compromise the structure and function of adjoining aquatic and terrestrial ecosystems as described in the Organic System Plan.

(c) Water sources for aquaculture facilities must be selected carefully and managed to avoid environmental contaminants that can harm human health.

(d) Facility boundaries shall be identified clearly.

(e) Organic aquaculture facilities shall provide buffers from potential contamination sources including pesticide drift and other possible contaminants from conventional aquaculture as documented in the Organic System Plan.

(f) Pond berms and tank tops shall be designed and constructed to prevent contamination from the environment during a 100-year flood event.

(g) Potentially adverse environmental impacts from aquaculture production must be minimized. The effluent discharge must not exceed the natural assimilative capacity of an area within 25 meters of the site boundary. For the purpose of this paragraph, the "site" described in the Organic System Plan is an identified area of land or a water body owned or licensed or leased and managed as certified organic by the facility operator.

(1) The aquaculture facility must develop and implement a suitable Waste Management Plan that must:

i. Include and meet performance targets for maximizing the utilization and recycling of nutrients as referenced by nutrient inputs (*i.e.,* in feed) including the nutrients contributing to the growth of the aquatic animal. Such targets must be appropriate for the species being grown and the growing system employed.

ii. Include and establish performance targets for minimizing the discharge of any feed nutrient (particularly nitrogen and phosphorous) that is limiting primary productivity in adjoining aquatic ecosystems, except this provision does not apply to bivalve molluscs grown in compliance with § 205.257 Bivalve molluscs.

iii. Be reviewed at least annually to delineate improvements in nutrient recycling when possible. In the event that improvement is not technically feasible, the producer shall prepare a detailed explanation for the accredited certifying agent.

(2) Appropriate methods for accomplishing (1) i. and (1) ii. include use of aquaculture discharge waters for irrigation of terrestrial crops, integrated aquaculture with molluscs and aquatic plants, filter feeding or scavenger fish, or in combination; constructed wetlands; and assimilation of nutrients by organisms retained in the facility. Recycling methods may include use of aquaculture discharge waters or recovered solids for fertilizing terrestrial crops; integrated aquaculture with molluscs and aquatic plants; constructed wetlands; and assimilation of nutrients by organisms retained in the system. Algae, vascular plants, molluscs, filter feeding aquatic animals or scavenger aquatic animals, or a combination, can be grown in or adjacent to the facility. Other biological means for recycling nutrients also may be employed.

(3) The aquaculture facility must implement a waste management plan for discharges into public water that includes:

i. documentation of peak nutrient discharges during a crop cycle considering such factors as maximum biomass and feeding rates.

ii. a determination of which nutrient or nutrients are limiting primary productivity in adjoining aquatic ecosystems.

iii. a determination if, and under what circumstances, the limiting nutrient or nutrients in facility discharges would make a significant contribution to eutrophication in adjoining aquatic ecosystems.

iv. a provision that if a significant contribution to eutrophication is possible, the

Waste Management Plan shall include specific protocols to prevent discharge of the nutrient at levels that would elevate the risks of eutrophication. These may included reducing feeding rates and biomass levels, collection and recycling animal metabolites and waste feed, including other cultured organisms that utilize the nutrient in the facility, and relocation of the facility to another site.

(h) Every organic aquaculture facility must develop a Nutrient Management Plan that evaluates the technical and economic feasibility of options appropriate for the culture system to recover solid and dissolved waste nutrients in other plant and animal crops. Options may include using settled solids as a soil amendment, suspended solids to grow filter-feeding aquatic animals, and dissolved nutrients as a nutrient source for terrestrial crops or aquatic plants.

(i) Construction and operation of aquaculture facilities shall not impair water quality to require a change in the designated use of receiving waters and must not salinate or otherwise contaminate soils.

(1) Structures used in aquaculture production must not contain or be treated with prohibited materials, except as provided § 205.611 or § 205.612.

(j) Aquaculture facilities must be managed with all reasonable security measures (mechanical, physical, and biological barriers) with the goal of eliminating escapes caused by predators, adverse weather conditions (including floods), facility malfunction, facility damage, or other causes. Facilities must be operated with preventative measures against possible escapes into the natural environment of the aquatic animals in production. The Organic System Plan must describe measures to prevent escape, procedures to detect and document escapes should they occur, and actions to be undertaken in the event of escape.

(k) Net-pens and enclosures in public water are permitted in situations where water depth, current velocities and direction, stocking densities, and other factors act to adequately disperse metabolic products in order to minimize any negative impacts on the environment in areas surrounding the pen location(s). Monitoring shall be employed to ensure that the natural assimilative capacity at the site is not overburdened and that performance standards and targets are met. An organic conversion period of at least one year, or one production cycle, whichever is less, shall be required.

(1) The net pens must be situated in such manner that avoid migratory routes of native species and do not disturb reproductive patterns of local wild fish populations and that of other local species like predators and birds or other flora or fauna.

(2) The aquatic animals cultivated in net pens in public water must be strains of native species or naturally reproducing species that have been established in the local environment for at least twenty (20) years. The Organic System Plan must include containment management.

(3) Net pen producers shall implement all practicable measures stated in § 205.253. Producers must implement measures to seek to prevent transmission of diseases and parasites between cultured and wild aquatic animals and must:

i. Site net pens in such a manner as to seek to prevent contamination and disease from conventional fish pens or native fish populations taking into account factors like current and seasonal changes.

ii. Consider buffer zones for other potential sources of contamination by any substances not allowed in organic production.

iii. Keep medication records indicating materials used, rates and methods of application, and application dates.

(4) Producers employing net pens shall implement all practicable measures stated in § 205.254

(5) Facility managers shall implement all practicable measures that seek to prevent escapes and must have in place a protocol for monitoring and reporting on escapes.

(6) Net pen anti-fouling practices.

i. Except as provided in ii. below, control of fouling on nets must be by physical or biological means.

ii. Except as may be provided in § 205.609 through § 205.612, chemical treatment of bio-fouling organisms on nets is not allowed.

iii. Copper based anti-fouling materials are prohibited.

(7) Use of multiple species of aquatic plants and/or animals for recycling nutrients is required along with pen rotation to allow for site regeneration.

i. Species of aquatic plants and animals placed outside of and adjacent to net pens for the purpose of recycling nutrients are encouraged to be native species or local genotypes when available.

(8) Farm level effluents and the potential influence of other aquatic farms must be shown not to exceed the natural assimilative capacity of the surrounding ecosystem.

(9) In all cases, benthic habitats surrounding net pens in public must be shown to not have significant measurable changes in chemistry and biodiversity.

(10) The Organic System Plan for an aquaculture operation using net pens in public water must include the following:

a. Justification for the location of the net pens including a detailed description of how the location minimizes impact to surrounding environment, limits waste accumulation, and seeks to prevent impact to the migratory and reproductive patterns of local wild fish populations, other local species like predators and birds, and any other flora or fauna.

b. Nutrient Management Plan which describes waste management approaches, monitoring system for all nutrient inputs, outputs, and waste, and location of any and all farms or net pen operations in the vicinity that could impact, positively or negatively, the nutrient management process of the net pen operation seeking certification.

c. A Containment Plan to assure that fish do not escape into public waters.

d. A description of anti-fouling practices.

(l) Production systems with direct soil-water contact are allowed, provided that a conversion period of 36 months occurs between the date of the last application of prohibited

substances and the harvest of aquatic animals under organic management and intended to be certified organic.

(m) Production systems with containment units of plastic, fiberglass, metal, concrete or other cleanable surfaces able to hold water are allowed, provided that the unit is filled with water to its capacity and then drained and cleaned before production can be certified organic.

(n) Recirculating systems are permitted if the system supports the health, growth, and well-being of the species, including:

(1) stocking or biomass density appropriate for the particular species being produced to ensure animal health and overall well-being, including the natural behavioral characteristics of the species; and

(2) the provision of emergency life support systems to provide appropriate maintenance of water quality, especially dissolved oxygen levels, in the event that primary life support systems fail.

§ 205.256 Aquaculture additional [Reserved].

§ 205.257 Bivalve Molluscs

(a) Bivalve molluscs general:

(1) Except as otherwise provided, all provisions of § 205.250 through § 205.259, Aquaculture, and § 205.609 through § 205.612 , 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 af-

fidavits 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, 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," "approved," or "conditionally approved" subject to specific provisions of these standards. Bivalves grown at locations that are not classified, or classified as "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/abpout/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 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 205.612, except as provided in 205.611.

(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.

(11) 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.

§ 205.258 Farmed aquatic plants.

Aquatic plants that are intended to be sold, labeled, or represented as organic must be managed according to all applicable rules stated § 205.200 and § 205.201 of the National Rule *Except*,

(a) Aquatic plants may be grown in closed containment organic systems provided that:

(1) any pond with soil from which aquatic plants are intended to be represented as organic must have had no prohibited substances, as listed in §205.201, applied for 36 months immediately preceding harvest of the crop, and containment vessels must have organic approved clean-out procedures prior to use to prevent contact or contamination with prohibited materials;

(2) aquatic plants may be provided dissolved macro-nutrients and micro-nutrients, including trace minerals, chelating compounds, and vitamins listed in §205.609; however, the dissolved amounts shall not exceed those necessary for health growth of the plants, and such culture media shall be disposed of in a manner that does not adversely impact the environment; and

(3) the pond or containment vessel has berm elevations with distinct defined bounda-

ries and buffer zones with runoff diversions to prevent the unintended application of a prohibited substance into the pond or containment vessel, or allowed contact with a prohibited substance applied to adjoining land that is not under organic management.

(4) pond drainage must be done in a manner that prevents any and all sediment materials and nutrients from being discharged into waterways, such that:

(i) the pond discharge water meets quality standards based on the Total Maximum Daily Load (TMDL) for the receiving waterway as provided on the current state code pond permit process

(ii) in cases where TMDL metrics are unavailable, discharge water must meet a minimum standard of secondary treatment, which is defined as less than 30 mg/l BOD total suspended solids where an 85% removal of BOD is attained [EPA Guidelines Ref. QAC 252:606-1-5…(i)A]

(5) Manure from terrestrial animals may be used to fertilize aquatic plants intended to feed organic fish, in aquaculture ponds for organic production systems, provided:

(i) the manure is composted in compliance with § 205.203,

(b) Aquatic plants may be grown in public water organic systems provided that:

(1) That, manure from terrestrial animals, in any form, may not be used to fertilize aquatic plants in public water.

(c) The producer must use organically grown starter culture and planting stock, except nonorganically produced starter culture and planting stock may be used to produce an organic crop when an equivalent organically produced culture or stock is not commercially available.

(d) Aquatic plants must be under continuous organic management beginning no later than when 5% of total harvest weight has been achieved. However, when initially grown with synthetic substances not allowed in § 205, the plants must we washed to remove inorganic growth media prior to being placed under organic management. If separating media from the plants is not possible, then the producer must take steps to minimize transfer of media with the plant when inoculating the organic production culture.

§ 205.259 Harvest, transport, post harvest handling, and slaughter of aquatic animals.

(a) Handling of stock during harvesting, transport, and slaughtering operations must be carried out with minimal disturbance and stress to the aquatic animal.

(b) Adverse environmental impacts associated with harvest operations must be minimized.

(c) Aquatic animals transported to slaughter and processing facilities, or to live haul markets, shall be transported under conditions appropriate to the species and in such manner to minimize the adverse effects of:

(1) water quality;

(2) time spent in transport;

(3) animal density;

(4) metabolic substances; and

(5) escape.

(d) Fish should be held in high quality water for the duration of food deprivation prior to transport and slaughter for a period not to exceed the time necessary to allow clearance of stomach and intestine contents.

(e) Just prior to slaughter and before or immediately after they are removed from water, finfish must be stunned by a method that renders them instantly insentient and maintains insentience until death.

(1) Permitted procedures include:

(i) concussion to the head promptly followed by prompt severing of the gill arches or decapitation;

(ii) electrical stunning sufficient to achieve insentience immediately followed by severing of the gill arches or decapitation;

(iii) electrocution with electric current sufficient to achieve insentience; or

(iv) ice slurry for warmwater marine finfish; provided that this method will be only permitted for five years after the date when organic standards for farmed aquatic animals are promulgated as an amendment to the Final Rule.

(2) Prohibited slaughtering methods for finfish include those that use:

(i) ice or ice slurry except as provided in (iv) above;

(ii) carbon dioxide;

(iii) synthetic anesthetics, including MS-222;

(iv) natural plant anesthetics not approved by the U.S. Food and Drug Administration for this purpose, including clove oil;

(v) suffocation or asphyxiation (leaving fish to die in air); or

(vi) exsanguination (bleeding) without stunning.

(f) Slaughter using ice or ice slurry is allowed for crustaceans, molluscs, and other aquatic animals that are non-sentient.

(g) The disposal of harvest water, blood water, viscera and disinfectant should pose no threat to wild or farmed fish or the environment and comply with existing laws.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as "100 percent organic."* A raw or processed agricultural product, including aquaculture products sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to §205.303.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product, including aquaculture products sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form,

or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303.

(1) Aquatic animals (and their products) that have been fed environmentally responsible wild caught fish meal or oil as a feed supplement pursuant to 205.612, and that are used as ingredients, must indicate ("Fed environmentally responsible wild caught fish") next to the name of the fish.

(2) Livestock (and their products) that have been fed environmentally responsible wild caught fish meal or oil as a feed supplement pursuant to 205.612, and that are used as ingredients, must indicate ("Fed environmentally responsible wild caught fish") next to the name of the Livestock or livestock product.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(b) Agricultural products in packages described in §205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(i) For aquatic animals fed wild caught fish meal or oil as a feed supplement pursuant to 205.612 must indicate ("Fed environmentally responsible wild caught fish") on the label directly beneath or next to the name of the fish.

(ii) For livestock fed wild caught fish meal or oil as a feed supplement pursuant to 205.612 must indicate ("Fed environmentally responsible wild caught fish") on the label directly beneath or next to the name of the livestock or livestock product.

§ 205.306 Labeling of livestock feed.

(a) Livestock and aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) may display on any package panel the following terms:

(1) The statement, "100 percent organic" or "organic," as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, Provided, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(c) Livestock and aquatic animal feed products described in § 205.301(e)(1), (e)(2) and (e)(3) must:

(i) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by...," or

similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(ii) Comply with other Federal agency or State feed labeling requirements as applicable.

(e) Livestock feed.

(1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with §205.237.

(3) A raw or processed aquatic animal feed product sold, labeled, or represented as "organic" must be produced in conformance with §205.252.

§ 205.308 Agricultural in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Agricultural in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided,* That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.

(1) If fish is labeled as "organic" and fed wild caught fish meal or oil as a feed supplement pursuant to 205.612, the label, display and display containers must indicate ("Fed environmentally responsible wild caught fish") directly beneath or next to the name of the fish.

(2) If livestock of livestock products are labeled as "organic" and fed wild caught fish meal or oil as a feed supplement pursuant to 205.612, the label, display and display containers must indicate ("Fed environmentally responsible wild caught fish") directly beneath or next to the name of the livestock or livestock product.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.609 Synthetic substances allowed for use in organic aquatic plant production. [Reserved]

§ 205.610 Nonsynthetic substances prohibited for use in organic aquatic plant production. [Reserved]

§ 205.611 – Synthetic substances allowed for use in organic aquatic animal production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic aquatic animal production**:**

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(c) As feed supplements—None.

(d) As feed additives.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

§ 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

The following nonsynthetic substances may not be used in organic aquatic animal production:

(a) Fish meal and fish oil from wild caught fish and other wild aquatic animals, *Except* if produced from environmentally responsible food grade wild caught fisheries and fed in the following step-wise levels: a maximum combined total of 25% during year 1 through 5 after this regulation is implemented, a maximum combined total of 15% during year 6 through 8, and a maximum combined total of 10% during year 9 through year 10, and a maximum combined total of 5% during year 11 and 12, with the percentages by weight of feed being averages over the production cycle of the aquatic animal.

(1) fish meal and fish oil may not be stabilized with synthetic stabilizers unless allowed on §205.611

(b) Feed from forage fisheries.

(c) –(z) [Reserved]