

**Proposal Subject** Oyster/Shellfish Gardening

**Specific NSSP Guide Reference** NSSP Guide Model Ordinance, Chapter VI. Shellfish Aquaculture

**Text of Proposal/ Requested Action** Modify Chapter VI of the Model Ordinance as per attached text.

**Public Health Significance** Due to declining wild stocks of oysters in the Mid-Atlantic and South Atlantic States over the past several decades, alternative methods of growing oysters have been explored to replenish natural beds and to meet market demand for fresh oysters. One such method has been oyster/shellfish gardening where private individuals obtain seed oysters (often through programs managed by government agencies or non-profit organizations) and raise them in trays on private property or private leases until they are market size. Once they reach market size, they are either placed on oyster reefs to help restore natural beds, or in some states, they are used for consumption. The concept of oyster/shellfish gardening is growing rapidly in the Mid-Atlantic and South Atlantic States due to its ability to allow private individuals to participate in the restoration of oyster beds.

Public health concerns with oyster/shellfish gardening are due to the facts that, 1) locations chosen for oyster/shellfish gardening are often waters classified as Prohibited or Restricted; 2) persons involved are often not familiar with shellfish sanitation and; 3) persons involved are often elderly and may be more susceptible to illness from consumption of tainted shellfish. With oysters readily available from non-Approved waters and with a lack of knowledge of shellfish sanitation, we feel that the growth in popularity of oyster/shellfish gardening comes with an increasing risk of illness by an ill-informed consumer. In addition to the public health concerns, such an occurrence of illness could have economic impacts to the shellfish industry in general.

The requested action makes a distinction in the Model Ordinance between commercial aquaculture where product is being marketed and oyster/shellfish gardening where it is not being marketed. It would allow the NSSP to more adequately address these public health concerns through increased education of oyster/shellfish gardeners and improved accountability for product being grown in non-Approved waters. It does this through requiring that the Authority permit or register oyster/shellfish gardening activities.

**Cost Information (if available)** Negligible

*PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC*

- Model Ordinance
- B. Definition of Terms
  - ( ) Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

*PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC*

- Model Ordinance
- VI. Shellfish Aquaculture
- Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

- A. The Authority shall recognize two types of aquaculture:
  - (1) Commercial – product cultivated for direct marketing.

**(2) Oyster/shellfish gardening – product cultivated to enhance water quality or for owners own consumption and not for direct marketing.**

**B.** The Authority shall maintain the following records while the aquaculture activity continues:

- (1) Construction and remodeling plans for any permitted aquaculture facility;
- (2) **Aquaculture** operational plans; and
- (3) Aquaculture permits.

**C.** The Authority shall inspect **commercial** aquaculture systems at least every six months.

**@.02 Seed Shellstock.**

**A.** The Authority shall establish the submarket size for each species of shellfish in accordance with §.01B. and §.01C.

**B.** All sources of seed shall be sanctioned by the Authority.

**@.03 Commercial Open Water and Land Based Aquaculture**

**A.** Inspection. The Authority shall inspect land-based **and float aquaculture** sites at least every six months.

**B.** The Authority shall approve the written operational plan for any land based **or float** aquaculture facility prior to its implementation.

**C. The Authority may not permit commercial aquaculture activities in areas that do not meet restricted, conditionally restricted, conditionally approved, or approved classification.D. Commercial float aquaculture sites, where the floats are attached to or near piers shall be inspected at least every year. This site evaluation by the Authority shall include:**

- (1) The survey of the commercial float aquaculture site, with special consideration of potential intermittent sources of pollution;**
- (2) The location of float; and**
- (3) The examination of the construction of shellstock containers to ensure the free flow of water to all shellstock.**

**@.04 Oyster/shellfish Gardening**

**A.** The Authority shall permit or register oyster/shellfish gardening activities.

**B.** The Authority shall establish permit or registration conditions and determine classification of waters where oyster/shellfish gardening can take place prior to its implementation.

**C.** The Authority shall provide information to the oyster/shellfish gardener on the risk of consuming shellfish from private docks, piers, and oyster floats attached to piers or docks.

**D.** The Authority shall require that the oyster/shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

- A. Hatcheries;
- B. Nursery products which do not exceed 10 percent of the market weight; and
- C. Nursery products which are 6 months or more growing time from market size.

.02 General.

**A. Commercial aquaculture** encompasses both monoculture and polyculture.

**B.** Any person who performs **commercial** aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

- (1) A permit from the Authority for the activity or for construction and functioning of his facility;
- (2) A harvester's license; and
- (3) Certification as a dealer, where necessary.

- C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.
- D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and **submit the following to the Authority for review and approval in accordance with @.01:**
  - 1. **Prior to beginning any activity, a detailed construction and operational plan describing the new facility location and activity.**
  - 2. **For an existing permitted facility, a detailed construction plan describing the proposed remodeling, modifications, or otherwise permanent alteration of the facility prior to any work commencing.**
  - 3. **An updated operational plan on an annual basis or whenever operational procedures change requiring the plan to be updated.**
- E. Water quality at any site used for **commercial** aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.
- F. Shellfish cultured in any **commercial aquaculture** system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.
- G. Any shellfish raised in **commercial** aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
  - (1) The closed status of the conditionally approved classification;
  - (2) The restricted classification; or
  - (3) The open status of the conditionally restricted classification.
- H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
- I. Harvesting, processing, storage, and shipping requirements for shellfish raised in **commercial** aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.
- J. Complete and accurate records shall be maintained for at least two (2) years by the **commercial** aquaculturist and shall include the:
  - (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
  - (2) Dates of transplanting and harvest; and
  - (3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

- A. Seed may come from any growing area, or from any growing area in any classification, provided that:
  - (1) The source of the seed is sanctioned by the Authority.
  - (2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
  - (3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 **Commercial** Open Water Aquaculture.

- A. Any open water **commercial** aquaculture activity shall be in compliance when it meets the requirements of §. 01, §.02, and §.03, as appropriate.

.05 **Commercial** Land Based Aquaculture.

- A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
  - (1) A description of the design and activities of the culture facility;
  - (2) The specific site and boundaries in which shellfish culture activities will be conducted;

- (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
- (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
- (7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
- (8) A description of the water source, including the details of any water treatment process or method, if necessary;
- (9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
- (10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
- (11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
- (12) Maintenance of the required records; and
- (13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

- (1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
- (2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:
  - (a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);
  - (b) Come from a source meeting the restricted classification criteria at a minimum;
  - (c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and
  - (d) Be measured at least five times per year.
- (3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:
  - (a) Collection of three water samples from the tank at least three days apart over a 14 day period; and
  - (b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

- (1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.
- (2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.
- (3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or depurated prior to direct marketing.

.06 Commercial Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in §. 05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
- C. Include in its operational plan requirements to:
  - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious

- (2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the Oyster/shellfish Gardener

- A. Oyster/shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. Oyster/shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.

Oyster/shellfish gardeners shall keep accurate records on the fate or final destination of all oysters grown at their oyster garden site and provide these records to the Authority upon request

**Action by 2005 Task Force II** Proposal 05-221 was referred to Task Force I.

**Action by 2005 Task Force I** Recommended referral of Proposal 05-221 to an appropriate committee as determined by the Conference Chairman. Task Force I recommended consideration by the Growing Area Classification Committee, the Restoration Committee, and the Patrol Committee.

**Action by 2005 General Assembly** Adopted recommendation of 2005 Task Force I.

**Action by USFDA** Concurred with Conference action.

**Action by 2007 Growing Area, Shellfish Restoration, and Patrol Committees** Recommended adoption of Proposal 05-221 as substituted.

*PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC*

Model Ordinance

B. Definition of Terms

( ) Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

“Shellfish Gardening (Non-commercial shellfish culture), to be generally distinguished from traditional shellfish culture, and be characterized by, though not limited, in definition, by the use of off-bottom culture / infrastructure, including; but not limited to suspension floats, and/or bags, and/or the use of docks, piers, and/or other rigid structures, to facilitate said culture – generally, though not limited to the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption.”

*PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC*

Model Ordinance

VI. Shellfish Aquaculture

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

- A. **The Authority shall recognize may distinguish between two types of aquaculture:**
  - (1) **Commercial – product cultivated for direct marketing.**
  - (2) **Oyster/Shellfish gardening – product cultivated to enhance water**

~~quality, or for or to improve shellfish resources, owners own consumption and not for sale for consumption direct marketing.~~

- B. The Authority shall maintain the following records while the aquaculture activity continues:
  - (1) Construction and remodeling plans for any permitted aquaculture facility;
  - (2) **Aquaculture** operational plans; and
  - (3) Aquaculture permits.
- C. The Authority shall inspect ~~commercial~~ aquaculture systems at least every six months.

@.02 Seed Shellstock.

- A. The Authority shall establish the submarket size for each species of shellfish in accordance with §.01B and §.01C.
- B. All sources of seed shall be sanctioned by the Authority.

@.03 ~~Commercial~~ Open Water and Land Based Aquaculture

- A. Inspection. The Authority shall inspect land-based **and float aquaculture** sites at least every six months.
- B. The Authority shall approve the written operational plan for any land based **or float** aquaculture facility prior to its implementation. ~~aquaculture activities in areas that do not meet restricted, conditionally restricted, conditionally approved, or approved classification. commercialC. The Authority may not permit float aquaculture site, with special consideration of potential intermittent sources of pollution;~~
  - (2) **The location of float; and**
  - (3) **The examination of the construction of shellstock containers to ensure the free flow of water to all shellstock commercial float aquaculture sites, where the floats are attached to or near piers shall be inspected at least every year. This site evaluation by the Authority shall include:**
    - (1) **The survey of the Commercial D.**

@.04 ~~Oyster/s~~Shellfish Gardening

- A. The Authority shall permit or register ~~oyster/s~~shellfish gardening activities.
- B. The Authority shall establish permit or registration conditions and determine classification of waters where ~~oyster/s~~shellfish gardening can take place prior to its implementation.
- C. The Authority shall provide information to the ~~oyster/s~~shellfish gardener on the risk of consuming shellfish from private docks, piers, and ~~oystershellfish~~ floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.
- D. The Authority shall require that the ~~oyster/s~~shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.
- E. The authority may not permit new shellfish gardening activities in areas that do not meet restricted, conditionally restricted, conditionally

approved or approved classification.

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

- A. Hatcheries;
- B. Nursery products which do not exceed 10 percent of the market weight; and
- C. Nursery products which are 6 months or more growing time from market size.

.02 General.

A. ~~Commercial aquaculture~~ encompasses both monoculture and polyculture.  
 B. Any person who performs ~~commercial~~ aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

- (1) A permit from the Authority for the activity or for construction and functioning of his facility;
- (2) A harvester's license; and
- (3) Certification as a dealer, where necessary.

C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and ~~submit the following to the Authority for review and approval in accordance with @.01:~~

~~1. Prior to beginning any activity, a detailed construction and operational plan describing the new facility location and activity.~~

~~2. For an existing permitted facility, a detailed construction plan describing the proposed remodeling, modifications, or otherwise permanent alteration of the facility prior to any work commencing.~~

~~3. An updated operational plan on an annual basis or whenever operational procedures change requiring the plan to be updated.~~

E. Water quality at any site used for ~~commercial~~ aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any ~~commercial aquaculture~~ system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.

G. Any shellfish raised in ~~commercial~~ aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:

- (1) The closed status of the conditionally approved classification;
- (2) The restricted classification; or
- (3) The open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in

~~commercial~~ aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.

J. Complete and accurate records shall be maintained for at least two (2) years by the ~~commercial~~ aquaculturist and shall include the:

- (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
- (2) Dates of transplanting and harvest; and
- (3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

A. Seed may come from any growing area, or from any growing area in any classification, provided that:

- (1) The source of the seed is sanctioned by the Authority.
- (2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
- (3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 ~~Commercial~~ Open Water Aquaculture.

A. Any open water ~~commercial~~ aquaculture activity shall be in compliance when it meets the requirements of §. 01, §.02, and §.03, as appropriate.

.05 ~~Commercial~~ Land Based Aquaculture.

A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

- (1) A description of the design and activities of the culture facility;
- (2) The specific site and boundaries in which shellfish culture activities will be conducted;
- (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
- (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
- (7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
- (8) A description of the water source, including the details of any water treatment process or method, if necessary;
- (9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
- (10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
- (11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
- (12) Maintenance of the required records; and
- (13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

- (1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
- (2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:
  - (a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);
  - (b) Come from a source meeting the restricted classification criteria at a minimum;
  - (c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and
  - (d) Be measured at least five times per year.
- (3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:
  - (a) Collection of three water samples from the tank at least three days apart over a 14 day period; and
  - (b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

- (1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.
- (2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.
- (3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or deperated prior to direct marketing.

.06 ~~Commercial~~ Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in §. 05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
- C. Include in its operational plan requirements to:
  - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
  - (2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the ~~Oyster/s~~Shellfish Gardener

- A. ~~Oyster/s~~Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. ~~Oyster/s~~Shellfish gardeners shall document that they understand the risks

associated with consumption for shellfish grown from docks or private piers.

Oyster/sShellfish gardeners shall keep accurate records on the fate or final destination of all oysters/shellfish grown at their oysters/shellfish garden site and provide these records to the Authority upon request.

**Action by 2007 Task Force II**

Recommended adoption of Growing Area Classification Committee, Shellfish Restoration Committee, and Patrol Committee recommendations on Proposal 05-221, as amended.

*PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC*

Model Ordinance

B. Definition of Terms

Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

~~“Shellfish Gardening (Non-commercial shellfish culture), to be generally distinguished from traditional shellfish culture, and be characterized by, though not limited, in definition, by the use of off bottom culture / infrastructure, including; but not limited to suspension floats, and/or bags, and/or the use of docks, piers, and/or other rigid structures, to facilitate said culture — generally, though not limited to the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption.”~~

**Shellfish gardening is non-commercial shellfish culture for the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption.**

*PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC*

Model Ordinance Chapter VI. Shellfish Aquaculture

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

- A. The Authority may distinguish between two types of aquaculture:
  - (1) Commercial – product cultivated for direct marketing.
  - (2) Shellfish gardening – product cultivated to enhance water quality, or to improve shellfish resources, and not for sale for consumption.
- B. The Authority shall maintain the following records while the aquaculture activity continues:
  - (1) Construction and remodeling plans for any permitted aquaculture facility;
  - (2) Aquaculture operational plans; and
  - (3) Aquaculture permits.
- C. The Authority shall inspect **commercial** aquaculture systems at least every six months.

@.02 Seed Shellstock.

- A. The Authority shall establish the submarket size for each species of shellfish in

accordance with §.01B. and §.01C.

- B. All sources of seed shall be sanctioned by the Authority.

@.03 Open Water and Land Based Aquaculture

- A. Inspection. The Authority shall inspect land-based and float aquaculture sites at least every six months.
- B. The Authority shall approve the written operational plan for any land based or float aquaculture facility prior to its implementation.

@.04 Shellfish Gardening

**If a state recognizes shellfish gardening the Authority**

- A. ~~The Authority~~ shall permit or register shellfish gardening activities.
- B. ~~The Authority~~ shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.
- C. ~~The Authority~~ shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.
- D. ~~The Authority shall~~ **may** require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.
- E. ~~The authority may not permit new shellfish gardening activities in areas that do not meet restricted, conditionally restricted, conditionally approved or approved classification.~~

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

- A. Hatcheries;
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.02 General.

- A. Aquaculture encompasses both monoculture and polyculture.
- B. Any person who performs aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
  - (1) A permit from the Authority for the activity or for construction and functioning of his facility;
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- D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and
- E. Water quality at any site used for aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.
- F. Shellfish cultured in any **aquaculture** system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.
- G. Any shellfish raised in aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
  - (1) The closed status of the conditionally approved classification;
  - (2) The restricted classification; or
  - (3) The open status of the conditionally restricted classification.
- H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
- I. Harvesting, processing, storage, and shipping requirements for shellfish raised in aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.
- J. Complete and accurate records shall be maintained for at least two (2) years by the aquaculturist and shall include the:
  - (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
  - (2) Dates of transplanting and harvest; and
  - (3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

- A. Seed may come from any growing area, or from any growing area in any classification, provided that:
  - (1) The source of the seed is sanctioned by the Authority.
  - (2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
  - (3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 Open Water Aquaculture.

- A. Any open water aquaculture activity shall be in compliance when it meets the requirements of §. 01, §.02, and §.03, as appropriate.

.05 Land Based Aquaculture.

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  - (1) A description of the design and activities of the culture facility;
  - (2) The specific site and boundaries in which shellfish culture activities will be conducted;
  - (3) The types and locations of any structures, including rafts, pens, cages,

- nets, tanks, ponds, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
- (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
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- (9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
- (10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
- (11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
- (12) Maintenance of the required records; and
- (13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

- (1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
- (2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:
  - (a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);
  - (b) Come from a source meeting the restricted classification criteria at a minimum;
  - (c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and
  - (d) Be measured at least five times per year.
- (3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:
  - (a) Collection of three water samples from the tank at least three days apart over a 14 day period; and
  - (b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

- (1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.
- (2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.
- (3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or depurated prior to direct marketing.

.06 Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in §. 05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
- C. Include in its operational plan requirements to:
  - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
  - (2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the Shellfish Gardener

- A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.

**If required by the Authority,** §shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.

**Action by 2007  
General Assembly**

Adopted recommendation of 2007 Task Force II.

**Action by  
USFDA**

December 20, 2007  
Concurred with Conference action.