



## **NATIONAL SHELLFISH SANITATION PROGRAM**

# **GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH**

**2009 Revision**  
**(Printed June 2011)**



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**National Shellfish Sanitation Program**  
**Guide for the Control of Molluscan Shellfish**  
**2009**

This document is intended to provide guidance and shall supersede the 2007 NSSP Model Ordinance. It represents the Agency's current thinking on the safe and sanitary control of the growing, processing, and shipping of molluscan shellfish for human consumption. It does not create any rights for or on any persons and does not operate to bind FDA or the public under federal law. However, through their participation in the National Shellfish Sanitation Program and membership in the Interstate Shellfish Sanitation Conference, states have agreed to enforce the Model Ordinance as the requirements which are minimally necessary for the sanitary control of molluscan shellfish.



U.S. Department of Health and Human  
Services  
Public Health Service  
Food and Drug Administration



Interstate Shellfish Sanitation  
Conference

**2009 Revision**

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## **Section I. Purpose**

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, EPA, NOAA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, State growing area classification and dealer certification programs, and FDA evaluation of State program elements.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference recognizing the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provide guidance and counsel on matters for the sanitary control of shellfish. The purpose of the ISSC is to provide a formal structure for State regulatory authorities to participate in establishing updated regulatory guidelines and procedures for uniform state application of the Program. The ISSC has adopted formal procedures for state representatives to review shellfish sanitation issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revisions of the NSSP Model Ordinance.

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

**National Shellfish Sanitation Program  
2009 NSSP Guide for the Control of Molluscan Shellfish****Section I. Definitions**

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**Purpose.**

This Ordinance established the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.

**Definitions.**

- A. General. The definitions provided below are consistent in intent with the National Shellfish Sanitation Program.
- B. Definition of Terms.
  - (1) **Adverse pollution condition** means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular growing area. [In States using total coliform standard, insert "total coliform" for "fecal coliform".]
  - (2) **Air gap** means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of that receptacle.
  - (3) **AOAC** means the Association of Official Analytical Chemists.
  - (4) **APHA** means the American Public Health Association.
  - (5) **Approved** means a classification used to identify a growing area where harvest for direct marketing is allowed.
  - (6) **Aquaculture** means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in growing areas.
  - (7) **Authority** means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this Code.
  - (8) **Assure** means to make best efforts within the reasonable limits of manpower and resources to fulfill the objectives of this Ordinance.
  - (9) **Backflow** means the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.
  - (10) **Back siphonage** means the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.
  - (11) **Blower** means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.
  - (12) **Broker** means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.

- (13) **Certification or certify** means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:
- (a) Permission from the Authority to conduct the activity; and
  - (b) Compliance with the requirements of this Code.
- (14) **Certification number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter State abbreviation and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this Ordinance using the following terms:
- (a) Shellstock shipper (SS);
  - (b) Shucker-packer (SP);
  - (c) Repacker (RP);
  - (d) Reshipper (RS); and
  - (e) Depuration processor (DP).
- (15) **Coliform group** means all of the aerobic and facultative anaerobic, gram negative, nonspore forming, rod shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 Fahrenheit ( $35 + 0.5^{\circ}$ Centigrade) .
- (16) **Commingle or Commingling** means the act of combining different lots of shellfish.
- (17) **Compliance schedule** means a written schedule that provides a correction time period to eliminate Key and Other deficiencies.
- (18) **Conditionally approved** means a classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.
- (19) **Conditionally restricted** means a classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.
- (20) **Container** means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.
- (21) **Corrosion resistant materials** means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.
- (22) **Critical Control Point (CCP)** means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.
- (23) **Critical deficiency** means a condition or practice which:
- (a) Results in the production of a product that is unwholesome; or
  - (b) Presents a threat to the health or safety of the consumer.
- (24) **Critical limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.
- (25) **Critical Nonconformity** means a deviation of a laboratory requirement which has the highest likelihood of adversely affecting the quality of the analytical results if out of conformance.
- (26) **Cross connection** means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connection, removable sections, swivel or change over devices, or other devices through which backflow could occur.
- (27) **Cull** means to remove dead or unsafe shellstock from a lot of shellstock.
- (28) **Dealer** means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.

- (29) **Depletion** means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.
- (30) **Depuration** or **depurate** means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.
- (31) **Depuration Processor (DP)** means a person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.
- (32) **Direct marketing** means the sale for human consumption of shellfish which:
- (a) Does not require depuration or relaying prior to sale; or
  - (b) Has been subjected to depuration or relaying activities.
- (33) **Dry storage** means the storage of shellstock out of water.
- (34) **Easily cleanable** means a surface which is:
- (a) Readily accessible; and
  - (b) Is made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.
- (35) **EPA** means the United States Environmental Protection Agency.
- (36) **Facility** means a structure. For other connotations, use person or activity.
- (37) **Fecal coliform** means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24 ( $\pm$  2) hours in a water bath maintained at 112 °Fahrenheit ( $44.5 \pm 0.2$  °Centigrade).
- (38) **FDA** means the United States Food and Drug Administration.
- (39) **Float Aquaculture** means open water aquaculture where the shellfish product is suspended at the water surface using floats.
- (40) **Food contact surface** means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.
- (41) **Food Safety Hazard** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.
- (42) **Geometric Mean** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).
- (43) **Growing area** means any site which supports or could support the propagation of shellstock by natural or artificial means.
- (44) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).
- (45) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 CFR 123.6 as adopted by the Interstate Shellfish Sanitation Conference.
- (46) **Harvest** means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.
- (47) **Harvest area** means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.
- (48) **Harvester** means a person who takes shellstock by any means from a growing area.
- (49) **Heat shock** means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.
- (50) **Importer** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.



- (51) **Includes or including** means includes or including by way of illustration and not by way of limitation.
- (52) **In Shell Product** means non-living, processed shellfish with one or both shells present.
- (53) **In-Shell Product Packing** means the process of placing in-shell product into containers for introduction into commerce.
- (54) **Inspection item** means one of the standard criteria listed in the NSSP Plant Inspection Form under which single or multiple observations of specific critical, key or other deficiencies can be debited. [Note: term "item" appears several places in the Ordinance with a larger connotation than this definition. In the section addressing the use of the inspection form, however, the Ordinance uses the term "inspection item" hence that is provided here as the defined term.]
- (55) **Interstate Certified Shellfish Shippers List (ICSSL)** means a FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in this Ordinance.
- (56) **Interstate Shellfish Sanitation Conference (ISSC)** means the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, the National Marine Fisheries Service of the U.S. Department of Commerce, and the U.S. Environmental Protection Agency. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.
- (57) **Key deficiency** means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.
- (58) **Key Nonconformity** means a deviation of a laboratory requirement has a significant potential to adversely affect the quality of the analytical results if out of conformance.
- (59) **Label** means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.
- (60) **License** means the document issued by the Authority to a person to harvest or transport shellstock for commercial sale. [In those States issuing permits as opposed to licenses, the term license would be replaced with the term "permit" which would be defined the same as "license".]
- (61) **Lot of In-Shell Product** means a single type of container of in-shell product of no more than one day's harvest from a single defined growing area.
- (62) **Lot of shellstock** means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters.
- (63) **Lot of shellstock for depuration** means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.
- (64) **Lot of shucked shellfish** means a collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.
- (65) **Male-specific Coliphage** are a group of bacterial viruses that infect and lyse *E. coli Famp* and produce plaques within 18±2 hours at 35-37±0.5°C.
- (66) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is:
- (a) Used for docking or otherwise mooring vessels; and
  - (b) Constructed to provide temporary or permanent docking space for more than ten boats.
- (67) **Marine biotoxin** means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include *Alexandrium spp.* [*Protogonyaulax* species], and *Karenia brevis*.
- (68) **May** means discretionary and is not mandatory or required.

- (69) **Milliliter** (ml) means a unit of measurement equal to the 0.001 portion of a liter.
- (70) **Monoculture** means the culture of a single bivalve species.
- (71) **MPN (Most Probable Number)** means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.
- (72) **National Shellfish Sanitation Program (NSSP)** means the cooperative State-FDA-Industry program for the sanitary control of shellfish that is adequate to ensure that the shellfish produced in accordance with these guidelines will be safe and sanitary.
- (73) **Open water aquaculture** means the cultivation of bivalve shellfish in natural shellfish growing areas.
- (74) **Other deficiency** means a condition or practice that is not defined as critical or key and is not in accordance with the requirements of this Model Ordinance.
- (75) **Other Nonconformity** means a deviation of a laboratory requirement which does not normally compromise the quality of the analytical results, but generally serve to enhance the overall operation of the laboratory.
- (76) **Person** means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation or other entity. Person includes the federal government, the State, and any other public or private entity.
- (77) **Point source** means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.
- (78) **Poisonous or deleterious substance** means a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.
- (79) **Polyculture** means the cultivation of:
- (a) Two or more species of shellfish; or
  - (b) Shellfish with other species in a common environment.
- (80) **Post Harvest Processing** means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.
- (81) **Post Harvest Processor** means a designation given to a shellfish dealer that has incorporated a post harvest process.
- (82) **Potable water** means a water supply, which meets the requirements of the Safe Drinking Water Act, as administered by the EPA, and any applicable state or local requirements.
- (83) **Principal display panel** means that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of retail sale.
- (84) **Process batch** means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single process water system for a specified depuration cycle in a depuration activity.
- (85) **Process water** means the water used in the scheduled depuration process.
- (86) **Prohibited** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.
- (87) **Raw** means shellfish that have not been thermally processed:
- (a) to an internal temperature of 145° or greater for 15 seconds (or equivalent); or
  - (b) altering the organoleptic characteristics.
- (88) **Relay** means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous

or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(89) **Remote status** means a designation applied to a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.

(90) **Repacker (RP)** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers.

(91) **Repacking In-Shell Product** means the practice of removing in-shell product from containers and placing it into other containers.

(92) **Repacking Shellstock** means the practice of removing shellstock from containers and placing it into other containers.

(93) **Replicate** is defined as two (2) filters for tdh analysis from the same homogenate at the same dilution.

(94) **Reshipper (RS)** means a person who purchases shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.

(95) **Restricted** means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

(96) **Restricted Use Shellstock** means shellstock that is harvested from growing areas classified as approved under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock is intended for further processing prior to distribution to retail or food service.

(97) **Safe materials** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.

(98) **Sanitation control record** means records that document the monitoring of sanitation practices and conditions during processing.

(99) **Sanitary survey** means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area.

(100) **Sanitize** means to adequately treat food contact surfaces by a process that is effective in:

- (a) Destroying vegetative cells of microorganisms of public health significance;
- (b) Substantially reducing the numbers of other undesirable microorganisms; and
- (c) Not adversely affecting the product or its safety for the consumer.

(101) **Seed** means shellstock which is less than market size.

(102) **Shall** means mandatory and required.

(103) **Shellfish** means all species of:

- (a) Oysters, clams or mussels, whether:
  - (i) Shucked or in the shell;
  - (ii) Raw, including post harvest processed;
  - (iii) Frozen or unfrozen;
  - (iv) Whole or in part; and

(b) Scallops in any form, except when the final product form is the adductor muscle only.

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

(105) **Shellstock** means live molluscan shellfish in the shell.

(106) **Shellstock packing** means the process of placing shellstock into containers for introduction into commerce.

(107) **Shellstock Shipper (SS)** means a dealer who grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish nor to repack shucked shellfish. A

shellstock shipper may also buy, repack, and sell in-shell product as well as ship shucked shellfish.

(108) **Should** means recommended but is not required.

(109) **Shucker-Packer (SP)** means a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

(110) **Standardization** means a process in which applicable staffs from the FDA and the Authority conduct evaluations using standard criteria in a uniform manner.

(111) **State shellfish standardization inspector** means a person that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a state standardization officer.

(112) **State shellfish standardization officer** means a person that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.

(113) **Swing deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a "Critical" or a "Key" deficiency.

(114) **Transaction record** means the form or forms used to document each purchase or sale of shellfish at the wholesale level, and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

(115) **Wet storage** means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility.

**National Shellfish Sanitation Program  
2009 NSSP Guide for the Control of Molluscan Shellfish****Section II. Model Ordinance  
Chapter I. Shellfish Sanitation Program**

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**Requirements for the Authority.**

Additional Guidance - Section IV Guidance Documents  
[Chapter I - General .02 Procedures for Initiating a New State Program](#)

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

**@.01 Administration.**

A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:

- (1) The classification of shellfish growing areas;
- (2) The harvesting of shellfish;
- (3) Shellfish processing procedures and facilities;
- (4) Product labeling;
- (5) Storage, handling and packing;
- (6) Shellfish shipment in interstate commerce;
- (7) Shellfish dealers; and
- (8) Bivalve aquaculture.

B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A.

C. Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available physically and/or electronically to any interested person upon request, consistent with appropriate state and federal law.

D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

E. Administrative Procedures. The Authority shall have administrative procedures sufficient to:

- (1) Regulate shellfish harvesting, sale, or shipment; and
- (2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock.
- (3) Detain, condemn, seize, and embargo shellfish.
- (4) Assure compliance with Shellfish Plant Inspection Standardization.

F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The Authority shall have procedures for investigating incidents of shellfish borne disease.

G. Commingling.

(1) Except for any shellfish included in the Authority's commingling plan, the Authority shall not permit the commingling of shellfish.

(2) If the Authority permits shellfish product commingling, the Authority shall develop a commingling management plan. The plan shall:

- (a) Minimize the commingling dates of harvest and growing areas;
- (b) Define a primary dealer;
- (c) Limit the practice of commingling to primary dealers;
- (d) Limit commingling to shellfish harvested from specific growing areas within the State as identified by the Authority and purchased directly from harvesters; and
- (e) Define how the commingled shellfish will be identified.

Additional Guidance - Section IV Guidance Documents

[Chapter III .02 Shellfish Plant Inspection Standardization Procedures](#)

[NSSP Standardized Shellfish Processing Plant Inspection Form](#)

**@.02 Dealer Certification.**

A. General

(1) A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120-day period immediately prior to the issuance or renewal of the certification.

(2) Certification shall be given only to persons who meet the established requirements established for certification.

(3) All certifications shall expire annually. The month selected for certification expiration shall be at the discretion of the Authority.

(4) The Authority shall issue only one certification number to a dealer for a location. A person or dealer may obtain more than one certification if each business is:

- (a) Maintained as a separate entity; and
- (b) Is not found at the same location.

(5) The Authority may permit separate certified dealers to share a facility.

(6) The certification number issued to each dealer by the Authority shall be unique.

(7) Adequate records documenting each dealer's compliance with certification requirements shall be maintained for at least three years. These records shall include:

- (a) Inspection reports of dealers;
- (b) Notification letters and enforcement actions;
- (c) Shellfish sample results and follow-up actions taken;
- (d) Records of complaints or inquiries and follow-up actions taken; and
- (e) Administrative hearing transcripts and records.

B. Initial Certification.

(1) Initial certification shall be given only to persons who meet the following requirements:

- (a) HACCP requirements:
  - (i) A HACCP plan accepted by the Authority;
  - (ii) No critical deficiencies;
  - (iii) ) Not more than 2 key deficiencies;
  - (iv) Not more than 2 other deficiencies.
- (b) Sanitation and additional Model Ordinance Requirements
  - (i) No critical deficiencies;

- (ii) Not more than 2 key deficiencies;
- (iii) ) Not more than 3 other deficiencies.
- (2) The initial certification shall include a compliance schedule to correct any deficiencies not corrected by the dealer during the inspection.
- C. Renewal of Certification.
  - (1) A dealer shall make application for certification renewal annually at the time specified by the Authority. The Authority shall not renew the certification for any dealer until the dealer:
    - (a) Meets the requirements of §B.1(a) and §B.1(b). The number of deficiencies allowed under §B.1(a) and §B.1(b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and
    - (b) Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the inspection.
- D. Revocation or Suspension of Certification.
  - (1) The Authority shall not allow any dealer whose certification has been suspended or revoked under §H. to deal in shellfish.
  - (2) The Authority shall not issue certification to a dealer whose certification has been suspended or revoked to deal in shellfish until the dealer meets the requirements for initial certification.
- E. Interstate Certified Shellfish Shippers List (ICSSL).
  - (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.

<b>Designations</b>			
<b>Certification</b>		<b>Permit</b>	
SP -	Shucker Packer	PHP -	Post Harvest Processing
RP -	Repacker	AQ -	Aquaculture
SS -	Shellstock Shipper	WS -	Wet Storage
RS -	Reshipper		
DP -	Depuration		

- (2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:
  - (a) Suspended; or
  - (b) Revoked.
- F. Inspections.
  - (1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities:
    - (a) During periods of activity; and
    - (b) At the following minimum frequencies:
      - (i) Within 30 days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;
      - (ii) At least monthly for dealer facilities certified as depuration processors;
      - (iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and
      - (iv) At least semiannually for other dealer activities

(2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance.

G. Performance Based Inspection Program (PIP).

(1) A performance based inspection program may be instituted by the Authority for any dealer who meets the requirements of this section.

(2) The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.

(3) To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. The three-year demonstration shall include:

(a) Full compliance with the minimum inspection frequency shown under §F.;

(b) Recertification of the dealer by the Authority;

(c) Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;

(d) Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and

(e) No repetition of the identified deficiencies.

H. Enforcement.

(1) General.

(a) The Authority shall use any combination of administrative hearings, fines, certification cancellations, temporary suspension of operating licenses, embargoes, product condemnations or product seizures to accomplish the implementation of this Ordinance.

(b) When a dealer has failed to meet the compliance schedule, the Authority shall:

(i) Consider whether it is appropriate to revise the compliance schedule, suspend or revoke the dealer's certification, or seek other administrative remedies; and

(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:

(i) The deficiency shall be corrected during that inspection; or

(ii) The dealer must cease production affected by the deficiency.

(b) When the dealer fails to comply with (a) above, the Authority shall immediately begin actions to suspend or revoke the dealer's certification.

(c) Product affected by a critical deficiency shall be controlled to prevent contaminated or adulterated product from reaching consumers. When necessary the Authority shall:

(i) Detain or seize any undistributed lots of shellfish that may have been adulterated;

(ii) Initiate a recall of any distributed shellfish; and

(iii) Immediately notify the enforcement officials for FDA and any other Authorities where the product was distributed.

(d) When any inspection detects any key or other deficiencies not already covered in a compliance schedule, the Authority, working with the dealer, shall develop a compliance schedule to correct the new key or other deficiencies.

(e) When any inspection detects four or more new key deficiencies, the Authority shall consider the following options and document the reasons for the selection of a particular option:

(i) Revise the existing compliance schedule;

(ii) Suspend or revoke the dealer's certification; or

(iii) Seek other administrative remedies.



**Section II. Model Ordinance****Chapter II. Risk Assessment and Risk Management**

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**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 Outbreaks of Shellfish-Related Illness.**

- A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:
- (1) Each consumer's food history;
  - (2) Shellfish handling practices by the consumer and/or retailer;
  - (3) Whether the disease has the potential or is known to be transmitted by shellfish; and
  - (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

- B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
- C. When the investigation outlined in §.02B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:
- (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
  - (2) Notify receiving states and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
  - (3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
  - (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7. The recall shall include all implicated products.
- D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:
- (1) Notify receiving states and the FDA Regional Shellfish Specialist of the problem; and
  - (2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7. The recall shall include all implicated products.
- E. When the investigation outlined in §.02B. cannot be completed within 24 hours, the Authority shall:
- (1) Follow the closure procedure outlined in § .01C; and if the investigation does not indicate a growing area problem, the area shall be immediately reopened and product recall terminated.

- F. Upon closing an implicated area for problems other than natural occurring pathogens and/or Biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:
- (1) A review of the growing area classification file records;
  - (2) A field review of existing pollution sources;
  - (3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
  - (4) Examination of water quality subsequent to the illness outbreak.
- G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or Biotoxins, the Authority:
- (1) Shall follow an existing marine Biotoxin contingency plan, if appropriate.
  - (2) Shall collect and analyze samples relevant to the investigation, if appropriate.
  - (3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or Biotoxins are not a public health concern.
  - (4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.
- H. When the growing area is determined the problem, the Authority shall:
- (1) Place the growing area in the closed status until:
    - (a) The Authority verifies that the area is properly classified, using current data, in compliance with the NSSP Model Ordinance; or
    - (b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;
  - (2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
  - (3) Develop a written report summarizing the findings of the investigation and actions taken.
- I. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA and the Authorities in other states involved in the recall. The Authority shall submit periodic recall status reports to the FDA Regional Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7, Subpart C, §7.53 (b) (1-6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the state of product origin regarding recall efforts within their state until such time that the Authority in the state of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities, and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

Additional Guidance - Section IV Guidance Documents  
[Chapter IV .03 \*Vibrio\* Control Plan Guidance Template](#)

- J. The Authority shall assess annually *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.

**@. 02 Presence of Human Pathogens in Shellfish Meats.**

Additional Guidance - Section IV Guidance Documents

[Chapter II .13 Protocol for Reviewing Classification of Area Implicated by Pathogens in Shellfish Meat Samples](#)

- A. Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.
- B. Growing Area Investigation.
  - (1) The Authority shall review the following factors:
    - (a) The documentation to trace the shellfish to its source;
    - (b) (The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
    - (c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
  - (2) The Authority shall take no further action when the Authority determines that:
    - (a) The growing area is properly classified;
    - (b) No illegal harvesting is taking place; and
    - (c) There is no reason to believe that the growing area is the source of the pathogens.
  - (3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
    - (a) Change the existing classification to the correct classification; or
    - (b) Close the growing area until the correct classification can be determined; and
    - (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.
  - (4) When the Authority determines that the growing area may be the source of pathogens the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7 if the pathogens exceed tolerance levels.
  - (5) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.
- C. Distribution and Processing Investigation.
  - (1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.
  - (2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.
  - (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.
- D. Risk Management and Tolerance Levels.

Additional Guidance - Section IV Guidance Documents [Chapter II @ .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood](#)

- (1) Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.
- (2) Established Tolerance Levels.
  - (a) When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:
    - (i) Shall maintain a written summary of its finding and the data supporting its finding in its central file; and
    - (ii) May leave the growing area in its present classification.
  - (b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:
    - (i) Leave the area in the open status of its classification when the tolerance level is not exceeded; and
    - (ii) Place the area in the closed status of its classification when the tolerance level is exceeded.
  - (c) When the tolerance level is exceeded, the Authority may:
    - (i) Maintain the growing area in the closed status of its current classification;
    - (ii) Reclassify the growing area to the restricted or prohibited classification;or
    - (iii) Reclassify the growing area to the conditionally restricted classification and establish a management plan.
  - (d) Any management plan based on shellstock exceeding established tolerance levels shall:
    - (i) Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;
    - (ii) Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;
    - (iii) Document the scientific basis for the additional criteria;
    - (iv) Provide for periodic retesting of the shellfish meats; and
    - (v) Provide for the growing area to be placed in the closed status if the criteria are exceeded.
- (3) Established Tolerance Levels Not Known.
  - (a) When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:
    - (i) The levels are acceptable, the growing area shall remain in the open status of its classification; or
    - (ii) The levels are unacceptable, the growing area shall be placed in the closed status of its classification.
  - (b) If a growing area is placed in the closed status, the Authority may elect to
    - (i) Maintain that status indefinitely;
    - (ii) Reclassify the area to the restricted or prohibited classification; or
    - (iii) Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of §D.(2)(d).

**@.03 Presence of Toxic Substances in Shellfish Meats.**

Additional Guidance - Section IV Guidance Documents [Chapter II @ .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood](#)

- A. Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in § @.02.
- B. When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in § @.02D., Risk Management and Tolerance Levels.

**@.04 *Vibrio vulnificus* Risk Management for Oysters.**

Additional Guidance - Section IV Guidance Documents [Chapter IV- Naturally Occurring Pathogens](#)

- A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement a *Vibrio vulnificus* Management Plan.
- B. The Source State's *Vibrio vulnificus* Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 -1999 of 0.303/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. State's compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.
- C. The Source State's *Vibrio vulnificus* Management Plan shall include, at a minimum:
  - (1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;
  - (2) A process to collected standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;
  - (3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;

(4) Identification and preparation for achieving a goal of post harvest processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction;

(5) Identification and preparation for implementation of required post harvest processing capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in @.04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest processing, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and

(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the Plan shall be completed no later than December 2007. The temperature and month-of-the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;

(b) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post harvest processing that reduces the *Vibrio vulnificus* levels to <30 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;

(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;

(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;

(e) Subjecting all oysters intended for the raw, half-shell market to a post harvest processing that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to <30 MPN/gram during the months of May through September, inclusive; and

(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Effective January 1, 2012:

@.04 *Vibrio vulnificus* Risk Management for Oysters

- A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement a *Vibrio vulnificus* Risk Management Plan.

- B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.
- C. The Source State's *Vibrio vulnificus* Risk Management Plan shall include, at a minimum:
- (1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;
  - (2) A process to collect standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;
  - (3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses; and
  - (4) Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states.

#### **@.05 *Vibrio parahaemolyticus* Control Plan**

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

- A. Risk Evaluation.
- Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)
- (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and
  - (2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and
  - (3) The water temperatures in the area; and
  - (4) The air temperatures in the area; and
  - (5) Salinity in the area; and
  - (6) Harvesting techniques in the area; and
  - (7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.
- B. Control Plan
- (1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or

- (2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:
- (a) Waters bordering the Pacific Ocean - 60°F.
  - (b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) - 81°F.
  - (c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in §A., that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.
    - (i) In conducting the evaluation, the State shall evaluate the factors listed in §A. for the area during periods when the temperatures exceed those listed in this section;
    - (ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in §A differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or
- (3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.
- (4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:
- (a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in § B. (2) where they apply, or other triggers as determined by the risk evaluation.
  - (b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:
    - (i) Post harvest processing using a process that has been validated to achieve a 2 log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a 3 log reduction for the Pacific Coast oysters;
    - (ii) Closing the area to oyster harvest;
    - (iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;
    - (iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;
    - (v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60 °F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;
    - (vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *Vp* illness is no longer reasonably likely to occur, as approved by the Authority.
  - (c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to



ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled “*for shucking only*”, or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

C. The Time When Harvest Begins

For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.

**Section II. Model Ordinance****Chapter III. Laboratory****Page 1 of 4****Requirements for the Authority.**

Additional Guidance - Section IV Guidance Documents

[Chapter II. 11. Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists](#)

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

**@.01 Quality Assurance.**

- A. NSSP Conformance Required. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA or FDA certified State Shellfish Laboratory Evaluation Officer (LEO) in accordance with the requirements established under the NSSP.
- B. State Program Requirements. The Authority shall assure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. The Authority shall:
  - (1) Require laboratories to develop a written quality assurance plan that:
    - (a) Describes the organization and management structure of the laboratory;
    - (b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised;
    - (c) Describes all procedures and methods used to collect, maintain, transport and analyze samples;
    - (d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance;
    - (e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration; and
    - (f) Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must include triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers or FDA certified state laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories, participation in the annual FDA sponsored proficiency test programs is also required; and
    - (g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.
  - (2) Require laboratories to implement their quality assurance plan;
  - (3) Ensure that the laboratory has appropriate facilities and resources to effectively manage the workload;
  - (4) Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin and analyses used to officially support the state shellfish program; and
  - (5) Require a laboratory to be re-evaluated when any major changes in personnel, workload, or facilities occur and when a laboratory is found in nonconformance.

- C. An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and FDA. The agreement shall be consistent with NSSP requirements.
- D. Laboratory Evaluation.
- (1) Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists, Guidance Documents Chapter II Growing Areas 11. Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
- (a) Conforms. In order to achieve or maintain its conforms status, a laboratory shall meet the following requirements under the NSSP standardized laboratory evaluation criteria:
- (i) No critical nonconformities have been identified;
  - (ii) Not more than 12 key nonconformities for microbiological or 5 for paralytic shellfish poisoning component have been identified;
  - (iii) Not more than 17 critical, key, and other nonconformities in total or 9 for paralytic shellfish poisoning component have been identified (not to exceed the critical and key criteria); and
  - (iv) No repeat key nonconformities have been identified in consecutive evaluations.
- (b) Provisionally Conforms. In order to achieve provisionally conforming status, a laboratory shall meet the following requirements under the NSSP standardized microbiological laboratory evaluation criteria:
- (i) Not more than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;
  - (ii) Not more than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified; and
  - (iii) Not more than one repeat Key nonconformity has been identified in consecutive evaluations.
- (c) Nonconformance. When a laboratory exceeds the following criteria, the laboratory shall be determined to be in nonconformance:
- (i) More than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;
  - (ii) More than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified;
  - (iii) More than 17 critical, key, and other nonconformities for microbiological or 9 for paralytic shellfish poisoning component have been identified; or
  - (iv) One or more repeat critical or two or more key nonconformities have been identified in consecutive evaluations.
- E. Time Limit on Laboratory Status.
- (1) Conforming Status. A laboratory found to be in conforming status has up to ninety (90) days to successfully correct all nonconformities noted in the evaluation or has an approved action plan. After this period, the laboratory's status shall be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.
- (2) Provisionally Conforms Status. A laboratory found to be in the provisionally conforming status has up to sixty (60) days to successfully correct all nonconformities found or has an approved action plan. After this period, the laboratory shall be assigned a status of:
- (a) Conforms if all the critical and key nonconformities have been successfully corrected; or
  - (b) Nonconforming if any critical or key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

- (3) Nonconformance.
  - (a) Upon a determination of nonconforming status, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory shall continue to be nonconforming; and as a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.
  - (b) When a laboratory is found to be nonconforming either for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority shall ensure that an action plan is developed to correct the situation in an expeditious manner.
  - (c) When all critical and key nonconformities have been successfully corrected by a nonconforming laboratory, the laboratory will be reevaluated either on-site or through a careful review of appropriate documentation as determined by the FDA or FDA certified State Shellfish LEO. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP.
- F. Laboratory Services for Depuration Processors. For any laboratory providing services for the quality assurance program (e.g. water quality) including end-product testing of any depuration processor, the Authority shall:
  - (1) Require the annual inspection of the laboratory in accordance with 01 and 02 of this Chapter; and
  - (2) Require the laboratory to retain its records for a minimum of the previous two years.

Additional Guidance - Section IV Guidance Documents  
[Chapter II.10 Approved NSSP Laboratory Tests](#)

**@.02 Methods.**

- A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.
- B. Chemical and Physical.
  - (1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
    - (a) Be the current AOAC or APHA method for all physical and chemical measurements; and
    - (b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
  - (2) When an AOAC or APHA method is not available, EPA methods may be used.
  - (3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.
- C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
  - (1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins : and
  - (2) The current APHA method used in the bioassay for *Karenia brevis* toxins; or
  - (3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance

Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

D. Emerging Methods.

(1) When there is an immediate or critical need and no NSSP approved methods exists, and the ISSC Executive Board considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided to the Executive Board and shall contain the following criteria:

- (a) Name of Method
- (b) Date of Submission
- (c) Specific purpose or intent of the method for use in the NSSP
- (d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method
- (e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable
- (f) Any peer reviewed articles detailing the method
- (g) Name of developer(s)/submitters
- (h) Developer/submitter contact information

(2) Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol should be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.

**Section II. Model Ordinance  
Chapter IV. Shellstock Growing Areas**

Additional Guidance - Section IV. Guidance Documents  
[Chapter II.03 Sanitary Survey and the Classification of Growing Waters](#)  
[Chapter II.05 Management Plans for Growing Areas in the Conditional Classification](#)  
[Chapter II.07 Systematic Random Sampling Monitoring Strategy](#)

**Requirements for the Authority**

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

**@.01 Sanitary Survey.**

**A. General.**

- (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:
  - (a) A shoreline survey;
  - (b) A survey of the bacteriological quality of the water;
  - (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;
  - (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; and
  - (e) A determination of the appropriate growing area classification.
- (2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with §C. to assure that data is current and that conditions are unchanged.
- (3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:
  - (a) The sanitary survey;
  - (b) The triennial reevaluation; and
  - (c) The annual review.
- (4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.
- (5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

**B. Sanitary Survey Required.**

- (1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.
- (2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:
  - (a) The harvest of shellstock for human consumption; and
  - (b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

- (1) A sanitary survey of each growing area shall be performed at least once every twelve years and shall include the components in §A. (1).
- (2) When a written sanitary survey report is not completed, the area shall be placed in the closed status.
- (3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three years.
  - (a) This triennial reevaluation shall include:
    - (i) A review in accordance with §C. (5) and (6) of the water quality samples;
    - (ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;
    - (iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;
    - (iv) A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and
    - (v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.
  - (b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.
- (4) The triennial reevaluation may include:
  - (a) Inspection of wastewater treatment plants or collection of additional effluent samples to determine their impact on the growing area;
  - (b) Hydrodynamic studies;
  - (c) Additional field work to determine the actual impact of pollution sources; and
  - (d) Collection of additional water samples.
- (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:
  - (a) A field observation of the pollution sources which may include:
    - (i) A drive-through survey;
    - (ii) Observations made during sample collection; and
    - (iii) Information from other sources.
  - (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in §.02;
  - (c) Review of available inspection reports and effluent samples collected from pollution sources;
  - (d) Review of available performance standards for various types of discharges that impact the growing area; and
  - (e) A brief report which documents the findings of the annual reevaluation.
- (6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

D. Shoreline Survey Requirements.

- (1) In the shoreline survey for each growing area, the Authority shall:
  - (a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;

- (b) Determine the distance from the pollution sources to the growing area and the impact of each source on the growing area;
  - (c) Assess the reliability and effectiveness of sewage or other waste treatment systems;
  - (d) Determine if poisonous or deleterious substances adversely affect the growing area; and
  - (e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.
- (2) The Authority shall assure that the shoreline survey meets the following minimum requirements:
- (a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;
  - (b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;
  - (c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel; and
  - (d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:
    - (i) The location of the site on a comprehensive map of the survey area; and
    - (ii) The determination that the pollution source has a direct or indirect impact on shellfish waters: and
  - (e) A written summary of the survey findings.

Additional Guidance - Section IV. Guidance Documents  
[Chapter II.01 Total Coliform Standards](#)

#### **@.02 Bacteriological Standards.**

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards.

- A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.
- B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.
- C. Exceptions.
  - (1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under §.03.
  - (2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an



- impact on the water quality, a minimum of 15 samples shall be required to classify any growing area not previously classified under §.03.
- D. Standard for the Approved Classification of Growing Areas in the Remote Status.
- (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard below.
  - (2) Fecal Coliform Standard for the Remote Status. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN or MF (mTEC) of:
    - (a) 43 MPN per 100 ml for a five tube decimal dilution test;
    - (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
    - (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
    - (d) 31 CFU per 100 ml for a MF (mTEC) test.
  - (3) Required Sample Collection.
    - (a) A minimum of two samples shall be collected annually.
    - (b) A minimum of the most recent 15 samples collected shall be used to calculate the median or geometric mean and percentage to determine compliance with the standard established for the approved classification of remote growing areas.
- E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.
- (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E. (2).
  - (2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN or MF (mTEC) of:
    - (a) 43 MPN per 100 ml for a five tube decimal dilution test;
    - (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
    - (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
    - (d) 31 CFU per 100 ml for a MF (mTEC) test.
  - (3) Required Sample Collection.
    - (a) A minimum of five samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
    - (b) A minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
    - (c) Sample station locations shall be adjacent to actual or potential sources of pollution.
- F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources.
- (1) Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.
  - (2) Pollution Sources. Growing areas shall be:
    - (a) Impacted only by randomly occurring, intermittent events; and
    - (b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.
  - (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E.(2) or §F.(4).
  - (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:
    - (a) 43 MPN per 100 ml for a five tube decimal dilution test;
    - (b) 49 MPN per 100 ml for a three-tube decimal dilution test; or
    - (c) 31 CFU per 100 ml for a MF (mTEC) test.
  - (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

- (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);
  - (b) Multiplying the standard deviation in (a) by 1.28;
  - (c) Adding the product from (b) to the arithmetic mean;
  - (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and
  - (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.
- (6) Required Sample Collection.
- (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §E.(2).
  - (b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:
    - (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;
    - (ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;
    - (iii) A minimum of six random samples shall be collected annually from each sample station in the growing area;
    - (iv) A minimum of two random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six random samples per station per year specified under @.02F(6)(b)(iii) must resume at least six months before an area is reactivated; and
    - (v) A minimum of the 30 most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.
  - (c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:
    - (i) Does not have 30 recent randomly collected sample results from each station, then the previous 15 samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum 30 sample requirement for a transition period not to exceed three years; and
    - (ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).
- G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.
- (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §G. (2).
  - (2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:
    - (a) 300 MPN per 100 ml for a three tube decimal dilution test;

- (b) 173 MPN per 100 ml for a twelve tube single dilution test; or
    - (c) 163 CFU per 100 ml for a MF (mTEC) test.
  - (3) Required Sample Collection. Samples shall be collected in accordance with §E. (3).
- H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.
  - (1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.
  - (2) Pollution Sources. Growing areas shall meet the requirements in §F. (2).
  - (3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in §G. (2) or §H. (4).
  - (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:
    - (a) 260 MPN per 100 ml for a five tube decimal dilution test;
    - (b) 300 MPN per 100 ml for a three-tube decimal dilution test; or
    - (c) 163 CFU per 100 ml for a MF (mTEC) test.
  - (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in §F. (5).
  - (6) Required Sample Collection.
    - (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §G. (2).
    - (b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in §F. (6) for the application of the standard under §H. (4).

**@. 03 Growing Area Classification.**

- A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.
  - (1) Emergency Conditions. A growing area shall be placed in the closed status under §.03A(5) when pollution conditions exist which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status.
  - (2) Classification of All Growing Areas. All growing areas which:
    - (a) Are not subjected to a sanitary survey every twelve years shall be classified as prohibited;
    - (b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with §E. Prohibited Classification; and
    - (c) Are subjected to a sanitary survey shall be correctly classified based on the twelve year sanitary survey, and its most recent triennial or annual reevaluation when available, as only one of the following:
      - (i) Approved;
      - (ii) Conditionally Approved;
      - (iii) Restricted;
      - (iv) Conditionally Restricted; or
      - (v) Prohibited.

- (3) Boundaries. The boundaries of each classified growing area shall be delineated on charts which are:
- (a) Of sufficient scale and detail so as to adequately describe the boundaries; and
  - (b) Maintained in the central file by the Authority.
- (4) Revision of Classifications.
- (a) Any upward revision of a growing area classification shall be supported by an adequate sanitary survey.
  - (b) The appropriate FDA regional office shall be notified of any revision in growing area classification.
- (5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock.
- (a) Open Status. Except for an area in the prohibited classification, any correctly classified growing area, is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.
  - (b) Closed Status. Any classified growing area may be closed for a limited or temporary period because of:
    - (i) An emergency condition or situation;
    - (ii) The presence of biotoxins in concentrations of public health significance; or
    - (iii) Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas; or
    - (iv) Failure of the Authority to complete a written sanitary survey or triennial review evaluation report.
    - (v) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and
    - (vi) Supporting information is documented by a written record in the central file.
  - (c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:
    - (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
    - (ii) For emergency closures (not applicable for conditional closures) of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of 50 male-specific coliphage per 100 grams from shellfish samples collected no sooner than 7 days after contamination has ceased and from representative locations in each growing area potentially impacted; or
    - (iii) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and
    - (iv) Supporting information is documented by a written record in the central file.
  - (d) Inactive Status. The authority may place an approved or restricted growing area affected by non-point sources in the inactive status for up to five years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one year.

- (i) While in inactive status, the required bacteriological sample collection under @.02F (6)(b)(iii) may be reduced to two water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01C.
  - (ii) The sample collection frequency of six random samples per station per year specified under @.02F (6)(b)(iii) must resume at least six months before an area is reactivated.
  - (iii) Before an area is reactivated, the results of the most recent 30 samples must be reviewed and comply with the requirements under @. 02F.
  - (e) Remote Status. A growing area may be placed in the remote status if:
    - (i) A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and
    - (ii) The area is in the approved classification.
  - (f) Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two water samples per year if the following criteria are met:
    - (i) The area is initially classified as approved;
    - (ii) The closure time period is defined; and
    - (iii) At least one sample be taken upon reopening the area.
- B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.
- (1) Survey Required. A sanitary survey finds that the area is:
    - (a) Safe for the direct marketing of shellfish;
    - (b) Not subject to contamination from human or animal fecal matter at levels that, in the judgement of the Authority, presents an actual or potential public health hazard; and
    - (c) Not contaminated with:
      - (i) Pathogenic organisms;
      - (ii) Poisonous or deleterious substances;
      - (iii) Marine Biotoxins; or
      - (iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.
  - (2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in §.02.
- C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:
- (1) Survey Required. The sanitary survey meets the following criteria:
    - (a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
    - (b) Each potential source of pollution that may adversely affect the growing area is evaluated;
    - (c) Bacteriological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area.
  - (2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:
    - (a) For management plans based on wastewater treatment plant function, performance standards that include:
      - (i) Peak effluent flow, average flow, and infiltration flow;
      - (ii) Bacteriological or viral quality of the effluent;

- (iii) Physical and chemical quality of the effluent;
- (iv) Conditions which cause plant failure;
- (v) Plant or collection system bypasses;
- (vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
- (vii) Provisions for monitoring and inspecting the waste water treatment plant; and
- (viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with §E. Prohibited Classification;
- (b) For management plans based on pollution sources other than waste water treatment plants:
  - (i) Performance standards that reliably predict when criteria for conditional classification are met; and
  - (ii) Discussion and data supporting the performance standards.
- (c) For management plans based on wastewater treatment plant function or pollution sources other than wastewater treatment plants, criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:
  - (i) Performance standards of the plan are fully met;
  - (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
  - (iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water; and
  - (iv) Shellstock feeding activity is sufficient to achieve coliform reduction.
- (d) For management plans based on a risk assessment made in accordance with Chapter II, Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;
- (e) For management systems based on marine Biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;
- (f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;
- (g) Provisions for patrol to prevent illegal harvest; and
- (h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.
- (3) Reevaluation of Conditional Classification.
  - (a) The classification shall be reevaluated at least once each year. The reevaluation shall include:
    - (i) Evaluation of compliance with the management plan;
    - (ii) Determination of adequacy of reporting of failure to meet performance standards;
    - (iii) Review of the cooperation of the persons involved;
    - (iv) Evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;
    - (v) Field inspection of critical pollution sources, where necessary; and
    - (vi) Written findings, evaluations and recommendations.
  - (b) Water Sample Collection.
    - (i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at

least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

(ii) When the conditional management plan is based on the operation and performance of a wastewater treatment plant(s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.

(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, stormwater runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.

(v) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area.

(vi) When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.

(a) The management plan shall be developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any wastewater treatment plants involved; and

(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two types of conditional areas:

(a) Conditionally approved; and

(b) Conditionally restricted.

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:

(a) Meet the requirements for:

(i) An approved area classification when the conditionally approved classification is in the open status; and

(ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and

(b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.

(7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:

(a) Meet the requirements for:

(i) A restricted classification when the conditionally restricted classification is in the open status; and

(ii) A prohibited classification when the conditionally restricted classification is in the closed status; and

(b) Designate in its management plan whether the harvested shellstock are to be relayed or depurated.

D. Restricted Classification.

(1) General

(a) A growing area may be classified as restricted when:

(i) A sanitary survey indicates a limited degree of pollution; and

(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

(b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:

(i) By special license; and

(ii) Under the supervision of the Authority.

(2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in §.02 for a growing area in the restricted classification if the growing area is used for depuration.

(3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:

(a) Chapter V. Shellstock Relaying; or

(b) Chapter XV. Depuration.

E. Prohibited Classification.

(1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters.

(2) General. The Authority shall:

(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed for aquaculture or the depletion of the areas classified as prohibited; and

(b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it is seed to be cultured as outlined in NSSP MO Chapter VI. Shellfish Aquaculture.02 Seed Shellstock.

(3) Sanitary Survey. A growing area shall be classified as prohibited if:

(a) No current sanitary survey exists;



- (b) A sanitary survey determines:
  - (i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;
  - (ii) Pollution sources may unpredictably contaminate the growing area;
  - (iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;
  - (iv) The concentration of Biotoxin is sufficient to cause a public health risk as identified in §.04. or
  - (v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.
- (4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II, Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.
- (5) Wastewater Discharges.
  - (a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.
  - (b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:
    - (i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological or viral quality of the effluent;
    - (ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
    - (iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
    - (iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

Additional Guidance - Section IV Guidance Documents  
[Chapter II.02 Guidance for Developing Marine Biotoxin Contingency Plans](#)

**@.04 Marine Biotoxin Control.**

A. Contingency Plan.

- (1) The Authority shall develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas.
- (2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
  - (a) Initiate an emergency shellfish sampling and assay program;
  - (b) Close growing areas and embargo shellfish;
  - (c) Prevent harvesting of contaminated species;
  - (d) Provide for product recall;
  - (e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies; and
  - (f) Coordinate control actions taken by Authorities and federal agencies.
- (3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine Biotoxins that the situation cannot be safely managed, the presence of marine Biotoxins shall not affect the classification of the shellfish growing area under §.03. The Authority may use the conditionally approved classification for areas affected by marine Biotoxins.

- (4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a growing area while other parts of the growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety, such as by batch release of shellfish lots only after samples of each lot are tested and found to be below the action levels specified in Section C.
- B. Marine Biotoxin Monitoring.  
In those areas where toxin-forming organisms are known to occur periodically and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine Biotoxins can be reasonably predicted to occur, representative samples of the water and/or shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples will be assayed for the presence of toxin-forming organisms and shellfish meat samples shall be assayed for the presence of toxins.
- C. Closed Status of Growing Areas.  
(1) A growing area, or portion(s) thereof as provided in §A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of Biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:  
(a) PSP - cells/L n/a; 80 µg/100 grams  
(b) NSP - 5,000 cells/L or 20 MU (approximate as 80 µg/100 g)  
(c) ASP - cells/L n/a; 2 mg/100 grams (20 ppm)  
(d) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or  
(e) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:  
(i) The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish; or  
(ii) The cell counts for *Karenia brevis* organisms in the water column exceed 5,000 per liter; or  
(f) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the edible portion of raw shellfish.  
(2) For any marine Biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or Biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.  
(3) When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine Biotoxin contingency plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.  
(4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.  
(5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.  
(6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.
- D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:  
(1) Toxicity limits for processing;  
(2) Controls for harvesting and transporting the shellstock to processor;  
(3) Special marking for unprocessed shellstock;  
(4) Scheduled processes; and

- (5) End product controls on the processed shellfish.
- E. Records. The Authority shall maintain a copy of all of the following records.
  - (1) All information, including monitoring data, relating to the levels of marine Biotoxins in the shellfish growing areas;
  - (2) Copies of notices placing growing areas in the closed status;
  - (3) Evaluation reports; and
  - (4) Copies of notices returning growing areas to the open status.

**@.05 Marinas.**

- A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as:
  - (1) Conditionally approved;
  - (2) Conditionally restricted; or
  - (3) Prohibited.
- B. Adjacent Waters. Waters adjacent to marina waters classified under §A. may be impacted by pollution associated with the marina.
  - (1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.
  - (2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.
  - (3) The dilution analysis shall incorporate the following:
    - (a) A slip occupancy rate for the marina;
    - (b) An actual or assumed rate of boats which will discharge untreated waste;
    - (c) An occupancy per boat rate (i.e., number of persons per boat);
    - (d) A fecal coliform discharge rate of  $2 \times 10$  fecal coliform per ninth power per day; and
    - (e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.
  - (4) If the dilution analysis predicts a theoretical fecal coliform loading greater than 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:
    - (a) Conditionally approved;
    - (b) Restricted;
    - (c) Conditionally restricted; or
    - (d) Prohibited.
  - (5) If the dilution analyses predicts a theoretical fecal coliform loading less than or equal to 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
    - (a) Approved; or
    - (b) Conditionally approved.
  - (6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two persons per boat.

Additional Guidance - Section IV Guidance Documents  
[Chapter II.06 Shellstock Relay](#)

**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.**

The Authority shall assure that:

- A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;
- B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
- C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms in the water, or poisonous or deleterious substances that may be present in shellstock to occur; and
- D. If shellstock are relayed in containers:
  - (1) The containers are:
    - (a) Designed and constructed so that they allow free flow of water to the shellstock; and
    - (b) Located so as to assure the contaminant reduction required in §C.; and
  - (2) The shellstock are washed and culled prior to placement in the containers.

**@.02 Contaminant Reduction.**

- A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.
- B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay activity:
  - (1) The bacteriological quality of each shellfish species, is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or
  - (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels.
- C. The authority may waive the requirements for a contaminant reduction study if:
  - (1) Only microbial contaminants need to be reduced; and

- (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV@.02.G and Chapter IV@.02H; and
- (3) The treatment period exceeds 60 days.
- D. The time period shall be at least 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.
- E. When container relaying is used and the Authority allows a treatment time of less than 14 days, the Authority shall require more intensive sampling including:
  - (1) Product sampling before and after relay, and
  - (2) Monitoring of critical environmental parameters such as temperature and salinity.
- F. The Authority shall establish the time period during the year when relaying may be conducted.

**@.03 Licenses to Relay Shellstock or to Harvest Shellstock for Delivery to a Low Acid Canned Food Processing Facility.**

- A. The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid harvester or relay license.
- B. The license conditions shall not be transferable.
- C. A license shall be valid only when issued for:
  - (1) A specific relay or harvest activity; and
  - (2) Not more than 365 days.
- D. The license conditions shall include:
  - (1) The source, destination, and species to be relayed or harvested for low acid canned food processing;
  - (2) The relayed or harvested for low acid canned food processing shellstock deposition method;
  - (3) The method used to maintain adequate separation between different lots of shellfish;
  - (4) A requirement for the licensee to keep records which:
    - (a) Specify the dates on which the shellstock is harvested, deposited for treatment and harvested again, or delivered to a low acid canned food processing facility;
    - (b) Identify the buyer and quantity of shellstock harvested for relaying or delivery to a low acid canned food processing facility; and
    - (c) Are submitted to the Authority at a specified frequency, if required by the Authority, or made available to the Authority upon request; and
  - (5) A provision for additional information at the discretion of the Authority.
- E. If the relay harvester or harvester for low acid canned food processing fails to comply with the conditions of the license, the Authority shall revoke the license.

**@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities.**

- A. The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program to control the harvest, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent shellstock from being illegally diverted to direct marketing.

- B. In the event that the control of relaying or harvesting for low acid canning activities is shared among two or more agencies, the Authority shall develop written operating procedures for joint use among the agencies. These procedures shall provide for the achievement of all requirements specified in this Chapter, and shall be reviewed annually and updated as necessary.
- C. If shellstock from growing areas classified as conditionally approved or restricted are to be relayed or harvested for low acid canned food processing across State boundaries, a memorandum of understanding outlining the procedures to be used shall be developed between the appropriate Authorities in each State.
- D. If a growing area in the conditionally approved classification meets the criteria for the restricted classification when the growing area is in the closed status, the Authority may permit shellstock to be harvested for relaying or low acid canned food processing during the period the area is in its closed status, provided that these activities are addressed in the management plan for the growing area classified as conditionally approved, and all other conditions of this Chapter are met.
- E. Locations designated to receive relayed shellstock within growing areas which are classified as approved or conditionally approved shall:
  - (1) Be placed in the closed status until the period of treatment is complete and the Authority returns the area to the open status; and
  - (2) Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Authority. These areas shall:
    - (a) Be marked prior to the placing of any shellstock;
    - (b) Remain marked until the Authority reopens the area and gives written permission to harvest shellstock; and
    - (c) Be adequately separated from the shellstock in adjacent waters to prevent cross-contamination and commingling.

### **Requirement for Harvesters.**

#### **.01 Harvester License Required.**

- A. Any person who wants to relay shellstock or to harvest shellstock from a growing area classified as conditionally approved, restricted, or conditionally restricted shall make application to the Authority for a valid license to relay or to harvest shellstock.
- B. No person shall relay shellstock or shall harvest shellstock for low acid canned food processing without a valid harvester license from the Authority.

**Section II. Model Ordinance****Chapter VI. Shellfish Aquaculture**

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**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.
- C.

**@.04 Shellfish Gardening.**

If a state recognizes shellfish gardening the Authority:

- A. Shall permit or register shellfish gardening activities.
- B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.
- C. 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. May require that the 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. 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;
  - (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.
- 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.**

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.**

- 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 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) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

#### **.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.
- C. 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.

**National Shellfish Sanitation Program  
2009 NSSP Guide for the Control of Molluscan Shellfish****Section II. Model Ordinance****Chapter VII. Wet Storage in Approved and Conditionally  
Approved Growing Areas**

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**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 permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.
- B. The Authority shall approve and maintain the following records while the wet storage activity continues:
  - (1) Construction and remodeling plans for any permitted wet storage facility;
  - (2) Wet storage operational plans;
  - (3) Wet storage permits; and
  - (4) Inspection documentation.
- C. The Authority shall inspect wet storage activities at the following frequency:
  - (1) Activities in offshore natural bodies of water at least annually;
  - (2) Activities at land-based sites with flow-through systems at least every six months; and
  - (3) Activities at land-based sites with recirculating systems semi-annually.
- D. The Authority shall immediately notify (within 24 hours) all wet storage permit holders affected by a change in growing area classification or status.
- E. Reshippers shall not engage in wet storage activities.

**Requirements for the Dealer.****.01 Source of Shellstock.**

- A. Dealers shall wet store shellstock harvested only from areas classified as approved, or conditionally approved, in the open status.
- B. Shellstock shall be harvested, identified and shipped to the wet storage activity in accordance with the requirements of Chapters VIII and IX.

**.02 General.**

- A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. Wet storage shall be deemed a processing activity.
- B. Wet storage of depurated product shall occur only within the facility in which it was depurated. The shellstock shall be packed and labeled according to the requirements in Chapter XV.
- C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.
- D. While awaiting placement in a wet storage activity, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.

- E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.
- F. Shellstock from a wet storage activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII, IX, and X.
- G. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the original harvest location and wet storage location, and include the dates the shellstock were held in wet storage. The records shall be maintained for a minimum of one year.
- H. Unless the dealer is in the Authority's commingling plan under Chapter I .01 F., different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

**.03 Wet Storage Sites in Natural Bodies of Water (Offshore).**

- A. Natural bodies of waters used for wet storage shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
  - (1) Subjected to relaying or depuration prior to human consumption; or
  - (2) Held in the wet storage site until the area is returned to the open status.
- B. Site evaluations of natural bodies of water shall include:
  - (1) The sanitary survey of the storage site, with special consideration of potential intermittent sources of pollution;
  - (2) The location of storage sites and/or floats;
  - (3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock; and
  - (4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.
- C. Different lots of shellstock shall not be commingled in wet storage. If more than one lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

**.04 Wet Storage in Artificial Bodies of Water (Land-Based).**

- A. General
  - (1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII .01 and .02.
  - (2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @ .01. B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer.
  - (3) Prior to commencing construction, all plans for construction or remodeling of wet storage facilities shall be reviewed and authorized by the Authority.
  - (4) The wet storage facility evaluation shall include a review of:
    - (a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
    - (b) Any species specific physiological factors that may affect design criteria; and
    - (c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system.
- B. Operation Specifications.

- (1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.
  - (a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
  - (b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
    - (i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
    - (ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
  - (c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
  - (d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.
- (2) Buildings. When a building is used for the wet storage activity:
  - (a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and
  - (b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.
- (3) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:
  - (a) Prevent entry of birds, animals or vermin; and
  - (b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. Wet Storage Source Water

- (1) General.
  - (a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.
  - (b) Any well used as source water for wet storage shall meet the requirements of Chapter XI. 02 (with the exception of the salt content in salt water wells).
  - (c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.
  - (d) Results of water samples and other tests to determine the suitability of the source water supply shall be maintained for at least 2 years.
  - (e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock's survival, quality or activity during wet storage.
  - (f) Disinfected process water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water and acceptable for use with marine water and follow the protocol of the Decision Tree (Section IV. Guidance Documents Chapter III. 06.)
  - (g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group daily sampling shall be immediately instituted until the problem is identified and eliminated.
  - (h) When the problem that is causing disinfected process water to show positive results for the coliform group is eliminated, the effectiveness of the correction shall be verified

- on the first operating day following correction through the collection, over a 24 hour period, of a set of three samples of disinfected process water.
- (i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.
  - (j) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.
- (2) Continuous Flow-through System.
- (a) If the system is of continuous flow-through design, water from a growing area classified as:
    - (i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or
    - (ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled and analyzed daily following disinfection.
  - (b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
    - (i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;
    - (ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
    - (iii) Use NSSP recognized methods to analyze the samples if determining coliform levels;
    - (iv) Require all samples of disinfected water to be negative for the coliform group; and
    - (v) Be repeated if any sample of disinfected process water during the study is positive for the coliform group.
  - (c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.
  - (d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.
- (3) Recirculating Water System.
- (a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in §C. (2) (b) above.
  - (b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group
  - (c) When make-up water of more than 10 percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected over a 24 hour period to reaffirm the ability of the system to produce process water free from the coliform group or viable bacteria.

(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Any deviation to this requirement is subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I @.01 F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage process water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

**Section II. Model Ordinance  
Chapter VIII. Control of Shellfish Harvesting**

Additional Guidance - Section IV Guidance Documents  
[Chapter II.08 Growing Area Patrol and Enforcement](#)  
[Chapter II.09 Control of Shellfish Harvesting](#)

**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 Control of Shellstock Growing Areas.****A. General**

- (1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only:
  - (a) From areas in an open status; and
  - (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification.
- (2) This program shall include:
  - (a) The patrol of growing areas;
  - (b) The licensing of harvesters;
  - (c) Enforceable legal penalties sufficient to encourage compliance; and
  - (d) Appropriate identification of harvest areas where shellstock harvest is not allowed.
- (3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with:
  - (a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and
  - (b) When requested, a current, comprehensive, itemized listing of all harvest areas including their geographic boundaries and their classification.

**B. Patrol of Growing Areas.**

- (1) The Authority shall assure that shellstock are harvested only as provided in this Chapter.
- (2) The Authority shall patrol harvest areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting. This patrol activity shall include consideration of the need for night, weekend, and holiday patrols. At a minimum, these growing areas shall be patrolled at the following frequencies, except as provided in B.(3), in order to ensure effective control:



<b>Risk Category</b>	<b>Minimum Frequency of Patrol</b>
Low	Four (4) times per 30 harvestable days
Medium	Eight (8) times per 30 harvestable days
High	Sixteen (16) times per 30 harvestable days

A patrol is accomplished when the majority of an area is monitored. No more than two patrols can be counted in a 24-hour period, and each must be a separate deliberate effort. A harvestable day refers to a day during which tidal, weather and other conditions make it possible to harvest shellfish. When tidal, weather, or other conditions prohibit harvesting on a particular day, that day is not included in the 30-day period.

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity, as demonstrated by one of the following methods:

a. pH, salinity, temperature, or turbidity are not favorable to the growth of shellfish; or

b. The water bottom does not support shellfish growth; or

c. The area has been depleted of shellfish by dredging, disease, or other means;

(ii) Harvest from the area is not economically feasible (i.e., the cost of harvesting exceeds the market value of the product)

(iii) The area meets all of the following conditions:

a. The area is unclassified;

b. Historically there has not been interest in commercial harvesting;

c. Known points of pollution do not exist; and

d. The Authority has current evidence that commercial harvesting does not occur.

This can be accomplished by information gathered from periodic patrols or reliable non-patrol sources.

(b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g. racks, bags, lantern nets, long lines and/or floats) are used in the area: The area shall be patrolled at the frequencies specified in §B.

(2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency of one (1) time per 30 harvestable days. The Risk Management Plan at least should include the following:

(i) Description of the area;

(ii) Classification of the area;

(iii) Description of adjacent growing areas;

(iv) Procedure used to prevent shellfish from prohibited or closed waters to be commingled with shellfish from an aquaculture area; and

(v) If, the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(c) If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential for marketing the shellfish is severely restricted:

- (i) The area shall be patrolled at the frequencies specified in § B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and the area should be patrolled at least one (1) time per 30 harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:
- a. Description of the area;
  - b. Classification of the area;
  - c. Description of adjacent growing areas; and
  - d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.
- (ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the Management Risk Plan should be reevaluated.
- (d) Where the entire state is closed to harvesting during traditional non-harvesting seasons:
- (i) The area shall be patrolled at the frequencies specified in § B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:
- a. Description of the area;
  - b. Classification of the area;
  - c. Description of adjacent growing areas; and
  - d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.
- (ii) The area shall be patrolled in low risk areas at least once (1) per 30 harvestable days, for medium risk areas at least twice (2) per 30 harvestable days, and for high-risk areas at least four (4) times per 30 harvestable days.
- (iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the state agency shall resume patrol at the frequency specified in B. (2).
- (4) The Risk Category for an area shall be determined as follows:
- (a) Shellfish Productivity. Estimate the abundance of shellfish based on density studies, historical information, and environmental conditions described in B.(3)(a). Consider only commercially marketable species. The descriptions below refer to the range of productivity within the state. The area shall be rated based on the highest density in any portion of the growing area.
    - (i) Low Production - 1
    - (ii) Medium Productivity - 3
    - (iii) High Productivity - 5
  - (b) Ease of Harvest. Determine the method used to harvest the shellfish. If multiple harvest techniques are used in an area, select the one with the highest score.

- (i) Highly mechanized requiring expensive equipment, deep water, difficult harvest - 1
  - (ii) Restricted access aquaculture relative shallow water dredging - 2
  - (iii) Scuba diving, tonging, bullraking - 3
  - (iv) Hand collection from a boat - 4
  - (v) Hand collection, no special tools or boat - 5
- (c) Difficulty of Patrol. Determine the difficulty of patrol. If the difficulty varies in an area, select the description with the highest score.
- (i) Resource within sight of population and a normal patrol route. Patrol Officer can observe illegal harvesting from the patrol vehicle - 1
  - (ii) Resource is near a shore and easily visible - 2
  - (iii) Moderate difficulty, deliberate effort is required to provide coverage to the area - 3
  - (iv) Long travel time to growing area, large open expanse of harvest area - 4
  - (v) Growing area is a marsh, short sight distance, canals system, extensive shoals - 5
- (d) Using the values determined in B.(4)(a), (b), and (c), calculate the total score for the area as follows:

Risk Factors	Score (1-5)	Weight	Rating	Explain Rating (optional)	Adjustment of Rating (if needed)
Shellfish Productivity (a)		0.40			
Ease of Harvest (b)		0.40			
Difficulty of Patrol (c)		0.20			
			<b>Subtotal</b>		

The rating for each risk factor is calculated by multiplying the risk factor score by the weight for that factor. The subtotal is calculated by adding all three of the risk factor ratings.

- (e) The following criteria should be used to adjust the rating, if warranted:
- (i) If a community-policing program is in place, the subtotal may be reduced by up to 0.25 points. If such a program leads to frequent citations, the subtotal may be reduced by up to 0.5 points. Community policing may include but is not limited to telephone hot lines, out-reach programs, financial incentives, local law enforcement activities not covered by B.(5), or private security arrangements.
  - (ii) If specialized equipment is available to the patrol agency, the subtotal may be reduced by up to 0.40 points. The actual reduction should be dependent upon the type of equipment that is available and its frequency of use. For example, frequent use of an aircraft can warrant a 0.4 point reduction, and frequent use of night vision or periodic use of aircraft can warrant a 0.2 point reduction.
  - (iii) If a growing area is conditionally managed or is poorly marked, the subtotal may be increased by up to 0.2 point. Adding or subtracting the appropriate adjustment(s) calculates the total score.

(f) The following risk categories shall be applied to the total score:

Total Score	Risk Category
less than 3	Low
3 or less than 4	Medium
4 or greater	High

(5) The Authority may delegate patrol activity to any State or local enforcement authority. If patrol activities are delegated, the Authority shall:

(a) Develop a Memorandum of Agreement with the delegated agency to assure that patrol requirements are met; and

(b) Require the delegated agency to maintain and file records of its patrol activities consistent with those required in B.(7).

(6) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:

(a) Basic law enforcement training, before assuming their patrol duties;

(b) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;

(c) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

(7) The Authority shall prepare and revise, as necessary, a patrol policy document which records the Authority's patrol organization and its activities to deter illegal shellstock harvesting. This documentation shall include:

(a) Citation of the law providing the legal basis for enforcement authority;

(b) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;

(c) The organizational structure of the unit responsible for patrol activities, including:

(i) Patrol unit(s) name, address, and phone number;

(ii) The roster and chain of command;

(iii) Area assignments that support the frequencies of patrol delineated in B.(2); and

(iv) A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in B.(2);

(d) Summaries of training in shellfish patrol techniques;

(e) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;

(f) A listing of growing areas where patrol is required;

(g) An identification of any patrol problems;

(h) The type and frequency of reporting by patrol personnel;

(i) Copy of agreements with other agencies responsible for shellfish control activities; and

(j) Citations/summons for the past year. If available, this information may include:

(i) The number of convictions or dismissals;

(ii) Fines in dollar amount;

(iii) Equipment or property confiscations and forfeitures;

(iv) License suspensions or revocations; and

(v) Jail sentences; and

(vi) Written warnings.

(8) Upon request by FDA, the Authority shall provide any available documentation that is used to support the determination that the patrol program was effective in providing the

required frequency of patrol. Ordinarily, this does not include providing reports not normally maintained by the Authority.

- (9) To comply with the Standardized Evaluation Criteria, the Authority shall:
- (a) Have a patrol policy document (Key item);
  - (b) Update patrol documents every year (Key item);
  - (c) Meet NSSP patrol training requirements (Key item);
  - (d) Patrol all areas that require patrol (Critical item);
  - (e) Meet NSSP requirements for frequency of patrol (Key item);
  - (f) Have formalized Memorandum of Agreement with other agency per Chapter VIII@.01B(5) (Key item);
  - (g) Have a risk management plan per Chapter VIII@.01B(3)(b)(c)(d) (Critical item); and
  - (h) Have a complete risk management plan per Chapter VIII@.01B(3)(b)(c)(d) (Other item).

C. Licensing of Harvesting.

- (1) The Authority shall assure that a license is required to commercially harvest shellstock, including shellstock harvested from aquaculture.
- (2) Each license shall:
- (a) Not be valid for more than one year;
  - (b) Require the harvester to sell only to dealers listed on the Interstate Certified Shellfish Shippers List; and
  - (c) Allow the harvester, at his discretion, to place shellstock in containers for transport of shellstock from a growing area to land or to a dealer.
- (3) A license to harvest shall not allow a harvester to engage in shellstock packing or engage in independent wet storage activities as defined in this Ordinance unless the harvester is a certified shellfish dealer and has a Wet Storage Permit issued by the Authority.
- (4) In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the Authority shall require a riparian owner or lessee to be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.
- (5) When a person has a special license to harvest shellstock for depuration, the Authority may not require individuals working under the supervision of the licensed harvester to have their own license.
- (6) The Authority shall inform each licensed harvester as to:
- (a) The classification and current status assigned to each growing area; and
  - (b) The methods used to notify harvesters of changes in growing area status or classification.
- (7) When the Authority authorizes shellstock relaying under Chapter V. or shellstock depuration under Chapter XV., the Authority shall issue special licenses to harvesters for the taking of shellfish from areas classified as restricted, conditionally restricted, or in the closed status of the approved or conditionally approved classification. The licenses shall specify the limitations and conditions for harvesting shellstock including requirements for the harvester to keep records which:
- (a) For depuration:
    - (i) Specify the date and amount of shellstock harvested from each area; and
    - (ii) Record the name of the depuration facility to which the shellstock was consigned or sold; and
  - (b) For relaying, meet the requirements of Chapter V.03D.
- (8) The Authority shall maintain a record of all licenses and special licenses issued.

D. Identification of Certain Growing Areas.

- (1) The Authority shall chart, describe, and mark the boundaries of growing areas classified as restricted, conditionally restricted, or prohibited, or in a closed status. The boundary descriptions shall:
    - (a) Be marked by fixed objects or landmarks; or
    - (b) Be described in a manner which allows easy recognition; and
    - (c) Allow successful prosecution of any illegal commercial harvesting activity.
  - (2) The Authority:
    - (a) Shall notify harvesters of the boundaries established under §D.(1) by dissemination of information with licenses, publication, or direct notification including registered mail; and
    - (b) May use warning signs.
- E. Prohibited Classification. The Authority shall exercise effective supervision over each depletion or seed gathering operation and maintain complete written documentation.

## Requirements for Harvesters

### .01 General.

- A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.
- B. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.
- C. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

### .02 Shellstock Harvesting and Handling.

- A. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall:
  - (1) Be a dealer; or
  - (2) Pack shellstock for a dealer.
- B. Non-Vessel Harvesting

Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition.

- C. Vessels.
  - (1) The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.
    - (a) Decks and storage bins shall be constructed and located to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
    - (b) Bilge pump discharges shall be located so that the discharge shall not contaminate shellstock.
    - (c) Containers used for storing shellstock shall be clean and fabricated from safe materials.
    - (d) Boat decks and storage bins used in the harvest or transport of shellstock for direct marketing shall be:

- (i) Kept clean with potable water or water from a growing area in the approved classification or in the open status of the conditionally approved classification; and
    - (ii) Provided with effective drainage.
  - (e) Vessels and all other equipment coming in contact with shellstock during handling or transport for relaying or depuration shall be thoroughly cleaned before the vessels or equipment are used to transport or handle shellfish for direct marketing.
  - (f) When necessary, effective coverings shall be provided on harvest boats to protect shellstock from exposure to:
    - (i) Hot sun;
    - (ii) Birds; and
    - (iii) Other adverse conditions.
  - (2) Cats, dogs, and other animals shall not be allowed on vessels.
- D. Disposal of Human Sewage from Vessels.
  - (1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.
  - (2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.
  - (3) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.
  - (4) Portable toilets shall:
    - (a) Be used only for the purpose intended;
    - (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
    - (c) Be emptied only into a sewage disposal system;
    - (d) Be cleaned before being returned to the boat; and
    - (e) Not be cleaned in equipment used for washing or processing food.
  - (5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:
    - (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
    - (b) Meet the requirements in §D.(3).
- E. Shellstock Washing.
  - (1) Shellstock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable.
  - (2) The harvester shall be primarily responsible for washing shellstock.
  - (3) If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility.
  - (4) Water used for shellstock washing shall be obtained from:
    - (a) A potable water source; or
    - (b) A growing area in the:
      - (i) Approved classification; or
      - (ii) In the open status of the conditionally approved classification.
  - (5) If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI.02.A.(3) and Chapter XIII.02.A.(3).
- F. Shellstock Identification.
  - (1) Each harvester shall affix a tag to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.
  - (2) If the shellstock was harvested at more than one location, each container shall be tagged at its growing area.

- (3) When the harvester is also the dealer, the harvester has the option to tag the shellfish with a harvester's tag or a dealer's tag meeting the requirements outlined in X. §05.
- (4) The harvester's tags shall:
  - (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
  - (b) Be at least 13.8 square inches (89.03 cm<sup>2</sup>) in size.
- (5) The harvester's tag shall contain the following indelible, legible information in the order specified below:
  - (a) The harvesters' identification number as assigned by the Authority;
  - (b) The date of harvest;
  - (c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
  - (d) The type and quantity of shellstock; and
  - (e) The following statement in bold capitalized type on each tag  
**"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."**
- (6) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.02 F.
- (7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities.
  - (a) When shellstock are harvested from one harvest area on a single day, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, or other container and the unit tagged with a single tag in accordance with the requirements of §.02 F.
  - (b) In addition to the information required in §.02 F. the unit tag shall also include:
    - (i) A statement that "All shellstock containers in this lot have the same harvest data and area of harvest"; and
    - (ii) Number of individual containers in the unit.
- (8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.02 F. with the addition of the name of the consignee.

### **.03 Shellstock Temperature Control.**

**Note: The Authority shall select one of the following options for implementation in its State. The time-temperature matrix for each of the options applies only to the original harvester or harvester/dealer of shellstock for the purposes of handling and transporting shellstock to the first point of processing or packing.**

#### **OPTION 1**

*(Mandatory for confirmed *Vibrio vulnificus* problem) If the waters of a State have been confirmed as an original source of product associated with two (2) or more *Vibrio vulnificus* illnesses, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below only for shellfish intended to be consumed raw.*



- A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at 50 degrees Fahrenheit (10 degrees Centigrade) or less.

Time-Temperature Matrix for <i>Vibrio vulnificus</i> :		
Action Level	Water Temperature	Maximum Hours from Exposure to Temperature Control
Level 1	<65 °F	36 hours
Level 2	65 °F - 74 °F (18 °C - 23 °C)	14 hours
Level 3	>74 °F - 84 °F (>23 °C - 28 °C)	12 hours
Level 4	> 84 °F (>28 °C)	10 hours

- B. The Authority shall establish the water temperature to be applied in the matrix above for each growing area by averaging the previous 5 years maximum monthly water temperatures.
- C. The time to refrigeration in the above matrix shall be based upon the first shellstock harvested.
- D. During Action Levels 2, 3, and 4, the product shall be shaded.
- E. The Authority may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in the above matrix.
- F. The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest processed with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.
- G. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

**OPTION 2**

If a growing area in the State has been confirmed as an original source of product associated with two (2) or more *Vibrio parahaemolyticus* illnesses within the past three years, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below or use Option 1. This *Vibrio parahaemolyticus* control measure applies only to shellfish from the affected growing area(s) which are intended to be consumed raw.

For the purposes of this control measure, identify and define growing areas in the State affected by *Vibrio parahaemolyticus* based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.

- A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at 50 °Fahrenheit (10 °Centigrade) or less.
- B. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.
- C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.

- D. The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest treated with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.
- E. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

<b>Time-Temperature Matrix for <i>Vibrio parahaemolyticus</i>:</b>		
<b>Action Level</b>	<b>Average Monthly Maximum Air Temperature</b>	<b>Maximum Hours from Exposure to Temperature Control</b>
<b>Level 1</b>	<66 °F (18 °C)	36 hours
<b>Level 2</b>	66 °F - 80 °F (19 °C - 27 °C)	12 hours
<b>Level 3</b>	≥81 °F (≥27 °C)	10 hours

**OPTION 3**

For those states that do not have to follow Option 1 or Option 2, the following time/temperature matrix will apply.

- A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50 °Fahrenheit (10 °Centigrade) or less.
- B. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.
- C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.
- D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

<b>Action Level</b>	<b>Average Monthly Maximum Air Temperature</b>	<b>Maximum Hours from Exposure to Temperature Control</b>
<b>Level 1</b>	<66 °F (18 °C)	36 hours
<b>Level 2</b>	66 °F - 80 °F (19 °C - 27 °C)	24 hours
<b>Level 3</b>	≥81 °F (≥27 °C)	20 hours

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**Requirements for the Authority**

**@.01 General.**

- A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.
- B. The Authority shall assure that:
  - (1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and
  - (2) Shellfish shipments originate from a dealer.
- C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.
- D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.

**@.02 Shipment Acceptability.**

Shellfish shipments shall be considered acceptable when:

- A. Shipments are properly identified with tags and/or labels and shipping documents;
- B. Shellstock is alive and cooled to an internal shellstock body temperature of 50° Fahrenheit (10 ° Centigrade) or less;
- C. Shucked shellfish and in-shell product are cooled to a temperature of 45° Fahrenheit (7.2 ° Centigrade) or less; and
- D. The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2 ° Centigrade) but the shellstock internal body temperature is 50 ° Fahrenheit (10 ° Centigrade) or less; and
- E. All other conditions of shipment in this Chapter are met.

Additional Guidance - Section IV Guidance Documents

[Chapter II.12 Bacteriological Examination of Shellfish Shipments Decision Tree](#)

**@.03 Shipment Rejection.**

- A. Shellfish shall be rejected when:
  - (1) Shellfish are not properly identified with tags or shipping documents;
  - (2) The internal shellstock body temperature exceeds 60° Fahrenheit (15.6 Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;
  - (3) Shucked shellfish temperature or the internal body temperature of in-shell product exceeds 50° Fahrenheit (10° Centigrade); or
  - (4) The Authority determines that the product is unwholesome or unsafe for human consumption.

- B. The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.

**@.04 Bacteriological Examination of Shellfish Shipments.**

If the State chooses to sample, the following protocol shall be used.

- A. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering a State.
- B. Bacteriological examination shall be made of the shellfish shipment if:
  - (1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10° Centigrade) and is less than or equal to 60° Fahrenheit (15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII @.03;
  - (2) The shucked shellfish temperature or the internal body temperature of in-shell product exceeds 45° Fahrenheit (7.2° Centigrade) and is less than or equal to 50° Fahrenheit (10° Centigrade);
  - (3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or
  - (4) The Authority determines it is necessary.

**Requirements for the Harvester/Dealer**

**.01 Trucks or Other Vehicles Used to Transport Shellstock to the Original Dealer.**

- A. The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
- B. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be:
  - (1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and
  - (2) Provided with effective drainage.
- C. Shellstock shall be transported in adequately refrigerated trucks when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
- D. Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
- E. When mechanical refrigeration units are used, the units shall be:
  - (1) Equipped with automatic controls; and
  - (2) Capable of maintaining the ambient air temperature in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
- F. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI.02A.(2).
- G. Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

**.02 Receiving Shellfish**

- A. The dealer shall reject or discard any shellfish shipments which:
  - (1) Do not originate from a licensed harvester or dealer; and/or
  - (2) Are unwholesome, inadequately protected, or whose source cannot be identified.
- B. Transportation agents or common carriers used by a dealer are not required to be certified.
- C. The dealer shall:
  - (1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;
  - (2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;
  - (3) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;
  - (4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and
  - (5) Ensure that frozen shellfish remain frozen.
- D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.

**.03 Transportation Containers.**

- A. All containers used to transport shellstock shall be:
  - (1) Constructed to allow for easy cleaning; and
  - (2) Operated and maintained to prevent product contamination.
- B. All containers shall be cleaned with:
  - (1) Potable water; and
  - (2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

**.04 Cargo Protection From Cross Contamination.**

- A. General. All containers used for storing shellfish shall be clean and fabricated from safe materials.
- B. Shellfish Cargo Only.
  - (1) The entire cargo shall consist of shellfish products only.
  - (2) Except for bulk shipments, shellstock shipments shall be shipped on pallets.
  - (3) In-shell product shipments shall be shipped on pallets.
  - (4) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.
- C. Mixed Cargoes. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when:
  - (1) Shellfish products are protected from contamination by the other cargo;
  - (2) All cargo is placed on pallets; and
  - (3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.
- D. Ice. Any ice used to cool shellfish shall meet the requirements of Chapter XI.02A.(2).

**.05 Shipping Times.**

- A. Shipping Time is No More Than Four Hours.
  - (1) When the shipping time is four hours or less, the dealer shall ship all shellfish:
    - (a) Well iced; or
    - (b) Using other acceptable means of refrigeration.
  - (2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
  - (3) The dealer shall not be required to provide thermal recorders during shipment.
  - (4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.
- B. Shipping Time is Greater Than Four Hours.
  - (1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:
    - (a) Mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less; or
    - (b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
  - (2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.
  - (3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.
  - (4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.
  - (5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.
  - (6) An inoperative temperature-indicating device shall be considered as no recording device.

**Section II. Model Ordinance****Chapter X. General Requirements for Dealers****.01 General HACCP Requirements**

- A. Hazard Analysis. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in Chapters XI., XII., XIII., XIV., and XV.
- B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:
- (1) Each location where shellfish products are processed by that dealer; and
  - (2) Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in §.01 C. are identical for all shellfish products so grouped or for all production methods so grouped.
- C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum:
- (1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with §.01 A. and that thus must be controlled for each shellfish product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:
    - (a) Natural toxins;
    - (b) Microbiological contamination;
    - (c) Chemical contamination;
    - (d) Pesticides;
    - (e) Drug residues;
    - (f) Unapproved use of direct or indirect food or color additives; and
    - (g) Physical hazards;
  - (2) List the critical control points for each of the identified food safety hazards, including as appropriate:
    - (a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during and after harvest. At a minimum, the critical control points shall include those identified in Chapter XI .01, Chapter XII .01, Chapter XIII .01, Chapter XIV .01 and Chapter XV .01, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving which shall always be considered as a critical control point
    - (b) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may

(c) establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in Chapter XI .01 A., Chapter XII .01 A., Chapter XIII .01 A., Chapter XIV .01 A., and Chapter XV .01 A., as applicable.

(d) Critical control points shall be designed to ensure that shellstock received with restricted use tags is processed consistent with the slated purpose. For Shellstock tagged for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified Dealer with the restricted use tag or processed consistent with the slated purpose.

(3) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Chapter XI .01, Chapter XII .01, Chapter XIII .01, Chapter XIV .01 and Chapter XV .01, as applicable. As an alternative the dealer may establish other critical limits which the dealer has demonstrated provide equivalent public health protection with the exception of receiving which shall always be considered as a critical control point. In any case, the critical limits identified in Chapter XI .01, Chapter XII .01, Chapter XIII .01, Chapter XIV .01, and Chapter XV .01 shall be met as components of good manufacturing practices.

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(5) Include any corrective action plans that have been developed in accordance with § .01 F. (2), to be followed in response to deviations from critical limits at critical control points.

(6) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and frequency thereof, that the dealer will use in accordance with §.01 G. (1).

D. Signing and Dating the HACCP Plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer.

(2) The HACCP plan shall be signed and dated:

(a) Upon initial acceptance;

(b) Upon any modification; and

(c) Upon verification of the plan in accordance with §.01 G. (1) (a).

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §.02 they need not be included in the HACCP plan, and vice versa.

F. Corrective Actions.

(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation, or

(b) Following the procedures in §.01 F. (3).

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with §.01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and



- (b) The cause of the deviation is corrected.
- (3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:
  - (a) Segregate and hold the affected product, at least until the requirements of Section .01 F. (3) (b) and (c) are met;
  - (b) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §.01 I.;
  - (c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
  - (d) Take corrective action, when necessary, to correct the cause of the deviation;
  - (e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §.01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.
- (4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §.01 G. and the record keeping requirements of §.01 H.

G. Verification.

- (1) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:
  - (a) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §.01 I. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §.01 C.
  - (b) Ongoing verification activities including:
    - (i) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
    - (ii) The calibration of process-monitoring instruments; and
    - (iii) At the option of the dealer, the performing of periodic end product or in-process testing.
  - (c) A review, including signing and dating, by an individual who has been trained in accordance with § .01 I., of the records that document:
    - (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made;
    - (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §.01 F. This review shall occur within one (1) week of the day that the records are made; and
    - (iii) The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic end product or in process testing that is

part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(2) Dealers shall immediately follow the procedures in §.01 F. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with §.01 G. (1) (b) (ii) and (iii) shall be documented in records that are subject to the record keeping requirements of §.01 H.

#### H. Records.

(1) All records required by §.01 and §.02 shall include:

- (a) The name and location of the dealer;
  - (b) The date and time of the activity that the record reflects;
  - (c) The signature or initials of the person performing the operation; and
  - (d) Where appropriate, the identity of the product and the production code, if any.
- Processing and other information shall be entered on records at the time that it is observed.

(2) All records required by §.01 and §.02 shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.

(3) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility.

(4) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.

(5) All records required by §.01 and §.02 and HACCP plans required by §.01 B. and §.01 C. shall be available for official review and copying at reasonable times.

(6) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of Chapter X .05.

(7) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

#### I. Training.

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the SSCA or who is otherwise qualified through job experience to perform these functions:

- (a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of §.01 C.;
- (b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in §.01 F. (3) (e), and the HACCP plan in accordance with the verification activities specified in § .01 G. (1) (a); and
- (c) Performing the record review required by §.01 G. (1) (c).

- (2) Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Authority.
- (3) The trained individual need not be an employee of the dealer.

Additional Guidance - Section IV Guidance Documents  
[Chapter III.01 Shellfish Industry Equipment Construction Guide](#)

### **.02 General Sanitation Requirements.**

- A. Sanitation Monitoring. Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformance with the requirements specified in Chapter XI .02, Chapter XII .02, Chapter XIII .02, Chapter XIV .02 and Chapter XV .02. The requirements specified in these Sections relate to the following sanitation items:
- (1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of Water for Processing and Ice Production;
  - (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and Cleanliness of Food Contact Surfaces;
  - (3) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of Cross Contamination;
  - (4) Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities;
  - (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from Adulterants;
  - (6) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper Labeling, Storage, and Use of Toxic Compounds;
  - (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of Employees with Adverse Health Conditions; and
  - (8) Exclusion of pests from the food plant hereinafter referred to as: Exclusion of Pests.

While monitoring of those specified conditions and practices (listed in 1-8) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

- B. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by §.02 A. These records are subject to the requirements of §.01 H.
- C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP Plan, required by §.01 B. However, to the extent that they are monitored in accordance with §.02 A. they need not be included in the HACCP Plan, and vice versa.

Additional Guidance - Section IV Guidance Documents

[Chapter V. Illness Outbreak Investigation and Recall, .02 Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak](#)

### **.03 Other Model Ordinance Requirements.**

- A. Each dealer shall comply with the requirements specified in Chapter XI .03, Chapter XII .03, Chapter XIII .03, Chapter XIV .03 and Chapter XV .03 that are appropriate to the plant and the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated.
- B. Recalls.
  - (1) Dealers shall adopt written procedures for conducting recalls of adulterated misbranded shellfish products. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy, (2002 NSSP Guide for the Control of Molluscan Shellfish, Federal Regulations).
  - (2) Dealers shall follow their written recall procedures to include timely notification of the SSCA of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product.

Additional Guidance - IV Guidance Documents

[Chapter III .04 Shellstock Tagging](#)

### **.04 Certification Requirements.**

- A. General.
  - (1) No person shall act as a dealer prior to obtaining certification.
  - (2) Any person who wants to be a dealer shall:
    - (a) Make application to the Authority for certification;
    - (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.
  - (3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.
- B. Types of Certification.
  - (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.
  - (2) Repacker.
    - (a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;
    - (b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;
    - (c) A repacker shall not shuck shellfish.
  - (3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.
  - (4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.

**.05 Shellstock Identification.**

*[Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags will supersede the tagging requirements in §.05.]*

A. General.

(1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:

- (a) Shipped; or
- (b) Emptied to wash, grade or pack the shellstock.

(2) When the dealer is also the harvester and he elects not to use a harvest tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment.

B. Tags.

(1) The dealers' tags shall:

- (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
- (b) Be at least 13.8 square inches (89.03 cm<sup>2</sup>) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:

- (a) The dealer's name and address.
- (b) The dealer's certification number as assigned by the Authority.
- (c) The original shellstock shipper's certification number. If deperated the original shellstock shipper's certification number is not required.
- (d) The harvest date; or if deperated, the date of deperation processing, or if wet stored, the original harvest date, and the final harvest date which is the date removed from wet storage.
- (e) If wet stored or deperated, the wet storage or deperation cycle or lot number. The wet storage lot number shall begin with the letter "w".
- (f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriated geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
- (g) The type and quantity of shellstock.
- (h) The following statement in bold capitalized type on each tag:  
**"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."**
- (i) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."
- (j) The statement "Keep Refrigerated" or an equivalent statement.

(3) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05 B. If the shellstock is received bearing a restricted use tag all specific use language shall be transferred to the new shipping tag.

(5) Country of origin information (USDA 2004) may be included on the dealer tag.

- (6) When shellstock intended for retail sale are packed in containers of 5 pounds or less and shipped in a master container which includes a tag in compliance with Chapter X .05 B. (1) the individual containers of 5 pounds or less shall not require tags as specified in Chapter X .05 B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the shellfish back to the lot of shellstock it is part of.
- (7) If a source state as defined in Chapter II. @ 04 A. selects to implement Chapter II. @ 04 C. (6) (a), the statement "For shucking by a certified shucker-packer" or an equivalent statement shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer for the purpose of shucking only.
- C. Bulk Tagging Lots of Shellstock for Sales Between Dealers.
- (1) When a single lot of shellstock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net bailer, or other container and the unit tagged with a single tag in accordance with §.05 B. (1-4).
- (a) This bulk tagging provision shall not apply to sales to reshippers;
  - (b) The shipment must be accompanied by a transaction record stating the name of the consignee who must be a certified dealer;
  - (c) In addition to the information required in §.05 b. (1-4) the unit tag shall also include:
    - (i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and
    - (ii) Number of individual containers in the unit.
- D. Tagging of a Lot of Shellstock During Intermediate Processing.
- (1) When the shellstock is removed from the original container, the dealer shall:
- (a) Keep the harvester tag for 90 days;
  - (b) Keep track of the growing area and date of harvest for shellstock; and
  - (c) Maintain the lot identity of all shellstock during any intermediate stage of processing.
- (2) A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.
- (3) In order for a dealer to tag a lot container (e.g. a pallet) of shellstock in lieu of meeting the requirement in §.05 B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority, which establishes the procedures, the dealer shall use to tag the lot during the washing, packing or staging of shellfish.
- (4) Unless the dealer is included in the Authority's commingling plan under Chapter I @.01 F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by:
- (a) A harvester's or dealer's tag which meets the requirements of §.05 B.; or
  - (b) A tag for each lot of shellstock that contains the following information:
    - (i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";
    - (ii) Harvest date;
    - (iii) Growing area;
    - (iv) Original dealer certification number; and
    - (v) Number of individual containers in each lot of shellstock container (e.g. a pallet) after washing, packing or staging has been completed.
- (5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant.

- E. All restricted use shellstock shall include a tag containing all information required in § .05 of Model Ordinance Chapter X. In addition the tag will include specific language detailing the intended use of the shellstock.
- F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.07 B. with the addition of the name of the consignee.

#### **.06 Shucked Shellfish Labeling.**

##### **A. Shellfish Labeling.**

- (1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers.
- (2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:
  - (a) The original shucker-packer's name and certification number;
  - (b) The shucking date; and
  - (c) The quantity of shellfish per container and the total number of containers.
- (3) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.
- (4) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.
- (5) The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish.
- (6) The dealer shall label each individual package containing less than 64 fluid ounces of fresh or fresh frozen shellfish with the following:
  - (a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life;
  - (b) The date shall consist of the abbreviation for the month and number of the day of the month; and
  - (c) For fresh frozen shellfish, the year shall be added to the date.
- (7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following:
  - (a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;
  - (b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and
  - (c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).
- (8) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.
- (9) If the dealer freezes fresh shucked shellfish, the dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of the shellfish and the year shall be added to the date (for non-Julian format).
- (10) If the dealer uses lot codes to track shellfish containers, the lot codes shall be distinct and set apart from any date listed on the container.
- (11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: "Consuming raw or

undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.”

- B. Shucked Shellfish. If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with §.06 except that the original date of shucking shall be added to the new repacked container as specified in §A. (7) or the original date of shucking shall be used in establishing the SELL BY DATE as specified in §A.(6).

#### **.07 In-Shell Product or Post Harvest Processed In-Shell Labeling**

- A. The dealer shall label all in-shell product with tags meeting the requirements of Chapter X .05. B. (1).
- B. In-Shell Product Tags.
- (1) The dealer tag on in-shell product shall contain the following indelible, legible information in the order specified below:
- (a) The dealer's name and address;
  - (b) The dealer's certification number as assigned by the Authority;
  - (c) The original shellstock shipper's certification number. If deperated the original shellstock shipper's certification number is not required;
  - (d) A “SELL BY DATE” which is a reasonable subsequent shelf-life or the words “BEST IF USED BY” followed by a date when the product would be expected to reach the end of its shelf-life. The date shall include, month, day and year;
  - (e) If deperated, the deperation cycle number or lot number;
  - (f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
  - (g) When the in-shell product has been transported across state lines and placed in wet storage in a dealer's operation, the statement: **“THIS PRODUCT IS A PRODUCT OF (NAME AND STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)”**;
  - (h) The type and quantity of in-shell product; and
  - (i) The following statement in bold capitalized type on each tag: **“THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.”**
  - (j) All in-shell product intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."
  - (k) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.
- (2) If the in-shell product is removed from the original container, the tag on the new container shall meet the requirements in §.07B.
- (3) Country of origin information (USDA 2004) may be included on the shucker-packer or reshipper tag.
- (4) When in-shell product intended for retail sale are packed in containers of 5 pounds or less and shipped in a master container which includes a tag in compliance with Chapter X .05 B. (1), the individual containers of 5 pounds or less shall not require tags as specified in Chapter X .05 B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the in-shell shellfish back to the lot of in-shell



product it is part of. Consumer advisory information identified in Chapter X .07 B. (1) (j) shall be included on each retail package.

NOTE: The Consumer Advisory shall be required for both A and B.

**.08 Shipping Documents and Records.**

A. Shipping Documents.

- (1) Each shellfish shipment shall be accompanied by a shipping document.
- (2) The shipping document shall contain:
  - (a) The name, address, and certification number of the shipping dealer;
  - (b) The name and address of the major consignee; and
  - (c) The kind and quantity of the shellfish product.
- (3) The receiving dealer shall:
  - (a) Maintain in his files a copy of the completed shipping document; and
  - (b) Make the shipping document available to the Authority upon request.
- (4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.

B. Transaction and Shipping Records.

- (1) Each dealer shall have a business address at which transaction records are maintained.
- (2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
  - (a) Document that the shellfish are from a source authorized under this Ordinance;
  - (b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
  - (c) Permit a lot (or commingled lots as per Chapter I. @.01. F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.
  - (d) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.
- (3) Purchase and sales shall be recorded:
  - (a) In a permanently bound ledger book; or
  - (b) Using other recording methods acceptable to and authorized by the Authority. Entries of purchases or sales of shellfish shall be made into a permanently bound ledger book, computer record, or other method acceptable to and authorized by the authority within 72 hours of any purchase or sales.
- (4) The transaction records shall be retained:
  - (a) In the case of fresh shellfish, for a minimum of one year; and
  - (b) In the case of frozen shellfish, for at least two years or the shelf life of the product, whichever is longer.
- (5) If computer records are maintained, the Authority shall approve the format and its use.

**National Shellfish Sanitation Program  
2009 NSSP Guide for the Control of Molluscan Shellfish****Section II. Model Ordinance  
Chapter XI. Shucking and Packing****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 Heat Shock.**

- A. The Authority shall approve the scheduled process for heat shock. The schedule may be developed by the Authority or qualified persons with adequate facilities for conducting the appropriate studies;
- B. The Authority shall assure that the critical factors, which may affect the heat shock process, have been adequately studied and provided for in establishing the process. The critical factors shall include:
  - (1) Type and size of shellfish;
  - (2) Time and temperature of exposure;
  - (3) Type of process;
  - (4) Size of tank, tunnel or retort;
  - (5) Water to shellfish ratios in tanks; and
  - (6) Temperature and pressure monitoring devices;
- C. The Authority shall assure that heat shock process does not:
  - (1) Change the physical and organoleptic properties of the species;
  - (2) Kill the shellfish prior to shucking; and
  - (3) Increase microbial deterioration of the shucked shellfish.
- D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.

Additional Guidance - Section IV Guidance Documents  
[Chapter II.15 Decision Tree for Shellfish from Non-MOU Countries](#)

**Requirements for Dealers.****.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only:
  - (1) Shellstock obtained from a licensed harvester who has:
    - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and [C]
    - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or [C]
  - (2) Shellstock obtained from a dealer other than the original harvester who has:

- (a) Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C]; and
  - (b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. [C]
- (3) In-shell product obtained from a dealer who has:
  - (a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperature or less; and [C]
  - (b) Identified the in-shell product with a tag on each container [C]
- B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
  - (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and [C]
  - (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
    - (a) Iced; or [C]
    - (b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and [C]
    - (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. [C]
- C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
  - (1) Iced; or [C]
  - (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]
- D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
  - (1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. [C]
  - (2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within four hours of removal from refrigeration. [C]
  - (3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. [C]
  - (4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two hours from time of heat shock. [C]
  - (5) For in-shell product the internal temperature of meats does not exceed 45°F (7.2°C) for more than 2 hours during processing. [C]
- E. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. [C]
- F. Shellstock Shipping Critical Control Point.
  - (1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

## .02 Sanitation.

- A. Safety of Water for Processing and Ice Production.

Additional Guidance - Section IV Guidance Documents

[Chapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide](#)

- (1) Water Supply.
    - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
    - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
      - (i) Prior to use of the water supply; [C]
      - (ii) Every six months while the water supply is in use; and [K]
      - (iii) After the water supply has been repaired and disinfected. [S<sup>C/K</sup>]
  - (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall be made on-site from potable water in a commercial ice machine;[C]
  - (3) Shellstock Washing.
    - (a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]
    - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
      - (i) Obtain approval for the construction or remodeling of the system from the Authority. [K]
      - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]
      - (iii) Test bacteriological water quality daily; [S<sup>C/K</sup>]
    - (c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
  - (4) Plumbing and Related Facilities.
    - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
      - (i) Prevent contamination of water supplies; [C]
      - (ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]
- B. Condition and Cleanliness of Food Contact Surfaces.
- (1) Equipment and utensil construction for food contact surfaces.
    - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guidelines*. [K]
    - (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
      - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]

- (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and [K]
  - (iii) Fabricated from food grade materials. [K]
- (c) The dealer shall assure that all joints on food contact surfaces
  - (i) Have smooth easily cleanable surfaces and [K]
  - (ii) Are welded. [K]
- (d) Shucking blocks shall be provided which are:
  - (i) Easily cleanable; [K]
  - (ii) Fabricated from safe material; [K]
  - (iii) Solid, one piece construction; and [K]
  - (iv) Easily removed from the shucking bench, unless the block is an integral part of the bench. [K]
- (e) The dealer shall provide a temperature measuring device accurate to +/- 2° Fahrenheit for use in monitoring product temperatures. [K]
- (f) All equipment used in heat shock processing shall meet the requirements of Chapter XI.02B.(1)(a), (b), and (c). [K]
- (g) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1)(a), (b), and (c). [K]
- (h) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
  - (i) Is easily accessible for cleaning and inspection; [K]
  - (ii) Is self draining; and [K]
  - (iii) Meets the requirements for food contact surfaces. [K]
- (2) Cleaning and sanitizing of food contact surfaces.
  - (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
    - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; [K]
    - (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]
    - (iii) Wash and rinse equipment and utensils at the end of each day. [K]
  - (b) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. [K]
  - (c) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. [K]
  - (d) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination:
    - (i) Fabricated from food grade materials; and [K]
    - (ii) Stored in a manner which assures their protection from contamination. [K]
  - (e) If used, the finger cots or gloves shall be:
    - (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]
    - (ii) Sanitized at least twice daily; [K]
    - (iii) Cleaned more often, if necessary [K];
    - (iv) Properly stored until used; and [K]
    - (v) Maintained in a clean, intact, and sanitary condition. [K]

C. Prevention of Cross Contamination.

(1) Protection of Cross Contamination.

- (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S<sup>C/K</sup>]
- (b) Shellfish shall be protected from contamination. [S<sup>C/K</sup>]
- (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K]
- (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S<sup>K/0</sup>]

(2) Separation of operations.

- (a) Facilities for shucking and packing activities shall be separated by use of:
  - (i) Separate rooms; [K]
  - (ii) Partitions; or [K]
  - (iii) Sufficient spacing. [K]
- (b) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]

(3) Employee practices.

- (a) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering. [K]
- (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
  - (i) Before starting work; [K]
  - (ii) After each absence from the work station; [K]
  - (iii) After each work interruption; and [K]
  - (iv) Any time when their hands may have become soiled or contaminated. [K]
- (c) Any employee handling shucked shellfish shall be required to:
  - (i) Wear effective hair restraints; [O]
  - (ii) Remove any hand jewelry that cannot be sanitized or secured; [O]
  - (iii) Wear finger cots or gloves if jewelry cannot be removed; and [O]
  - (iv) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]
  - (v) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
    - a. Store clothing or other personal belongings; [O]
    - b. Eat or drink; [K]
    - c. Spit; and [K]
    - d. Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

- (1) Handwashing facilities with warm water at a minimum temperature of 100° F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [S<sup>K/0</sup>]
- (2) Handwashing facilities shall be provided which are:
  - (a) Convenient to work areas; [O]
  - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
  - (c) Directly plumbed to an approved sewage disposal system, and [S<sup>O/K</sup>]
  - (d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
- (3) The dealer shall provide at least one handsink in the packing room. [O]
- (4) The dealer shall provide at each handwashing facility:
  - (a) Supply of hand cleansing soap or detergent; [K]

- (b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
- (c) Easily cleanable waste receptacle; and [O]
- (d) Handwashing signs in a language understood by the employees; [O]
- (5) Sewage [C] and liquid disposable wastes shall be properly removed from the facility [K]
- (6) The dealer shall provide:
  - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
  - (b) An adequate number of conveniently located, toilets [K]
  - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S<sup>K/O</sup>]
- E. Protection from Adulterants.
  - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. [K]
  - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
  - (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. [K]
  - (4) Protection of ice used in shellfish processing.
    - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S<sup>C/K</sup>]
    - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S<sup>C/K</sup>]
    - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
  - (5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. [S<sup>K/C</sup>]
  - (6) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]
  - (7) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]
- F. Proper Labeling, Storage and Use of Toxic Compounds.

Additional Guidance - Section IV Guidance Documents

[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

- (1) Storage of toxic compounds.
  - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
  - (b) Each of the following categories of toxic substances shall be stored separately:
    - (i) Insecticides and rodenticides/; [K]
    - (ii) Detergents, sanitizers, and related cleaning agents; and [K]
    - (iii) Caustic acids, polishes, and other chemicals. [K]
  - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]

- (2) Use and labeling of toxic compounds.
  - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
  - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. [K]
  - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. [K]
  - (d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]
- G. Control of Employees with Adverse Health Conditions
  - (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
    - (a) Norovirus
    - (b) Hepatitis A virus,
    - (c) *Shigella* spp.,
    - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
    - (e) *Salmonella typhi*;
  - (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
    - (a) Has any of the following symptoms:
      - (i) Vomiting
      - (ii) Diarrhea,
      - (iii) Jaundice,
      - (iv) Sore throat with fever, or
      - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
    - (b) Has an illness diagnosed by a health practitioner due to:
      - (i) Norovirus
      - (ii) Hepatitis A virus,
      - (iii) *Shigella* spp.,
      - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
      - (v) *Salmonella typhi*;
    - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
    - (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
      - (i) Norovirus within the past 24 hours of the last exposure:



- (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
    - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
  - (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. Within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
    - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]
- H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

### .03 Other Model Ordinance Requirements.

#### A. Plants and Grounds.

- (1) General.
  - (a) The physical facilities shall be maintained in good repair. [O]
- (2) Flooding.
  - (a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]
  - (b) If facilities are flooded:
    - (i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]
    - (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]
- (3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S<sup>C/K</sup>]
- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.
  - (a) Tight fitting, self closing doors: [K]

- (b) Screening of not less than 15 mesh per inch; **[K]** and
- (c) Controlled air current. **[K]**.
- (5) Plant Interior.
  - (a) Sanitary conditions shall be maintained throughout the facility. **[O]**
  - (b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**
  - (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
    - (i) Are graded to provide adequate drainage; **[O]**
    - (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**
    - (iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**
  - (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.
- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
  - (a) Rodent attraction and harborage; and **[O]**
  - (b) Inadequate drainage. **[O]**
- B. Plumbing and Related Facilities.
  - (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks; **[K]**
  - (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
    - (a) Used in shellfish storage; **[K]**
    - (b) Used for food holding units **[K]** (e.g. refrigeration units);
    - (c) Cleaned by hosing, flooding, or similar methods **[K]**; and
    - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**
  - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[S<sup>C/K</sup>]**
  - (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**
- C. Utilities.
  - (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[S<sup>C/K</sup>]**
  - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S<sup>C/K</sup>]**
- D. Disposal of Other Wastes.
  - (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**
  - (2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. **[O]**
  - (3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and **[O]**
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.

- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced. [O]
  - (2) The dealer shall use easily cleanable, corrosion-resistant impervious materials, free from cracks to construct:
    - (a) Shucking benches and contiguous walls; and [O]
    - (b) Stands or stalls and stools for shucker. [O]
    - (c) Any non-food contact surfaces in shellfish storage or handling areas. [O]
  - (3) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches. [O]
  - (4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. [K]
  - (5) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellfish Storage and Handling.  
The dealer shall:
- (1) Assure that shellstock is:
    - (a) Reasonably free of sediment [O]; and
    - (b) Culled; [K]
  - (2) Assure shucking buckets are completely empty at the packing room so that no overage is returned to the shucker; [K]
  - (3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock; [K]
  - (4) Not allow the use of dip buckets for hand or knife rinsing; [K]
  - (5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; [K]
  - (6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. [K]
  - (7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room; [K]
  - (8) Conduct packing activities so as to conform to applicable food additive regulations; [K]
  - (9) During storage frozen shellfish shall be maintained frozen. [S<sup>K0</sup>]
  - (10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. [K]
- G. Heat Shock. A dealer may elect to use heat shock to prepare shellstock for shucking.
- (1) The dealer shall:
    - (a) Post the schedule for the heat shock process in a conspicuous location; and [K]
    - (b) Make sure all responsible persons are familiar with requirements. [K]
    - (c) Cool all hot dipped shellstock immediately after the heat shock process [K]. This cooling shall be accomplished by:
      - (i) Dipping in a ice bath; or [K]
      - (ii) Use of flowing potable water. [K]
  - (2) If a heat shock tank is used, and the water is maintained at or above 140°F degrees the dealer shall completely drain and flush the tank at the end of each day's operation so that all the mud and debris which have accumulated in the dip tank are eliminated. If the temperatures are maintained below 140°F degrees, the dealer shall completely drain and flush the tank at three hour intervals. [K]

H. Supervision.

- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**
- (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**
- (3) All supervisors shall be:
  - (a) Trained in proper food handling techniques and food protection principles; and **[K]**
  - (b) Knowledgeable of personal hygiene and sanitary practices **[K]**
- (4) The dealer shall require:
  - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**
  - (b) Supervisors to assure that proper sanitary practices are implemented, including:
    - (i) Plant and equipment clean-up; **[K]**
    - (ii) Rapid product handling; and **[K]**
    - (iii) Shellfish protection from contamination. **[K]**
  - (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**
  - (d) Employees shall:
    - (i) Be trained in proper food handling and personal hygiene practices, and **[K]**
    - (ii) Report any symptoms of illness to their supervisor. **[K]**

Additional Guidance - Section IV Guidance Documents  
[Chapter II.15 Decision Tree for Shellfish from Non-MOU Countries](#)

**.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
  - (1) Originated from a dealer who has:
    - (a) Shipped the shellfish iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature; [C] and
    - (b) Identified the shellfish with a label as outlined in Chapter X.06. [C]
- B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° F (7.2° C) for more than 2 hours. [C]
- C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45 ° F (7.2 ° C) or less or covered in ice. [C]

**.02 Sanitation.**

- A. Safety of Water for Processing and Ice Production.
  - (1) Water Supply.
    - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
    - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
      - (i) Prior to use of the water supply; [C]
      - (ii) Every six months while the water supply is in use; and [K]
      - (iii) After the water supply has been repaired and disinfected. [S<sup>C/K</sup>]
  - (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall be made on-site from potable water in a commercial ice machine; or [C]
  - (3) Plumbing and Related Facilities.
    - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
      - (i) Prevent contamination of water supplies; [C]
      - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]

Additional Guidance - Section IV Guidance Documents  
[Chapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide](#)

A. Condition and Cleanliness of Food Contact Surfaces.

- (1) Equipment and utensil construction for food contact surfaces.
  - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides*. [K]
  - (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
    - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]
    - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and [K]
    - (iii) Fabricated from food grade materials. [K]
  - (c) The dealer shall assure that all joints on food contact surfaces
    - (i) Have smooth easily cleanable surfaces and [K]
    - (ii) Are welded [K]
  - (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). [K]
  - (e) The dealer shall provide a temperature measuring device accurate to +/- 2° Fahrenheit for use in monitoring product temperatures.
- (2) Cleaning and sanitizing of food contact surfaces.
  - (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
    - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; [K]
    - (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]
    - (iii) Wash and rinse equipment and utensils at the end of each day. [K]
  - (b) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. [K]
  - (c) Shucked shellfish shall be packed in clean covered containers:
    - (i) Fabricated from food grade materials; and [K]
    - (ii) Stored in a manner which assures their protection from contamination. [K]
  - (d) If used, the finger cots or gloves shall be:
    - (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]
    - (ii) Sanitized at least twice daily; [K]
    - (iii) Cleaned more often, if necessary [K];
    - (iv) Properly stored until used; and [K]
    - (v) Maintained in a clean, intact, and sanitary condition. [K]

B. Prevention of Cross Contamination.

- (1) Protection of shellfish.
  - (a) Shucked shellfish shall be protected from contamination. [S<sup>C/K</sup>]
  - (b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S<sup>K/O</sup>]
- (2) Employee practices

- (a) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness. [K]
  - (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
    - (i) Before starting work; [K]
    - (ii) After each absence from the work station; [K]
    - (iii) After each work interruption; and [K]
    - (iv) Any time when their hands may have become soiled or contaminated. [K]
  - (c) Any employee handling shucked shellfish shall be required to:
    - (i) Wear effective hair restraints; [O]
    - (ii) Remove any hand jewelry that cannot be sanitized or secured; [O]
    - (iii) Wear finger cots or gloves if jewelry cannot be removed [O]
    - (iv) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]
    - (v) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
      - a. Store clothing or other personal belongings; [O]
      - b. Eat or drink; [K]
      - c. Spit; and [K]
      - d. Use tobacco in any form. [K]
- C. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
- (1) Handwashing facilities with warm water at a minimum temperature of 100°F (37.8°C) dispensed from a hot and cold mixing or combination faucet shall be provided. [S<sup>K/0</sup>]
    - (a) Handwashing facilities shall be provided which are:
      - (i) Convenient to work areas; [O]
      - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
      - (iii) Directly plumbed to an approved sewage disposal system, and [S<sup>O/K</sup>]
      - (iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
    - (b) The dealer shall provide at least one handsink in the packing room. [O]
    - (c) The dealer shall provide at each handwashing facility:
      - (i) Supply of hand cleansing soap or detergent; [K]
      - (ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
      - (iii) Easily cleanable waste receptacle; and [O]
      - (iv) Handwashing signs in a language understood by the employees; [O]
  - (2) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility.
  - (3) The dealer shall provide:
    - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area. [K]
    - (b) An adequate number of conveniently located, toilets [K]
    - (c) An adequate supply of toilet paper at each toilet facility [K] in a suitable holder. [S<sup>K/0</sup>]
- D. Protection from Adulterants.
- (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. [K]
  - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in area where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]

- (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**
  - (4) Protection of ice used in shellfish processing:
    - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[S<sup>C/K</sup>]**
    - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[S<sup>C/K</sup>]**
    - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**
  - (5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[S<sup>K/C</sup>]**
  - (6) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. **[K]**
- E. Proper Labeling, Storage and Use of Toxic Compounds.
- (1) Storage of toxic compounds.
    - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**
    - (b) Each of the following categories of toxic substances shall be stored separately:
      - (i) Insecticides and rodenticides; **[K]**
      - (ii) Detergents, sanitizers, and related cleaning agents; and **[K]**
      - (iii) Caustic acids, polishes, and other chemicals. **[K]**
    - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**
  - (2) Use and labeling of toxic compounds.
    - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**
    - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**
    - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**
    - (d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. **[K]**

Additional Guidance - Section IV Guidance Documents

[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

A. Control of Employees with Adverse Health Conditions

- (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: **[K]**



- (a) Norovirus
  - (b) Hepatitis A virus,
  - (c) *Shigella* spp.,
  - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
  - (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
- (a) Has any of the following symptoms:
    - (i) Vomiting
    - (ii) Diarrhea,
    - (iii) Jaundice,
    - (iv) Sore throat with fever, or
    - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
  - (b) Has an illness diagnosed by a health practitioner due to:
    - (i) Norovirus
    - (ii) Hepatitis A virus,
    - (iii) *Shigella* spp.,
    - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
    - (v) *Salmonella typhi*;
  - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
  - (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
    - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
  - (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
    - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]

- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]
- B. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

**.03 Other Model Ordinance Requirements.**

- A. Plants and Grounds.
- (1) General.
- (a) The physical facilities shall be maintained in good repair. [O]
- (2) Flooding.
- (a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]
- (b) If facilities are flooded:
- (i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]
- (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]
- (3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S<sup>C/K</sup>]
- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.
- (a) Tight fitting, self closing doors: [K]
- (b) Screening of not less than 15 mesh per inch; [K] and
- (c) Controlled air current. [K].
- (5) Plant Interior.
- (a) Sanitary conditions shall be maintained throughout the facility. [O]
- (b) All dry area floors shall be hard, smooth, easily cleanable; and [O]
- (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
- (i) Are graded to provide adequate drainage; [O]
- (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O]
- (iii) Have sealed junctions between floors and walls to render them impervious to water; and [O]
- (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials [O].
- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
- (a) Rodent attraction and harborage; and [O]

- (b) Inadequate drainage. [O]
- B. Plumbing and Related Facilities.
- (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks; [K]
- (2) Adequate floor drainage, including backflow prevention such as air gaps, shall be provided where floors are:
- (a) Used in shellfish storage; [K]
- (b) Used for food holding units [K] (e.g. refrigerations units);
- (c) Cleaned by hosing, flooding, or similar methods [K]; and
- (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. [K]
- (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S<sup>C/K</sup>]
- (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
- C. Utilities.
- (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S<sup>C/K</sup>]
- (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S<sup>C/K</sup>]
- D. Disposal of Other Wastes.
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
- (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; [O]
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-food Contact Surfaces
- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and [O]
- (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
- (3) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and non-food contact surfaces. [K]
- (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellfish Storage and Handling.
- (1) The dealer shall:
- (a) Not commingle shellfish from different lots; [K]
- (b) Repack shucked shellfish meats only into containers labeled with the authorized certification number; [K]
- (c) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source. [K]
- (d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. [K]
- (e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly; [K]

(f) Conduct repacking activities so as to conform to applicable food additive regulations; [K]

(g) During storage frozen shellfish shall be maintained frozen. [S<sup>K/0</sup>]

G. Heat Shock. N/A

H. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. [K]

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and [K]

(b) Knowledgeable of personal hygiene and sanitary practices. [K]

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant and equipment clean-up [K]

(ii) Rapid product handling; and [K]

(iii) Shellfish protection from contamination. [K]

(c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

(d) Employees shall:

(i) Be trained in proper food handling and personal hygiene practices, and [K]

(ii) Report any symptoms of illness to their supervisor. [K]

**National Shellfish Sanitation Program  
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**Section II. Model Ordinance  
Chapter XIII. Shellstock Shipping**

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*Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.*

**.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only:
  - (1) Shellstock obtained from a licensed harvester who has:
    - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]
    - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or [C]
  - (2) Shellstock obtained from a dealer other than the original harvester who has:
    - (a) Shipped the shellstock adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature or 50°F (10°) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less [C]; and
    - (b) Identified the shellstock with a tag on each container. [C]
  - (3) In-shell product obtained from a dealer who has;
    - (a) Shipped the in-shell product adequately iced; or in a conveyance or at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperature or less; and [C]
    - (b) Identified the in-shell product with a tag on each container. [C]
- B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
  - (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and [C]
  - (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
    - (a) Iced; or [C]
    - (b) Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and [C]
    - (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B(1) or §B (2) for more than 2 hours at points of transfer such as loading docks. [C]
- C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
  - (1) Iced; or [C]
  - (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]
- D. Shellstock Shipping Critical Control Point
  - (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

**.02 Sanitation.**

- A. Safety of Water for Processing and Ice Production.
  - (1) Water Supply.
    - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]

- (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
  - (i) Prior to use of the water supply; [C]
  - (ii) Every six months while the water supply is in use; and [K]
  - (iii) After the water supply has been repaired and disinfected. [S<sup>C/K</sup>]
- (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall be made on-site from potable water in a commercial ice machine; or [C]
- (3) Shellstock Washing.
  - (a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]
  - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
    - (i) Obtain approval for the construction or remodeling of the system from the Authority. [K]
    - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]
    - (iii) Test bacteriological water quality daily; [S<sup>C/K</sup>]
  - (c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
- (4) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
  - (a) Prevent contamination of water supplies; [C]
  - (b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source [C]
  - (c) The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]

Additional Guidance - Section IV Guidance Documents

[Chapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide](#)

B. Condition, and Cleanliness, of Food Contact Surfaces.

- (1) Equipment and utensil construction for food contact surfaces.
  - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides*. [K]
  - (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
    - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]
    - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and [K]
    - (iii) Fabricated from food grade materials. [K]
  - (c) The dealer shall assure that all joints on food contact surfaces

- (i) Have smooth easily cleanable surfaces and [K]
- (ii) Are welded [K]
- (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). [K]
- (e) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
  - (i) Is easily accessible for cleaning and inspection; [K]
  - (ii) Is self-draining; and [K]
  - (iii) Meets the requirements for food contact surfaces [K]
- (2) Cleaning and sanitizing of food contact surfaces.
  - (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
    - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; [K]
    - (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]
    - (iii) Wash and rinse equipment and utensils at the end of each day. [K]
  - (b) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. [K]
- (3) If used, the finger cots or gloves shall be:
  - (a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]
  - (b) Cleaned more often, if necessary [K];
  - (c) Properly stored until used; and [K]
  - (d) Maintained in a clean, intact, and sanitary condition. [K]

C. Prevention of Cross Contamination.

- (1) Protection of shellfish.
  - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S<sup>C/K</sup>]
  - (b) Shellfish shall be protected from contamination. [S<sup>C/K</sup>]
  - (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K]
  - (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S<sup>K/O</sup>]
- (2) Employee practices.
  - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
    - (i) Before starting work; [K]
    - (ii) After each absence from the work station; [K]
    - (iii) After each work interruption; and [K]
    - (iv) Any time when their hands may have become soiled or contaminated. [K]
  - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
    - (i) Store clothing or other personal belongings; [O]
    - (ii) Eat or drink; [K]
    - (iii) Spit; and [K]
    - (iv) Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

- (1) Handwashing facilities with warm water at a minimum temperature of 100° F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [S<sup>K/O</sup>]
  - (a) Handwashing facilities shall be provided which are:
    - (i) Convenient to work areas: [O]
    - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
    - (iii) Directly plumbed to an approved sewage disposal system, and [S<sup>O/K</sup>]
    - (iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
  - (b) The dealer shall provide at each handwashing facility:
    - (i) Supply of hand cleansing soap or detergent; [K]
    - (ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
    - (iii) Easily cleanable waste receptacle; and [O]
    - (iv) Handwashing signs in a language understood by the employees; [O]
- (2) Sewage [K] and liquid disposable wastes [K] shall be properly removed from the facility.
- (3) The dealer shall provide
  - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area. [K]
  - (b) An adequate number of conveniently located, toilets. [K]
  - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S<sup>K/O</sup>].

E. Protection from Adulterants.

- (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. [K]
- (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
- (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. [K]
- (4) Shellstock shall be packed in clean containers. [K]
- (5) Protection of ice used in shellfish processing.
  - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S<sup>C/K</sup>]
  - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S<sup>C/K</sup>]
  - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
- (6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. [S<sup>K/C</sup>]
- (7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

- (1) Storage of toxic compounds.



- (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
  - (b) Each of the following categories of toxic substances shall be stored separately:
    - (i) Insecticides and rodenticides; [K]
    - (ii) Detergents, sanitizers, and related cleaning agents; and [K]
    - (iii) Caustic acids, polishes, and other chemicals. [K]
  - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
- (2) Use and labeling of toxic compounds.
- (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
  - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. [K]
  - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. [K]
  - (d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use [K]

Additional Guidance - Section IV Guidance Documents

[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

G. Control of Employees with Adverse Health Conditions.

- (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
- (a) Norovirus
  - (b) Hepatitis A virus,
  - (c) *Shigella* spp.,
  - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
  - (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
- (a) Has any of the following symptoms:
    - (i) Vomiting
    - (ii) Diarrhea,
    - (iii) Jaundice,
    - (iv) Sore throat with fever, or
    - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
  - (b) Has an illness diagnosed by a health practitioner due to:
    - (i) Norovirus

- (ii) Hepatitis A virus,
- (iii) *Shigella* spp.,
- (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
- (v) *Salmonella typhi*;
- (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
- (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
  - (i) Norovirus within the past 24 hours of the last exposure;
  - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
  - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
  - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
- (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
  - (i) Norovirus within the past 24 hours of the last exposure;
  - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. Within the past 3 days of the last exposure;
  - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
  - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**

### .03 Other Model Ordinance Requirements.

#### A. Plants and Grounds.

- (1) General.
  - (a) The physical facilities shall be maintained in good repair. **[O]**
- (2) Flooding.
  - (a) Facilities in which shellfish are stored, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**
  - (b) If facilities are flooded:

- (i) Shellfish processing, repacking or shipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]
    - (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]
  - (3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S<sup>C/K</sup>]
  - (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.
    - (a) Tight fitting, self closing doors: [K]
    - (b) Screening of not less than 15 mesh per inch; [K] and
    - (c) Controlled air current. [K].
  - (5) Plant Interior.
    - (a) Sanitary conditions shall be maintained throughout the facility. [O]
    - (b) All dry area floors shall be hard, smooth, easily cleanable; and [O]
    - (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
      - (i) Are graded to provide adequate drainage; [O]
      - (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O]
      - (iii) Have sealed junctions between floors and walls to render them impervious to water; and [O]
    - (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials [O].
  - (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
    - (a) Rodent attraction and harborage; and [O]
    - (b) Inadequate drainage. [O]
- B. Plumbing and Related Facilities.
  - (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks; [K]
  - (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
    - (a) Used in shellfish storage; [K]
    - (b) Used for food holding units [K] (e.g. refrigeration units);
    - (c) Cleaned by hosing, flooding, or similar methods [K]; and
    - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. [K]
  - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S<sup>C/K</sup>]
  - (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
- C. Utilities.
  - (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S<sup>C/K</sup>]
  - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S<sup>C/K</sup>]

- D. Disposal of Other Wastes.
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
  - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.
- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and [O]
  - (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
  - (3) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. [K]
  - (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellfish Storage and Handling.
- (1) The dealer shall:
    - (a) Assure that shellstock is:
      - (i) Alive; [K]
      - (ii) Reasonably free of sediment [O]; and
      - (iii) Culled; [K]
  - (2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock; [K]
  - (3) A dealer whose activity consists of trucks or docking facilities only shall:
    - (a) Have a permanent business address at which records are maintained and inspections can be performed; and [K]
    - (b) Not repack shellstock. [K]
  - (4) A dealer who stores or repacks shellstock shall have:
    - (a) His own facility for proper storage or repacking of shellstock; or [K]
    - (b) Arrangements with a facility approved by the Authority of the storage or repacking of shellstock. [K]
  - (5) During storage frozen shellfish shall be maintained frozen. [S<sup>K/O</sup>]
- G. Heat Shock. - N/A
- H. Supervision.
- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
  - (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. [K]
  - (3) All supervisors shall be:
    - (a) Trained in proper food handling techniques and food protection principles; and [K]
    - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
  - (4) The dealer shall require:
    - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
    - (b) Supervisors to assure that proper sanitary practices are implemented, including:
      - (i) Plant and equipment clean-up; [K]
      - (ii) Rapid product handling; and [K]
      - (iii) Shellfish protection from contamination. [K]

- (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**
- (d) Employees shall:
  - (i) Be trained in proper food handling and personal hygiene practices, and **[K]**
  - (ii) Report any symptoms of illness to their supervisor. **[K]**

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**Section II. Model Ordinance  
Chapter XIV. Reshipping**

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*Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.*

**.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
  - (1) Originated from a dealer other than the original harvester who has:
    - (a) Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C]; and/or
    - (b) Shipped the shucked shellfish and/or in-shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; [C] and
    - (c) Identified the shellstock with a tag as outlined in Chapter X.05, identified the in-shell product with a tag as outlined in Chapter X .07, and/or identified the shucked shellfish with a label as outlined in Chapter X.06. [C]
- B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
  - (1) Iced; or [C]
  - (2) Placed in a storage area or conveyance maintained at 45 °F (7.2 ° C) or less; and [C]
  - (3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. [C]
- C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
  - (1) Iced; or [C]
  - (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]
- D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 ° F (7.2 ° C) or less.[C]
- E. Shellstock Shipping Critical Control Point
  - (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

**.02 Sanitation.**

- A. Safety of Water for Processing and Ice Production.
  - (1) Water Supply.
    - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations.[C]
    - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
      - (i) Prior to use of the water supply; [C]
      - (ii) Every six months while the water supply is in use; and [K]
      - (iii) After the water supply has been repaired and disinfected. [S<sup>C/K</sup>]

- (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:
  - (a) Be made on-site from potable water in a commercial ice machine; or [C]
- (3) Plumbing and Related Facilities.
  - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
    - (i) Prevent contamination of water supplies; [C]
    - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]
- B. Condition, and Cleanliness of Food Contact Surfaces.

Equipment and utensil construction for food contact surfaces. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). [K]
- C. Prevention of Cross Contamination.
  - (1) Protection of shellfish
    - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S<sup>C/K</sup>]
    - (b) Shellfish shall be protected from contamination. [S<sup>C/K</sup>]
    - (c) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S<sup>K/0</sup>]
  - (2) Employee practices.
    - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
      - (i) Before starting work; [K]
      - (ii) After each absence from the work station; [K]
      - (iii) After each work interruption; and [K]
      - (iv) Any time when their hands may have become soiled or contaminated. [K]
    - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
      - (i) Store clothing or other personal belongings; [O]
      - (ii) Eat or drink; [K]
      - (iii) Spit; and [K]
      - (iv) Use tobacco in any form. [K]
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
  - (1) Handwashing facilities with warm water at a minimum temperature of 100°F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [S<sup>K/0</sup>]
    - (a) Handwashing facilities shall be provided which are:
      - (i) Convenient to work areas; [O]
      - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
      - (iii) Directly plumbed to an approved sewage disposal system, and [S<sup>O/K</sup>]
      - (iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use. [K]
    - (b) The dealer shall provide at each handwashing facility:
      - (i) Supply of hand cleansing soap or detergent; [K]
      - (ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
      - (iii) Easily cleanable waste receptacle; and [O]
      - (iv) Handwashing signs in a language understood by the employees; [O]
  - (2) Liquid disposable wastes shall be properly removed from the facility [K]
  - (3) The dealer shall provide:

- (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; **[K]**
- (b) An adequate number of conveniently located, toilets **[K]**
- (c) Each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[S<sup>K/O</sup>]**
- E. Protection from Adulterants.
  - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**
  - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**
  - (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**
  - (4) Protection of ice used in shellfish reshipping.
    - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[S<sup>C/K</sup>]**
    - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[S<sup>C/K</sup>]**
    - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**
  - (5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[S<sup>K/C</sup>]**
- F. Proper Labeling, Storage and Use of Toxic Compounds.
  - (1) Storage of toxic compounds.
    - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**
    - (b) Each of the following categories of toxic substances shall be stored separately:
      - (i) Insecticides and rodenticides; **[K]**
      - (ii) Detergents, sanitizers, and related cleaning agents; and **[K]**
      - (iii) Caustic acids, polishes, and other chemicals. **[K]**
    - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**
  - (2) Use and labeling of toxic compounds.
    - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**
    - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**
    - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

Additional Guidance - Section IV Guidance Documents  
[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

- G. Control of Employees with Adverse Health Conditions.
  - (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in



contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]

- (a) Norovirus
  - (b) Hepatitis A virus,
  - (c) *Shigella* spp.,
  - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
  - (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
- (a) (a) Has any of the following symptoms:
    - (i) Vomiting
    - (ii) Diarrhea,
    - (iii) Jaundice,
    - (iv) Sore throat with fever, or
    - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
  - (b) Has an illness diagnosed by a health practitioner due to:
    - (i) Norovirus
    - (ii) Hepatitis A virus,
    - (iii) *Shigella* spp.,
    - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
    - (v) *Salmonella typhi*;
  - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
  - (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
    - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
  - (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. Within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
    - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a

- hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]
- H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

### .03 Other Model Ordinance Requirements.

#### A. Plants and Grounds.

- (1) General.
- (a) The physical facilities shall be maintained in good repair. [O]
- (2) Flooding.
- (a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]
- (b) If facilities are flooded:
- (i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]
- (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]
- (3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S<sup>C/K</sup>]
- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.
- (a) Tight fitting, self closing doors; [K]
- (b) Screening of not less than 15 mesh per inch; [K] and
- (c) Controlled air current. [K].
- (5) Plant Interior.
- (a) Sanitary conditions shall be maintained throughout the facility. [O]
- (b) All dry area floors shall be hard, smooth, easily cleanable; and [O]
- (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
- (i) Are graded to provide adequate drainage; [O]
- (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; and [O]
- (iii) Have sealed junctions between floors and walls to render them impervious to water.; and [O]
- (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials [O].
- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

- (a) Rodent attraction and harborage; and [O]
- (b) Inadequate drainage. [O]
- B. Plumbing and Related Facilities.
  - (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks. [K]
  - (2) Adequate floor drainage, including backflow preventer such as air gaps, shall be provided where floors are:
    - (a) Used in shellfish storage; [K]
    - (b) Used for food holding units (e.g. refrigeration units); [K]
    - (c) Cleaned by hosing, flooding, or similar methods [K]; and
    - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. [K]
  - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S<sup>C/K</sup>]
  - (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
- C. Utilities.
  - (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S<sup>C/K</sup>]
  - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S<sup>C/K</sup>]
- D. Disposal of Other Wastes.
  - (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
  - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.
  - (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and [O]
  - (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
  - (3) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and non food contact surfaces. [K]
  - (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellfish Storage and Handling.
  - (1) The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. [K]
  - (2) The dealer shall not:
    - (a) Commingle, sort, or repack shellfish; or [K]
    - (b) Remove or alter any existing tag or label. [K]
  - (3) A dealer whose activity consists of trucks only shall:
    - (a) Have his own facility for the storage of shellfish; or [K]
    - (b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and [K]
    - (c) Have a permanent business address at which records are maintained and inspections can be performed. [K]

- (4) During storage frozen shellfish shall be maintained frozen. [S<sup>K/O</sup>]
- G. Heat Shock. - N/A
- H. Supervision.
- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
  - (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. [K]
  - (3) All supervisors shall be:
    - (a) Trained in proper food handling techniques and food protection principles; and [K]
    - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
  - (4) The dealer shall require:
    - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
    - (b) Supervisors to assure that proper sanitary practices are implemented, including:
      - (i) Plant and equipment clean-up; [K]
      - (ii) Rapid product handling; and [K]
      - (iii) Shellfish protection from contamination. [K]
    - (c) Supervisors to not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
    - (d) Employees shall:
      - (i) Be trained in proper food handling and personal hygiene practices, and [K]
      - (ii) Report any symptoms of illness to their supervisor. [K]

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2009 NSSP Guide for the Control of Molluscan Shellfish****Section II. Model Ordinance  
Chapter XV. Depuration**

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**Note: In those States where depuration is not practiced, this Chapter may be deleted from the Ordinance, as well as references to depuration throughout the Ordinance.**

**Requirements for the Authority**

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

- A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
  - (1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;
  - (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
  - (3) Approve the design and construction of the depuration facility or activity including subsequent changes;
- B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.
- C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.
- D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.
- E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
  - (1) Inspection reports and reviews of the plant performance in accordance to §D. (above);
  - (2) Current Depuration Plant Operations Manual for each dealer (§.03).
- F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

**Requirements for the Dealer****.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall receive and depurate only shellstock which is:
  - (1) Obtained from a licensed harvester who has:
    - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and
    - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and
  - (2) Originates from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment; [C] and
  - (3) Obtained from a special licensed harvester who has:

- (a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and
  - (b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]
- B. Processing Critical Control Points - Critical Limits. The dealer shall assure that:
- (1) All depuration lots are treated for a minimum of 44 hours; [C] and
  - (2) The water treatment system is operating to design specifications; [C] and
  - (3) All critical limits established during verification of the specific depuration process are being met. [C]
- C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that:
- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; [C] and
  - (2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:
    - (a) Iced; [C] or
    - (b) Placed in a storage area or conveyance maintained at 45 °Fahrenheit (7.2 °Centigrade) or less; [C] and
    - (c) Not permitted to remain outside temperature control for more than 2 hours at points of transfer such as loading docks. [C]

## .02 Sanitation

- A. Safety of Water for Processing and Ice Production
- (1) Water Supply.
    - (a) Dealers shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
    - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
      - (i) Prior to use of the water supply; [C]
      - (ii) Every six months while the water supply is in use; [K] and
      - (iii) After any water supply has been repaired and disinfected. [S<sup>C/K</sup>]
  - (2) Ice production. Any ice used in the processing or storage of shellfish shall:
    - (a) Be made on-site from potable water in a commercial ice machine; [C] or
  - (3) Shellstock washing
    - (a) Water from either a potable water supply, a growing area in the approved classification, a saltwater well approved by the authority, or the restricted area at the time and place of harvest, shall be used to wash shellstock. [C]
    - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
      - (i) Obtain approval for the construction or remodeling of the system from the Authority; [K]
      - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing, which, after disinfection, meets the coliform standards for drinking water; and does not leave any unacceptable residues in the shellstock; [C]
      - (iii) Test wash water daily for bacteriological water quality; [S<sup>C/K</sup>]
      - (iv) Clean, service, and test disinfection units at the frequency necessary to ensure effective disinfection. [K]

- (c) The dealer may use ultra-violet (UV) disinfection in his recirculating wash water system, provided that the turbidity of the water to be disinfected:
  - (i) shall not exceed 20 nephelometric turbidity units (NTUs); [K] and
  - (ii) Is measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
- (d) Food contact plumbing which is designed and installed to permit effective cleaning and sanitization shall be used. [C]
- (4) Depuration Process Water. The dealer shall:
  - (a) Continuously treat process water with a disinfection system approved by the Authority that does not leave any unacceptable residue in the shellstock; [C] and
  - (b) Verify that the disinfection system produces process seawater with no detectable coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols.
    - (i) If the source water is an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch; [C]
    - (ii) If the source water is a restricted growing area, then:
      - a. A study meeting the requirements of Chapter VII. 04. C. is required; [C]
      - b. The tank influent produced by each disinfection unit is evaluated daily; [C] and
      - c. Source water prior to final disinfection must meet the water quality criteria for restricted for depuration in accordance with Chapter IV.02. G-H. [C]
    - (iii) If the source water is a recirculating water system, then:
      - a. A study meeting the requirements of Chapter VII. 04. C. [C] is required; and
      - b. The tank influent produced by each disinfection unit is verified daily. [C]
      - c. A prohibited growing area may not be used for source water. [C]
- (5) Plumbing and Related Facilities.
  - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
    - (i) Prevent contamination of water supplies; [C] and
    - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]
  - (b) Depuration Plant Design and Construction. The dealer shall ensure that:
    - (i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; [K]
    - (ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; [K]
    - (iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. [K]
- (6) Depuration unit
  - (a) Depuration unit including depuration tanks, all reservoir tanks, and related piping shall be fabricated from safe materials, and depuration unit construction is such that it:
    - (i) Is easily accessible for cleaning and inspection; [K]
    - (ii) Is self-draining; [K] and
    - (iii) Meets the requirements for food contact surfaces. [K]

Additional Guidance - Section IV Guidance Documents

[Chapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide](#)

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to Shellfish Industry Equipment Construction Guides (August 1993), U.S. Department of Health and Human Services. [K]

(b) The dealer shall use only equipment and utensils, including approved plastic ware which is:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces [K] and

(iii) Fabricated from food grade materials. [K]

(c) The dealer shall assure that all joints on food contact surfaces:

(i) have smooth easily cleanable surfaces; [K] and

(ii) are welded. [K]

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in §.02 B (1) (a), (b), and (c). [K]

(e) Shellstock washing tanks and related plumbing shall be fabricated from safe materials.

(i) Is easily accessible for cleaning and inspection: [K]

(ii) Meets requirements for food contact surfaces [K]

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses. [K]

(ii) Wash, rinse and sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]

(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]

(c) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K]

B. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S<sup>C/K</sup>]

(b) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment; [K]

(2) Separation of Operations: Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. [K]



- (3) Employee practices.
  - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
    - (i) Before starting work; [K]
    - (ii) After each absence from the work station; [K]
    - (iii) After each work interruption; [K] and
    - (iv) Any time when their hands may have become soiled or contaminated. [K]
  - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
    - (i) Store clothing or other personal belongings [O]
    - (ii) Eat or drink; [K]
    - (iii) Spit; and [K]
    - (iv) Use tobacco in any form. [K]
- C. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities
  - (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided; [S<sup>K/O</sup>]
  - (2) Handwashing facilities shall be provided which are:
    - (a) Convenient to work areas; [O]
    - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
    - (c) Directly plumbed to an approved sewage disposal system, and [S<sup>K/O</sup>]
    - (d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
  - (3) The dealer shall provide at each handwashing facility;
    - (a) Supply of hand cleansing soap or detergent; [K]
    - (b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
    - (c) Easily cleanable waste receptacle; and [O]
    - (d) Handwashing signs in a language understood by the employees; [O]
  - (4) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility.
  - (5) The dealer shall provide:
    - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
    - (b) An adequate number of conveniently located toilets. [K]
    - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S<sup>K/O</sup>]
- D. Protection from Adulterants.
  - (1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; [K]
  - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
  - (3) Conveyances or devices used to transport shellstock shall be constructed, maintained and operated to prevent contamination of the shellstock. If overhead monorails or conveyors are used, the dealer shall take precautions to assure that hydraulic fluids or lubricants do not leak or drip onto the shellstock or conveyance surfaces. [K]
  - (4) Adequate ventilation shall be provided to minimize condensation in areas where shellfish are stored, processed or packed. [S<sup>K/C</sup>]
  - (5) Shellstock packing activities shall be conducted to provide adequate protection from contamination and adulteration. [K]
  - (6) Protection of ice used in shellstock shipping.

- (a) Any ice which is not made on-site in the depuration facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S<sup>C/K</sup>]
- (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S<sup>C/K</sup>]
- (c) Any ice used in the processing, storage, or transport of shellstock shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
- (7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations; [K]
- (8) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]
- E. Proper Labeling, Storage and Use of Toxic Compounds.
  - (1) Storage of toxic compounds.
    - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
    - (b) Each of the following categories of toxic substances shall be stored separately:
      - (i) Insecticides and rodenticides; [K]
      - (ii) Detergents, sanitizers, and related cleaning agents; [K] and
      - (iii) Caustic acids, polishes, and other chemicals. [K]
    - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
  - (2) Use and labeling of toxic compounds.
    - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
    - (b) Cleaning compounds/supplies, detergents and sanitizing agents shall be used only in strict accordance with the manufacturer's label instructions and all applicable federal and state laws and regulations. [K]
    - (c) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. [K]
    - (d) Provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

Additional Guidance - Section IV Guidance Documents  
[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

- F. Control of Employees with Adverse Health Conditions.
  - (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
    - (a) Norovirus
    - (b) Hepatitis A virus,
    - (c) *Shigella* spp.,
    - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or

- (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
- (a) Has any of the following symptoms:
    - (i) Vomiting
    - (ii) Diarrhea,
    - (iii) Jaundice,
    - (iv) Sore throat with fever, or
    - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
  - (b) Has an illness diagnosed by a health practitioner due to:
    - (i) Norovirus
    - (ii) Hepatitis A virus,
    - (iii) *Shigella* spp.,
    - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
    - (v) *Salmonella typhi*;
  - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
  - (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
    - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
  - (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
    - (i) Norovirus within the past 24 hours of the last exposure;
    - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past 3 days of the last exposure;
    - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
    - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]

- G. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or where food handling equipment, utensils, and packaging materials are cleaned and stored. [K]

### .03 Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General

- (a) The physical facilities shall be maintained in good repair. [O]

(2) Flooding.

- (a) Facilities in which shellstock are stored, packed, or repacked shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]

(b) If facilities are flooded:

- (i) Shellstock processing or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized. [C]

- (ii) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. [C]

- (3) The dealer shall operate his/her facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from the facility and activities. [S<sup>C/K</sup>]

- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure insects and vermin are not present in the facility.

- (a) Tight fitting, self closing doors; [K]

- (b) Screening of not less than 15 mesh per inch; [K] and

- (c) Controlled air current. [K]

(5) Plant Interior.

- (a) Sanitary conditions shall be maintained throughout the facility. [O]

- (b) Interior surfaces are kept in good repair. [O]

- (c) All dry area floors are hard, smooth, easily cleanable and in good repair; [O] and

- (d) All wet area floors used in areas to store shellstock, food processing, and cleaning equipment are constructed of easily cleanable, impervious, and corrosion resistant materials which:

- (i) Are graded to provide adequate drainage; [O]

- (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O] and

- (iii) Have sealed junctions between floors and walls to render them impervious to water. [O]

- (e) Walls and ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials shall be constructed of easily cleanable, corrosion resistant, impervious and light colored materials. [O]

- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

- (a) Rodent attraction and harborage; [O]

- (b) Inadequate drainage. [O]

B. Plumbing and Related Facilities.

- (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks. [K]

- (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
    - (a) Used in shellstock storage; [K]
    - (b) Used for food holding units (e.g. refrigeration units); [K]
    - (c) Cleaned by hosing, flooding, or similar methods; [K] and
    - (d) Subject to the discharge of water or other liquid waste, including, if applicable, three compartment sinks, on the floor during normal activities; [K]
  - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S<sup>C/K</sup>]
  - (4) Installation of drainage or waste pipes over processing or storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
  - (5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials such that it:
    - (a) Is easily accessible for inspection. [K]
    - (b) Is self draining. [K]
- C. Utilities.
- (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S<sup>C/K</sup>]
  - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S<sup>C/K</sup>]
- D. Disposal of Wastes.
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
  - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. [O]
- E. Equipment Condition, Cleaning, Maintenance and Construction of Non-food Contact Surfaces.
- (1) The dealer shall use only equipment which is constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock. [O]
  - (2) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks, to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
  - (3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]
  - (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellstock Storage and Handling.
- (1) The dealer shall assure that shellstock is:
    - (a) Reasonably free of sediment; [O] and
    - (b) Culled. [K]
  - (2) Shellstock shall be stored in a protected location which assures complete and rapid drainage of water away from the shellstock by:
    - (a) Placing shellstock at an adequate height off the floor; [K] or
    - (b) Grading the floor. [O]
  - (3) Any mechanical refrigeration equipment used for shellstock storage shall be adequate in size and are equipped with:
    - (a) An automatic temperature regulating control; [K] and
    - (b) Installed thermometers to accurately measure temperature within the storage compartments. [K]

- (4) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. [K]
  - (5) Ensure that separate dry storage facilities are provided for depurated and undepurated shellfish. [K]
  - (6) Cull and wash the shellstock prior to loading into the depuration tanks. This process may occur before the shellstock is received at the facility by;
    - (a) Licensed harvester(s) at the harvest site; [K] or
    - (b) Certified dealer(s) at their certified facility. [K]
  - (7) Assure that culled shellfish are destroyed or disposed of in such a manner as to prevent their use for human food. [K]
  - (8) Transport, store, and handle shellstock so that:
    - (a) Shellstock potential for normal physiological activity during depuration is not compromised; [K] and
    - (b) Shellstock quality is not degraded. [K]
  - (9) Assure that different harvest lots of shellfish are not commingled during washing, culling, processing, or packing. If more than one harvest lot of shellfish is being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. [K]
  - (10) Wash and cull shellstock after depuration and pack the shellstock in clean shipping containers fabricated from safe materials. [K]
  - (11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45 °Fahrenheit (7.2 °Centigrade). [K]
- G. Heat Shock. N/A
- H. Supervision.
- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
  - (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. [K]
  - (3) All supervisors shall be:
    - (a) Trained in proper food handling techniques and food protection principles; [K] and
    - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
  - (4) The dealer shall require:
    - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, smoking and/or storing personal items and clothing at work stations. [K]
    - (b) Supervisors to assure that proper sanitary practices are implemented, including:
      - (i) Plant equipment clean up; [K]
      - (ii) Rapid product handling; [K] and
      - (iii) Shellstock protection from contamination. [K]
    - (c) Supervisors shall not allow unauthorized persons in those portions of the facility where shellfish are processed, handled, stored or packaged or where food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
    - (d) Employees
      - (i) shall be trained in proper food handling and personal hygiene practices, [K] and
      - (ii) shall report any symptoms of illness to their supervisor. [K]
- I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:
- (1) Introduction including;
    - (a) Status of document (to create, revise, or update DPOM);

- (b) Ownership and principal(s) involved with operation of facility;
  - (c) Address and phone number of owners and principles; and
  - (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
- (2) Description of the Facility including:
- (a) Site plan drawings;
  - (b) Facility layout including detailed schematic of the entire depuration system;
  - (c) Schematic drawing of process;
  - (d) Product flow diagram showing product movement through facility (may be combined with §01.B.(3));
  - (e) Statement that construction materials and fabrication will meet the requirements of §.03.E. (1) and (2); and
  - (f) Schematic of seawater delivery and distribution system.
- (3) Design Specifications of Depuration Unit including:
- (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
  - (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
  - (c) Shellfish containers construction and material meets §.04 and §.08 of this Chapter; and
  - (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.
- (4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
- (5) Depuration process monitoring including:
- (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
  - (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
  - (c) Process water monitoring protocol for physical and chemical parameters; and
  - (d) Data analysis and evaluation.
- (6) Standard Operating Procedure for:
- (a) Receiving and holding;
  - (b) Washing, culling, and placement of undepurated product in process tanks;
  - (c) Depuration unit operation;
  - (d) Monitoring of depuration unit operation;
  - (e) Removal of depurated product from process tanks;
  - (f) Storage parameters and procedures;
  - (g) Labeling/tagging procedures;
  - (h) Plant cleaning and sanitation; and
  - (i) Data analysis.
  - (j) Recall procedures.
- (7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
- (a) Shipping and receiving records;
  - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;

- (c) Maintenance and Sanitation Log(s);
- (d) Laboratory records;

J. Process

Verification.

The Dealer shall continually:

- (1) Routine Verification. Perform process verification on a continuous basis according to the following protocol:
  - (a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample;
    - (i) from each lot of restricted shellstock to be depurated in the depuration unit.
    - (ii) weekly from each lot of approved shellfish to be depurated in the depuration unit.
  - (b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90<sup>th</sup> percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
  - (c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

<b>Limits for Verification of Depuration Plant Performance</b>		
<b>Fecal coliform per 100 grams</b>		
<b>Species</b>	<b>Geometric Mean</b>	<b>90<sup>th</sup> Percentile</b>
Soft Clams ( <i>Mya arenaria</i> )	50	130
Hard Clams ( <i>Mercenaria mercenaria</i> )	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

- (d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.
- (e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.
- (2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:
  - (a) The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;
  - (b) Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may inhibit the physiological process and must be identified. The condition(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly;



- (c) Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:
- (i) Geometric mean (from three samples) of soft clams not to exceed 110 and no single sample to exceed 170; or
  - (ii) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.
- (d) If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:
- (i) The Authority, in consultation with the depuration processor, may order the destruction of the shellfish; or
  - (ii) The Authority, in consultation with the depuration processor, may allow non-food use of the shellfish; or
  - (iii) The Authority, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter V.
- (e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90<sup>th</sup> percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each harvest area used
- (i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.
  - (ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in XV§.03 J. (1).
  - (iii) If either the geometric mean or the 90<sup>th</sup> percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.
- (f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90<sup>th</sup> percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
- (i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.
  - (ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in §XV.03 J. (1).
  - (iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90<sup>th</sup> percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.

- (3) When depuration units with multiple tanks are used, it is necessary to determine whether the individual tanks are similar.
  - (a) Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.
  - (b) If they are not similar, then the process verification protocols contained in Section .03 J. (1) - (2) must be employed for each tank.
- (4) The dealer shall ensure that all microbiological assays of end-point samples of shellstock:
  - (a) Are analyzed by a laboratory which has been evaluated and approved pursuant to the requirements in Chapter III, using an NSSP-approved method;
  - (b) Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish); and
  - (c) Samples are collected at locations within the depuration unit that are considered to be most compromised as regards shellfish activity, based on the sampling plan contained in the Depuration Plant Operations Manual.

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2009 NSSP Guide for the Control of Molluscan Shellfish**

**Section II. Model Ordinance  
Chapter XVI. Post Harvest Processing**

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**Post-Harvest Processing**

- A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, and wishes to make labeling claims regarding the reduction of pathogens, the dealer shall:
- (1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process. The HACCP Plan shall include:
    - (a) Process controls to ensure that the end point criteria are met for every lot; and
    - (b) A sampling program to periodically verify that the end point criteria are met.
    - (c) Analytical results used for validation and verification of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements.

Additional Guidance - Section IV Guidance Documents  
[Chapter II. Growing Areas. 10 Approved NSSP Laboratory Tests](#)

- (2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens, Section .04 and be approved by the Authority, with concurrent of FDA.
    - (a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of *V. vulnificus* and/or *V. parahaemolyticus* levels must be done using the MPN protocols described in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 followed by confirmation using methods approved for use in the NSSP.
    - (b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.
  - (3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 as determined by the Authority and shall be reviewed annually by the Authority.
  - (4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subject to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.
  - (5) Keep records in accordance with Chapter X.07.
- B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:
- (1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

- (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
  - (3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
  - (4) A term that describes the type of process applied (e.g. "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B) (1)-(3).
- C. For the purposes of refrigeration, if the product is dead, the product shall be treated as shucked product. If the product is live, the product shall be treated as shellstock.