

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2007

Section II. Model Ordinance
Chapter I. Shellfish Sanitation Program

[Guide Contents](#)

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.]

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

@.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 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 shellstock included in the Authority's commingling plan, the Authority shall not permit the commingling of shellstock.
 - (2) If the Authority permits shellstock 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 shellstock harvested from specific growing areas within the State as identified by the Authority and purchased directly from harvesters; and
 - (e) Define how the commingled shellstock will be identified.

@.02 Dealer Certification.

A. General

- (1) A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria

Additional Guidance - Section IV Guidance Documents
[Chapter III .02 Shellfish Plant Inspection Standardization Procedures](#)
[NSSP Standardized Shellfish Processing Plant Inspection Form](#)

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.

Designations			
Certification		Permit	
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.