National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

This document is intended to provide guidance and shall supersede the 2003 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

2005 Revision

GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH

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National Shellfish Sanitation Program

Guide for the Control of Molluscan Shellfish

2005

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
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II. Model Ordinance

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°Centigrade) .

(16) **Commingle or Commingling** means the act of combining different lots of shellstock or shucked 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 (+ 2) hours in a water bath maintained at 112 $^{\circ}$ Fahrenheit (44.5 ± 0.2 $^{\circ}$ Centigrade).

(38) **FDA** means the United States Food and Drug Administration.

(39) **Food contact surface**
means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.

(40) **Food Safety Hazard**
means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(41) **Geometric Mean** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).

(42) **Growing area**
means any site which supports or could support the propagation of shellstock by natural or artificial means.

(43) **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).

(44) **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.

(45) **Harvest**
means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

(46) **Harvest area**
means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.

(47) **Harvester** means a person who takes shellstock by any means from a growing area.

(48) **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.

(49) **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.

(50) **Includes or including** means includes or including by way of illustration and not by way of limitation.

(51) **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.]

(52) **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.

(53) **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.

(54) **Key deficiency**
means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.

(55) **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.

(56) **Label**
means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.

(57) **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".]

(58) **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.

(59) **Lot of shellstock for depuration**
means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.

(60) **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.

(61) **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.

(62) **Marine biotoxin**
means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include *Alexandrium spp.* [*Protogonyaulax* species], and *Karenia brevis*.

(63) **May** means discretionary and is not mandatory or required.

(64) **Milliliter** (ml) means a unit of measurement equal to the 0.001 portion of a liter.

(65) **Monoculture** means the culture of a single bivalve species.

(66) **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.

(67) **National Shellfish Sanitation Program (NSSP)** means the cooperative state-FDA-Industry program for the sanitary control of shellfish that is adequate to insure that the shellfish produced in accordance with these guidelines will be safe and sanitary.

(68) **Open water aquaculture** means the cultivation of bivalve shellfish in natural shellfish growing areas.

(69) **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.

(70) **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.

(71) **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.

(72) **Point source**
means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.

(73) **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.

(74) **Polyculture** means the cultivation of:

a. Two or more species of shellfish; or
b. Shellfish with other species in a common environment.

(75) **Post Harvest Processing**
means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in NSSP Model Ordinance Chapters XI. through XIV.

(76) **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.

(77) **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.

(78) **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.

(79) **Process water** means the water used in the scheduled depuration process.

(80) **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.

(81) **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.

(82) **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.

(83) **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.

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

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

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

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

(88) **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.

(89) **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.

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

(91) **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.

(92) **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.

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

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

(95) **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.

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

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

(98) **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 ship shucked shellfish.

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

(100) **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.

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

(102) **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.

(103) **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.

(104) **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.

(105) **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.

(106) **Wet storage**
means the temporary 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.

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II. Model Ordinance
I. Shellfish Sanitation Program

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 - 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. 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.

C. 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.

D. 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.

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

F. 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.

Additional Guidance - 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 notice shall be in the format of FDA Form 3038.

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate 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
(iv) Seek other administrative remedies.

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II. Model Ordinance
II. Risk Assessment and Risk Management

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 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.

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 of the problem; and
(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7.

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 shall:

(1) Follow an existing marine biotoxin contingency plan, if appropriate.
(2) Collect and analyze samples relevant to the investigation, if appropriate.
(3) Keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

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. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market and issue public warnings if necessary to protect public health. FDA will decide whether to audit or issue public warnings after consultation with the Authority(s), 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 - IV Guidance Documents
Chapter IV .03 *Vibrio parahaemolyticus* Interim Control Plan

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, actions taken by the Authority in response to the illnesses, and a summary description of the state's shellfish illness reporting procedures, from patient presentation through laboratory diagnosis of food vehicle and etiological agent, to final public health documentation and reporting of specific illnesses to CDC. The initial assessment should be made for the most recent three calendar years and completed by March 1, 2002.

@. 02 Presence of Human Pathogens in Shellfish Meats.

Additional Guidance - 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.

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.

D. Risk Management and Tolerance Levels.

(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.

Additional Guidance - IV Guidance Documents
Chapter II @ .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

(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 - 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 - 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, 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 0.306/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.

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 Stat'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.

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II. Model Ordinance
III. LABORATORY

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 - IV Guidance Documents
Chapter II. 11. Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

@.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.

@.02 Methods.

Additional Guidance - IV Guidance Documents
Chapter II.10 Approved NSSP Laboratory Test

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods required by the National Shellfish Sanitation Program.
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.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and
(2) The current APHA method used in bioassay for *Karemia breve* toxins.

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II. Model Ordinance
IV. Shellstock Growing Areas

Additional Guidance - 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 - 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 geometic 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 of the water sample results shall not exceed 88 per 100 ml and not more than 10 percent of the samples shall exceed an MPN of: (a) 260 MPN per 100 ml for a five tube decimal dilution test; or (b) 300 MPN per 100 ml for a three tube decimal dilution test; or (c)

173 MPN per 100 ml for a twelve tube single dilution 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 of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN of:

(a) 260 MPN per 100 ml for a five tube decimal dilution test; or

(b) 300 MPN per 100 ml for a three-tube decimal dilution 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, than 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.

(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) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and

(iii) 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 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 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.

@.04 Marine Biotoxin Control.

Additional Guidance - IV Guidance Documents
II.02 Guidance for Developing Marine Biotoxin Contingency Plans

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 safety 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:

PSP - cells/L n/a; 80 µg/100 grams
NSP - 5,000 cells/L or 20 MU (approximate as 80 µg/100 g)
ASP - cells/L n/a; 2 mg/100 grams (20 ppm)

(a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or

(b) 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

(c) 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 x 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.

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II. Model Ordinance
V. Shellstock Relaying

Requirements for the Authority.

Additional Guidance - IV Guidance Documents
II.06 Shellstock Relay

[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 IV@.02.G and 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 shellstockfrom 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.

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II. Model Ordinance
VI. Shellfish Aquaculture

Requirements for the Authority

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

@.01 General.

A. The Authority shall maintain the following records while the aquaculture activity continues:
   (1) Construction and remodeling plans for any permitted aquaculture facility;
   (2) Aquacultural operational plans; and
   (3) Aquaculture permits.
B. The Authority shall inspect land based and polyculture 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 Land Based Aquaculture

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

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 open water and land based monoculture and polyculture.
B. Any person who performs open water aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
   (1) A permit from the Authority for the activity or for construction and functioning of his facility;
   (2) A harvester's license; and
   (3) Certification as a dealer, where necessary.
C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.
D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and any construction.
E. Water quality at any site used for open water or land based aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any open water or land based 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.

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II. Model Ordinance
VII. Wet Storage In Approved And Conditionally Approved Growing Areas

Requirements for the Dealer.

.01 Source of Shellstock.

A. The dealer shall wet store shellstock harvested only from areas classified as approved, conditionally approved, or taken from a certified depuration facility following successful completion of the depuration process.
B. Shellstock shall be harvested, identified and shipped to the wet storage operation 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.
B. Wet storage of depurated product shall occur only within the facility in which it was depurated.
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 operation, shellstock shall be protected from physical, chemical or thermal conditions which may compromise the shellstock's 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. For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats, or the wet storage operation.
G. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Chapters VIII, IX and X. Any dealer who wet stores shellstock from another state and ships the shellstock as a product of the state where the shellstock was wet stored shall be required to:
   (1) Have an operational plan approved by the Authority which describes how this labeling change will be employed in assuring that shellstock can be traced to its source; and
   (2) Meet the requirements of Chapter IX.
H. When the product from wet storage was depurated prior to wet storage, the shellstock shall:
   (1) Be packed and labeled according to the requirements in Chapter XV.; and
   (2) Include the dates of wet storage on the labels or tags.
I. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the wet storage location. The records shall be maintained for at least:
   (1) 90 days from the date of removal of the shellstock from wet storage; and
   (2) 120 days from the date of removal of the shellstock from wet storage where the state of origin labeling is changed under §G.2.

.03 Wet Storage Sites.

A. Near shore waters used for wet storage in containers and floats 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. The near shore site evaluation shall include:

(1) The sanitary survey of the near shore storage site, with special consideration of potential intermittent sources of pollution;

(2) The location of near shore storage sites and floats; and

(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.

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.

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II. Model Ordinance
VIII. Control of Shellfish Harvesting

Additional Guidance - IV Guidance Documents
II.08 Growing Area Patrol and Enforcement
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 oyster 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:

Risk Category	Minimum Frequency of Patrol
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:

(a) Description of the area;

(b) Classification of the area;

(c) Description of adjacent growing areas;

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

(e) 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 from 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.

- Low Production - 1
- Medium Productivity - 3
- 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.

- Highly mechanized requiring expensive equipment, deep water, difficult harvest - 1
- Restricted access aquaculture relative shallow water dredging - 2
- Scuba diving, tonging, bullraking - 3
- Hand collection from a boat - 4
- 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.

- Resource within sight of population and a normal patrol route. Patrol Officer can observe illegal harvesting from the patrol vehicle - 1
- Resource is near a shore and easily visible - 2
- Moderate difficulty, deliberate effort is required to provide coverage to the area - 3
- Long travel time to growing area, large open expanse of harvest area - 4
- 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			
			Subtotal		

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 an 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 (Critical 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 as defined in this Ordinance unless the harvester is a shellstock shipper or packs for a dealer.
(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. Penalties.
(1) The Authority shall develop a written guideline or enforcement policy which is used to recommend penalties to the courts.
(2) Authority shall insert appropriate references to its penalties.

E. 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 §E.(1) by dissemination of information with licenses, publication, or direct notification including registered mail; and

(b) May use warning signs.

F. 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. 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.

C. 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) 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 §C.(4).

D. 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).

E. 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^2) 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 §.02E.
(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 §.02E.

(b) In addition to the information required in §.02E 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 §.02E. 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 harvest 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 *Vibrio vulnificus*:

Action Level	Water Temperature	Maximum Hours from Harvest 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 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.
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 illness within the past three years, the Authority shall adopt the following harvest 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.

Time-Temperature Matrix for *Vibrio parahaemolyticus*:

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Harvest to Temperature Control
Level 1	<66 °F (18 °C)	36 hours
Level 2	66 °F - 80 °F (19 °C - 27 °C)	12 hours
Level 3	≥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.

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

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II. Model Ordinance
IX. Transportation

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 or post harvest processed shellfish 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 (l0 ° Centigrade) or less; and
E. All other conditions of shipment in this Chapter are met.

@.03 Shipment Rejection.

Additional Guidance - IV Guidance Documents
II.12 Bacteriological Examination of Shellfish Shipments Decision Tree

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 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 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 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) 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.

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II. Model Ordinance
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 §.01C. 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 §.01A. 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 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.01A., Chapter XII.01A., Chapter XIII.01A., Chapter XIV.01A and Chapter XV.01A., as applicable.

(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 §.01F.(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 §.01G.(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 §.01G.(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 §.01F.(3).

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with §.01C.(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 §.01F.(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 §.01I.;

(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 §.01I., 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 §.01G. and the record keeping requirements of §.01H.

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 §.01I. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §.01C.

(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 § .01I., 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 §.01F. 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 §.01F. 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 §.01G(1)(b)(ii) and (iii) shall be documented in records that are subject to the record keeping requirements of §.01H.

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 §.01B. and §.01C. 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 §.01C.;

(b) Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in §.01F.(3)(e), and the HACCP plan in accordance with the verification activities specified in § .01G.(1)(a); and

(c) Performing the record review required by §.01G.(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.

.02 General Sanitation Requirements.

Additional Guidance - IV Guidance Documents
Chapter III .01 Shellfish Industry Equipment Construction Guide

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.2, 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 compound

(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 §.02A. These records are subject to the requirements of §.01H.

C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP plan, required by §.01B. However, to the extent that they are monitored in accordance with §.02A. they need not be included in the HACCP plan, and vice versa.

.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 conducing 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.

.04 Certification Requirements.

Additional Guidance - IV Guidance Documents
Chapter III .04 Shellstock Tagging

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) When shipping individual containers of shellstock the dealers' tags on those containers shall:

(a) Be durable, waterproof and sanctioned by the Authority prior to use; and

(b) Be at least 13.8 square inches (89.03cm^2) in size.

(c) Contain the following indelible, legible information in the order specified below:

(i) The dealer's name and address.

(ii) The dealer's certification number as assigned by the Authority.

(iii) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.

(iv) The date of harvest; or if depurated, the date of depuration processing.

(v) If depurated, the depuration cycle number or lot number.

(vi) 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).

(vii) When the shellstock 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 OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";

(viii) The type and quantity of shellstock; and

(ix) 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.**"

(x) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the 2005 Food Code, or an equivalent statement, shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS" Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(xi) The statement "Keep Refrigerated" or an equivalent statement.

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

(3) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05B.

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

(5) 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.

(6) 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 Section .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 §.05B. 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@.01F., 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 §.05B.; 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. 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 §.07B. 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:

(a) The shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish;

(b) Packages containing less than 64 fluid ounces have:

(i) 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; and

(ii) The date as a month and day of the month.

(c) Packages containing 64 fluid ounces or more have on the lid and sidewall or bottom the "DATE SHUCKED" indicated as the number of the day of the year or the month and day of the month.

(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 IS 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.

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 Post Harvest Process Labeling

A. If a dealer elects to post harvest process shellfish and the final product form is live, the dealer shall label in accordance with Chapter X. 05.

B. If a dealer elects to post harvest process shellfish and the final product form is not live, the dealer shall label in accordance with Chapter X. 06. and include the following, or equivalent statement: These shellfish have been post harvest processed.

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, and if possible, the harvester or group of harvesters.

(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.

.09 Wet Storage in Artificial Bodies of Water.

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 operation shall be evaluated annually. The evaluation shall include the operation's plan and operating procedures for an onshore activity as submitted by the dealer.

(3) Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Authority.

(4) The wet storage facility or operation 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 onshore storage facility, source and quantity of water to be used for wet storage, and details of any water treatment system.

B. Operation Specifications.

(1) General. Each onshore wet storage operation 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 operation:

(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 operation 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. Water Supply.

Additional Guidance - NSSP Guide Section IV. Guidance Documents
Chapter III.06 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body

(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.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02.

(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 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) or unless they do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected 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 follow the protocol of the Decision Tree (Guidance Documents Chapter III.06).

(g) When the laboratory analysis of a single sample of disinfected 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 water to show positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.

(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 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) Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.

(b) When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will 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 to d determine 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 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.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that the disinfection system for the recirculating system will 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 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 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 within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

(d) When multiple tube UV treatment with redundant capacity is used as a water disinfectant, each time a bulb change is required either to replace a burned out bulb or for periodic servicing, new UV bulbs shall be installed and old bulbs discarded. When a single tube UV treatment unit or a multi tube unit without redundancy is utilized, each time a bulb change is required either to replace a burned out bulb or for periodic servicing, new UV bulbs shall be installed and old bulbs discarded, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group. UV systems using either a single tube or multiple-tube unit with no redundancy as their disinfection system may utilize an Authority approved UV wavelength intensity monitoring unit to demonstrate bulb integrity. When a UV Authority approved UV wavelength intensity monitoring unit is used to demonstrate bulb integrity, Laboratory verification for fecal coliform testing shall be waived.

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. Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage, subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., 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 water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

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II. Model Ordinance
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.

Requirements for Dealers.

Additional Guidance - IV. Guidance Documents
Chapter II.15 Decision Tree for Shellfish from Non-MOU Countries

.01Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack 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; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[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° Fahrenheit (7.2° Centigrade) 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. 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° Centigrade) 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° Centigrade) 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° Fahrenheit (7.2° Centigrade) 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° Fahrenheit (7.2° Centigrade) within two hours from time of heat shock. **[C]**

D. 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° Fahrenheit (7.2° Centigrade) or less or covered with 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. **[$S^{C/K}$]**

(c) 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]**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[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; **[$S^{C/K}$]**

(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 an unacceptable source. **[C]**

The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

(b) 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]**

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 that conforms to *Shellfish Industry Equipment Construction Guides* (August l993), U.S. Department of Health and Human Services. **[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, 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.02.B.(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]**

(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) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; **[K]** and
(iv) Wash and rinse equipment and utensils at the end of each day. **[K]**

(b) 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]**

(c) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. **[K]**

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

(e) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination. **[K]**

(f) 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 shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(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. **[$S^{K/0}$]**

(2) Employee practices.

(a) Where the same employee works in 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 hand washing 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]**

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

(1) Hand washing facilities with warm water at a minimum temperature of 100° Fahrenheit (38° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder **[$S^{K/O}$]**.

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. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{K/C}$]**

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]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer 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 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*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

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

(b) Animals or unauthorized persons 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]**

(c) 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]**

(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 floodwaters 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. **[$S^{C/K}$]**

(4) 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]**

(5) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. **[K]**

(6) 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 shellstock, 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 creates sanitary problems and interferes 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]**.

(7) Grounds. 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) Hand washing 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; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at least one hand sink in the packing room. **[O]**

(3) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees; **[O]**

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
(a) Cold and warm water at all sinks; and **[K]**
(b) Hand washing facilities adequate in number and size for the number of employees and located where supervisors can observe employee use; **[K]**

(5) 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 **[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]**

(6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(7) 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. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
(a) Tight fitting, self-closing doors; **[K]**
(b) Screening of not less than 15 mesh per inch; **[K]** and
(c) Controlled air current. **[K]**

E. 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. **[O]**

F. Equipment Construction for 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]**

G. Cleaning Non-food Contact Surfaces.

(1) 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]**

(2) 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]**

H. Shellfish Storage and Handling. The dealer shall:

(1) Assure that shellstock is:
(a) Reasonably free of sediment **[O]**; and
(b) Culled; **[K]**

(2) Completely empty shucking buckets 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) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0° Fahrenheit (-17.8° Centigrade) or less; and frozen solid within twelve hours following the initiation of freezing. **[$S^{K/0}$]**
(10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. **[K]**

I. 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 the 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 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 that have accumulated in the dip tank are eliminated. If the temperatures are maintained below 140 degrees, the dealer shall completely drain and flush the tank at three hour intervals. **[K]**

J. Personnel. Any employee handling shucked shellfish shall be required to:
(1) Wear effective hair restraints; **[O]**
(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**
(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**
(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**
(5) In any area where shellfish are shucked or packed and in any area that 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]**

K. 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 hand washing, 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) Employees
(i) To be trained in proper food handling and personal hygiene practices, and **[K]**
(ii) To report any symptoms of illness to their supervisor. **[K]**

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II. Model Ordinance
XII. Repacking Of Shucked Shellfish

.01 Critical Control Points.

Additional Guidance - IV. Guidance Documents
Chapter II.15 Decision Tree for Shellfish from Non-MOU Countries

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a dealer; and **[C]**
(2) Are identified 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° Fahrenheit (7.2° Centigrade) 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 ° Fahrenheit (7.2 ° Centigrade) 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 any water supply has been repaired and disinfected. **[$S^{C/K}$]**
(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces if free from any additives or deleterious substances consistent with federal and state laws and regulations. **[K]**
(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
(a) Be made on-site from potable water in a commercial ice machine; or **[C]**
(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency.**[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.
(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 that conforms to *Shellfish Industry Equipment Construction Guides* (August l993), 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; and **[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. **[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) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and **[K]**
(iv) Wash and rinse equipment and utensils at the end of each day. **[K]**

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

(4) Shucked shellfish shall be repacked in clean containers:
(a) Fabricated from food grade materials; and **[K]**
(b) Stored in a manner which assures their protection from contamination. **[K]**

(5) 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) Sanitized at least twice daily; **[K]**
(c) Cleaned more often, if necessary; **[K]**
(d) Properly stored until used; **[K]** and
(e) Maintained in a clean, intact, and sanitary condition.**[K]**

C. Prevention of Cross Contamination.
(1) Protection of shellfish.
(a) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**
(b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(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 hand washing 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]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Hand washing facilities with warm water at a minimum temperature of 100° Fahrenheit (38° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper**[K]** in a suitable holder. **[S$^{K/O}$]**

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$^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[S$^{C/K}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[S$^{C/K}$]**

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 repackaging 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 manufacturers label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer 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 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*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

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

(b) Animals or unauthorized persons 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]**

(c) 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]**

(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 floodwaters 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. **[$S^{C/K}$]**

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. **[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 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 shall be constructed of easily cleanable, corrosion resistant, impervious and packaged materials. **[O]**

(6) Grounds. 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) Hand washing 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; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at least one hand sink in the packing room. **[O]**

(3) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees. **[O]**

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(5) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
   (a) Used for food holding units (e.g. refrigeration units); **[K]**
   (b) Cleaned by hosing, flooding, or similar methods; and **[K]**
   (c) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[S$^{C/K}$]**

(7) 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$^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S$^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
   (a) Tight fitting, self-closing doors; **[K]**
   (b) Screening of not less than 15 mesh per inch; and **[K]**
   (c) Controlled air currents. **[K]**

E. 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]**

F. Equipment Construction for 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]**

G. Cleaning Non-food Contact Surfaces.

(1) Cleaning activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

(2) 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]**

H. 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 **[K]** shucked shellfish meats promptly;
   (f) Conduct repacking activities so as to conform to applicable food additive regulations; **[K]**
   (g) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0° Fahrenheit (-17.8° Centigrade) or less and frozen solid within twelve hours following the initiation of freezing. **[S$^{K/O}$]**

I. Heat Shock. N/A.

J. Personnel. Any employee handling shucked shellfish shall be required to:
(1) Wear effective hair restraints; **[O]**
(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**
(3) Wear finger cots or gloves if jewelry cannot be removed. **[O]**
(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**
(5) In any area where shellfish are shucked or packed and in any area that is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
(a) Store clothing or other personal belongings; **[K]**
(b) Eat or drink; **[K]**
(c) Spit; and **[K]**
(d) Use tobacco in any form. **[K]**

K. 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 hand washing, 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) Employees
(i) to be trained in proper food handling and personal hygiene practices, and **[K]**
(ii) to report any symptoms of illness to their supervisor. **[K]**

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2005

II. Model Ordinance
XIII. Shellstock Shipping

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 shellstock that 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 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) Obtained from a dealer who has identified the shellstock 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° Fahrenheit (7.2° Centigrade) 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]**

.02 Other Model Ordinance Requirements.

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 any water supply has been repaired and disinfected. **[$S^{C/K}$]**

(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces if free from any additives or deleterious substances consistent with federal and state laws and regulations. **[K]**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[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 **[$S^{C/K}$]**

(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 an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it is easily accessible for cleaning and inspection; **[K]**

(i) Is self-draining; and **[K]**

(ii) Meets the requirements for food contact surfaces. **[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 that conforms to *Shellfish Industry Equipment Construction Guides* (August l993), 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 shellstock; and **[K]**

(ii) Free from 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.02B.(1) (a), (b), and (c). **[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 shellstock 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) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and **[K]**

(iv) 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]**. Sanitized at least twice daily;

(b) Cleaned more often, if necessary; **[K]**

(c) Properly stored until used; and **[K]**

(d) Maintained in a clean, intact, and sanitary conditions. **[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. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(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. **[$S^{C/K}$]**

(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]**

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

(1) Hand washing facilities with warm water at a minimum temperature of 100° Fahrenheit (38° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[K]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

E. 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) 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 shellstock processing.

(a) Any ice, which is not made on site in the shellstock 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. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

(6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

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 shellstock 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]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer 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 shellstock or with food contact surfaces. The 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*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests, which may be a source of shellstock contamination, are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

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

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**

(2) Flooding:

(a) Facilities in which shellstock 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) Shellstock processing, repacking or shipping 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 facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[S$^{C/K}$]**

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. **[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 in good repair; and **[O]**

(c) All wet area floors used in areas to store shellstock, 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 shellstock are stored, handled, processed, or shall be constructed of easily cleanable, corrosion resistant, impervious packaged materials. **[O]**

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

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

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

(1) Hand washing 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; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[S$^{O/K}$]**

(2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(3) Hand washing facilities: The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees; **[O]**

(4) 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 **[K]** (e.g. refrigeration units);
  (c) Cleaned by hosing, flooding, or similar methods; and **[K]**
  (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities; **[K]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[K]**

(6) 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. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
  (a) Tight fitting, self-closing doors; **[K]**
  (b) Screening of not less than 15 mesh per inch; and **[K]**
  (c) Controlled air currents. **[K]**

E. Disposal of Other Waste

(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]**

F. Equipment Construction for 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 shellstock storage or handling areas. **[O]**

G. Cleaning of Non-food Contact Surfaces.

(1) Cleaning and sanitizing activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. **[K]**

(2) 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]**

H. Shellstock Storage and Handling.

(1) The dealer shall:
  (a) Assure that shellstock is:
    (i) Alive; **[K]**

(ii) Reasonably free of sediment; and **[O]**

(iii) Culled. **[K]**

(b) Not commingle shellstock during repacking unless the dealer is included in the Authority's commingling plan. **[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 for the storage or repacking of shellstock. **[K]**

I. Heat Shock - N/A

J. Personnel. In any area where shellstock are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(1) Store clothing or other personal belongings; **[O]**

(2) Eat or drink; **[K]**

(3) Spit; and **[K]**

(4) Use tobacco in any form. **[K]**

K. 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; and **[K]**

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

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at workstations, 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) Employees:

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

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

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II. Model Ordinance
XIV. Reshipping

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; **[C]**

(2) Are identified with a tag as outlined in Chapter X.05 or 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 °Fahrenheit (7.2 ° Centigrade) 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. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 ° Fahrenheit (7.2 ° Centigrade) or less. **[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 any water supply has been repaired and disinfected. **[$S^{C/K}$]**

(2) Ice Production. Any ice used in the storage or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[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.02B.(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. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Equipment shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/O}$]**

(2) Employee practices. 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:

(a) Before starting work; **[K]**

(b) After each absence from the work station; **[K]**

(c) After each work interruption; and **[K]**

(d) Any time when their hands may have become soiled or contaminated. **[K]**

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

(1) Hand washing facilities with warm water at a minimum temperature of 100° Fahrenheit (38 ° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

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. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{K/C}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

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. **[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]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer 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 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*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

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

(b) Animals or unauthorized persons 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]**

(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, repacking, or reshipping 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 floodwaters 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. **[C/K]**

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. **[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 shellstock, 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. 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) Hand washing 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; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities 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 hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees; **[O]**

(4) 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; and **[K]**

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(6) 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. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:

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

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

(c) Controlled air currents; **[K]**

E. 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]**

F. Equipment Construction for 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 any non-food contact surfaces in shellfish storage or handling areas. **[O]**

G. Cleaning Non-food Contact Surfaces.

(1) 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]**

(2) All conveyances and equipment that come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellfish Storage and Handling

(1) The dealer shall:

(a) Buy shellfish only from sources certified by the Authority or listed in the ICSSL; and **[K]**

(b) Add his name and certification number to the package. **[K]**

(2) The dealer shall not:

(a) Comingle, sort, or repack shellstock or shucked 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]**

I. Heat Shock - N/A

J. Personnel. 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:

(1) Store clothing or other personal belongs; **[O]**

(2) Eat or drink; **[K]**

(3) Spit; and **[K]**

(4) Use tobacco in any form. **[K]**

K. 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 hand washing, 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) Employees

(i) to be trained in proper food handling and personal hygiene practices **[K]**

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

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II. Model Ordinance
XV. Depuration

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 Operation Manuals for each dealer (§.02).
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$^{C/K}$]**
   (2) Ice production. Any ice used in the processing or storage of shucked shellfish shall:
      (a) Be made on-site from potable water in a commercial ice machine; **[C]** or
      (b) Come from a facility approved by the Authority or the appropriate regulatory agency. **[C]**
   (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$^{C/K}$]**
         (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 X. 08 C.(2)(b) 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 X. 08. C.(2) (b) **[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) Shellstock 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; **[K]** and

(iii) meets the requirements for food contact surfaces; **[K]** and

(c) 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 uniformity 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]**

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]**

(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) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and a frequency as necessary to prevent shellstock contamination. **[O]**

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

(d) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. **[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. **[$S^{C/K}$]**

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

(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 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]**

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

(1) Hand washing facilities with warm water at a minimum temperature of 100° Fahrenheit (38° Centigrade) ,dispensed from a hot and cold mixing or combination faucet, shall be provided; **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located toilets shall be provided.**[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

E. 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. **[$S^{K/C}$]**

(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. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

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; **[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 and sanitizing agents shall be used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Detergents, sanitizers, and other cleaning supplies shall be used only in strict accordance with the manufacturer's label instructions. **[K]**

(d) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer 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 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.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General

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

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials are cleaned or stored. **[K]**

(2) Flooding. 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. If facilities are flooded: **[C]**

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

(b) 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 facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

(4) Separation of operations. Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. **[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]**

(6) 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]**

(7) Grounds. 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) Hand washing 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]**; and

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; **[O]** and

(d) Hand washing signs in a language understood by the employees; **[O]**

(3) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; **[K]** and

(b) Hand washing facilities adequate in number and size for the number of employees, and are located where supervisors can observe employee use. **[K]**

(4) 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]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(6) 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]**

C. Utilities.
Ventilation, heating, or cooling systems shall not create conditions that may cause the shellstock to become contaminated. **[$S^{C/K}$]**

D. Insect and Vermin Control.
The dealer shall employ necessary internal and external insect and vermin control measures to assure that insects and vermin are not present in the facility, including:

(1) Tight fitting, self-closing doors; **[K]**
(2) Screening of not less that 15 mesh per inch; **[K]** or
(3) Controlled air currents. **[K]**

E. 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]**

F. Equipment Construction for 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]**

G. Cleaning and Sanitizing of Non-food Contact Surfaces.

(1) 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]**
(2) 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]**

H. 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]**

I. Heat Shock. N/A

J. Personnel. Any employee handling shucked shellfish shall be required to:
(1) Wear effective hair restraints; **[O]**
(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**
(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**
(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**
(5) 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 belongs; **[O]**
  (b) Eat or drink; **[K]**
  (c) Spit; and **[K]**
  (d) Use tobacco in any form. **[K]**

K. 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 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]**
  (b) Employees
    (i) to be trained in proper food handling and personal hygiene practices, **[K]** and
    (ii) to report any symptoms of illness to their supervisor. **[K]**

L. Plant Operating 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 Operating 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 §B.(3);

(e) Statement that construction materials and fabrication will meet the requirements of §.04, §.08, and §.09; 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;

M. Process Verification.
The Dealer shall continually:

(1) 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 from each lot of shellstock 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 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each restricted 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.

Limits for Verification of Depuration Plant Performance Fecal coliform per 100 grams		
Species	**Geometric Mean**	**90th Percentile**
Soft Clams *(Mya arenaria)*	50	130
Hard Clams *(Mercenaria mercenaria)*	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 conditions(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 90th 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 .03L(1) .

(iii) If either the geometric mean or the 90^{th} 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^{th} 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 L . (1).

(iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90^{th} 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 (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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II. Model Ordinance
XVI. Post Harvest Processing

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, 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.

(a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction, to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or other method approved for NSSP use.

(b) The dealer must demonstrate that the process reduces the level of *Vibrio parahaemolyticus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction.

(c) 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.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study as outlined in Guidance Documents Chapter IV Naturally Occurring Pathogens, Section .04 approved by the Authority, with the concurrence of FDA.

(e) The HACCP plan shall include:

(i) Process controls to ensure that the end point criteria are met for every lot; and,

(ii) A sampling program to periodically verify that the end point criteria are met.

(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(3) 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.

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III. Public Health Reasons and Explanations

Introduction

Oysters, clams, and mussels are unique foods that have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use.

Public health controls of shellfish became a national concern in the U.S. in the late 19th and early 20th century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. During the winter of 1924, there occurred a widespread typhoid fever outbreak, which resulted in a request that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consuming public. In accordance with this request, the Surgeon General called a conference, which was held in Washington, D.C., on February 19, 1925.

The members of the conference recommended eight resolutions for the sanitary control of the oyster industry, which formed the basis for development of the National Shellfish Sanitation Program. The conference also established a committee to develop further necessary guidelines to recommend practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to State health officers and all others concerned. This letter set forth the following understandings:

> 1. "The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual States; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the States, with the assistance and cooperation of the Public Health Service..."
>
> 2. "In accordance with this principle, it is considered that each producing State is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other States..."
>
> 3. "In order that each state may have full information concerning the measures carried out in other States, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing State, and will report thereon for the information of the authorities of other States. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane." "The officers of the Public Health Service assigned to this survey work will assist the State agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."
>
> 4. "In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between State authorities."

To implement this program, the members of the 1925 conference agreed that the producing states would issue "Certificates," i.e., a permit to operate, to shellfish shippers that met agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the State control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Health Service Act

resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under State laws with federal technical support and industry participation. The National Shellfish Sanitation Program is dependent entirely upon the States adopting the recommended requirements and the cooperative and voluntary efforts of State regulatory agencies and the shellfish industry.

The NSSP went beyond the original objective set forth in the 1925 Conference of insuring that shellfish shipped interstate would not be the cause of communicable disease. In the 1940's paralytic shellfish poison became a matter of public health concern and steps were taken to protect the public against this hazard. In 1957 it was recognized that shellfish might concentrate certain radionuclides and that a radiation surveillance activity might become a necessary addition to the established procedures. In the 1960's and 1970's it became apparent that shellfish have the ability to concentrate poisonous and deleterious substances such as metals, pesticides, hydrocarbons, etc. to potentially unsafe levels. To ensure the safety of shellfish, the State must supervise the growing, harvesting, relaying and transportation of shellfish. It is also important that shellfish be protected against contamination.

If State supervision is to be effective, the activity must be supported by legal authority. This authority may be either a specific law or a regulation. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority. The unique nature of shellfish as a food consumed whole and raw also makes it necessary for the State shellfish control agency to have authority to take immediate emergency action without recourse to lengthy administrative procedures, to halt harvesting and processing of shellfish. This authority should include placing restrictions on harvesting on the basis of a potential as well as an actual public health hazard. As examples, a State may find it necessary to close a shellfish growing area following a breakdown of a wastewater treatment plant or the unexpected finding of marine toxin(s), or when a growing area is implicated in confirmed illnesses.

Periodic revisions of State shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments which have called for revision of State laws include: (1) the increased use of pleasure boats with the resulting probability of contamination of shellfish growing areas with fresh untreated fecal material, (2) the conditionally approved area concept resulting from the construction of wastewater treatment facilities, (3) the effect of non-point source pollution, and (4) the ability of shellfish to concentrate certain radionuclides and hazardous chemicals. Experience has demonstrated that all actual and potential shellfish growing waters of the State must be classified by their sanitary suitability for shellfish harvesting. Harvesting should be permitted only from those areas that have been found by sanitary survey to meet the criteria of this Manual. Harvesting should accordingly be specifically prohibited from areas which do not meet the criteria, or which have not been surveyed, or which have outdated survey information.

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 in any form, except when the final product form is the adductor muscle only) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Participants in the NSSP include agencies from shellfish producing States, FDA, 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 provides 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 sanction issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revision 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.

Chapter I. Shellfish Sanitation Program

Requirements for the Authority

@01. Administration

A. Scope.
Because shellfish can be contaminated either in the growing area before harvest or during activities involved in harvesting, processing, distribution, or shipping, State laws or regulations must provide an adequate legal basis for sanitary control of all of these phases of handling shellfish. This legal authority must enable one or more departments or agencies of the state to regulate and supervise the classification of growing areas, harvest, relaying and transport of shellstock at its source; the shipment, tagging and storage of shellstock; the operation of depuration plants; and the shucking, packing, labeling and repacking of shellfish. The State must be able to apply the NSSP requirements to every actual and potential growing area, and to all shellfish harvesters to insure that shellfish available to certified dealers have been produced and harvested under acceptable sanitary conditions. The state must also have the authority to certify and suspend or revoke the certification of interstate shellfish shippers; to conduct laboratory examinations of shellfish; to prevent the sale of unsafe shellfish or shellfish from uncertified dealers by such legal means as detention, monetary fines, seizure, embargo and destruction; and to suspend harvesting and certificates of interstate shippers in public health emergencies.

B. Records.
States must maintain data and files that will provide evidence and demonstrate the effective administrative management of the shellfish sanitary control program as part of their participation in the NSSP. States must keep records in a central file to facilitate the FDA review of their shellfish sanitation programs and must assist the FDA in making such reviews. The purpose of this FDA review is to evaluate the adequacy of each state program in meeting the requirements of the NSSP Model Ordinance. The maintenance of proper records, organized files and adoption of accepted public administrative procedures provides the State control agencies with the means to conduct an effective program. The State program should have clearly written administrative procedures to affect the controls specified in the NSSP Model Ordinance.

C. Shared Responsibilities.
When two or more State agencies are involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

D. Administrative Procedures.

If state supervision is to be effective, the activity must be supported by legal authority applied through law, regulation or appropriate administrative procedures. Periodic revisions of state shellfish laws, regulations or administrative procedures may be necessary to cope with new public health hazards and to reflect new knowledge. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority.

E. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The intrinsic risk associated with consumption of raw or partially cooked shellfish products compels the shellfish control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. Development of administrative procedures in advance of outbreaks supports quick effective action and avoids costly mistakes and inadvertent destruction of evidence through delay.

F. Commingling.

Commingling means the act of combining different lots of shellstock or shellfish from different days in the same growing area, or combining different lots of shellstock from different growing areas. Health departments and other appropriate state and federal agencies must be able to determine the source of shellfish contamination when an outbreak of disease attributable to shellfish occurs so they can prevent any further illnesses from this source. Separating shellfish from different sources is necessary to maintain lot identity during harvest, transport, storage, shucking, and repacking operations. This lot separation assists in tracing shellfish back to its source when questions of public health safety arise. Maintaining lot identity will prevent implication of sources that are not associated with the outbreak and can prevent unnecessary regulatory action and liability. When commingling is allowed under any state management plan, the objective is to minimize the commingling of different dates of harvest and different growing areas. For additional information concerning commingling, see the NSSP Model Ordinance Guidance Document: *Shellstock Tagging* (ISSC/FDA, 2002).

@.02 Dealer Certification

A. - D. General, Initial Certification, Renewal of Certification, and Revocation or Suspension of Certification. A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. This NSSP objective is achieved through establishment of criteria and procedures to allow a producing or processing state to "certify" to receiving states that the product from a specific dealer has been grown, harvested, transported, processed, or shipped in compliance with the NSSP Model Ordinance guidelines. Dealer certification is dependent on a dealer maintaining acceptable operational and sanitary conditions and is determined through uniform inspections by standardized inspectors. For more information concerning standardized inspections, see the NSSP Model Ordinance Guidance Document: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2002).

State officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable Model Ordinance sanitation guidelines pertaining to the type of operation involved. For a full discussion of the certification process, see the NSSP Model Ordinance Guidance Document: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

E. Interstate Certified Shellfish Shippers List (ICSSL). Placement of a dealer on the ICSSL serves as nationwide notification to receiving states and the shellfish industry of dealer certification. Food control officials throughout the United States use the ICSSL to determine that shellfish offered for sale at the wholesale or retail level have been produced under the sanitary guidelines of the NSSP Model Ordinance. These officials generally rely upon the certification process instead of holding up shipments or sales of shellfish lots pending examination. The ICSSL is also used by the seafood and other food

industries to find sources of safe shellfish. For a full discussion of the ICSSL purpose and use, see the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

F. Inspections.

Through inspections by both the shellfish control agency and the dealer, as part of the dealer's HACCP plan, unsanitary conditions may be detected and corrected. Unannounced shellfish control agency inspections serve to verify that NSSP Model Ordinance guidelines are being met by the dealer. For additional information concerning inspections, see the NSSP Model Ordinance Guidance Documents: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2002).

G. Performance Based Inspection Program (PIP).

Performance based inspections for dealers with a significant history of satisfactory compliance result in improved regulatory efficiency. Regulatory inspections can be concentrated on more high-risk shellfish operations or operations with poor performance histories. Dealers recognized as having a record of excellent performance may be rewarded with the privilege of a reduced number of inspections.

H. Enforcement.

The unique nature of shellfish as a food consumed whole and raw in the form as it comes from the growing area requires the state shellfish control authority to have sufficient growing area patrol capacity to enforce the public health based restrictions on harvesting and to obtain meaningful penalties for violation of those harvesting restrictions. Information concerning enforcement activities at the growing area level can be found in the NSSP Model Ordinance, Chapter V, @04 and Chapter VIII, @01, B., *Patrol of Growing Areas* (ISSC/FDA, 2002) and in Guidance Documents: *Growing Area Patrol and Enforcement* and *Shellstock Relay*
(ISSC/FDA, 2002). Dealer certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. Dealers having major non-conformities with the NSSP Model Ordinance should not be certified. Certified dealers found to have major non-conformities should have their licenses or permits suspended or certifications revoked. Information concerning enforcement activities at the dealer certification level can be found in the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

Chapter II. Risk Assessment and Risk Management

Requirements for the Authority

@.01 Outbreaks of Shellfish-Related Illness.

Shellfish are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, from the water column if these organisms are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result.

When illness has occurred, immediate closure of the implicated growing area and/or recall of implicated product will significantly reduce the chance of additional illnesses. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Model

Ordinance Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2002). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2002).

Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health. Shellfish growing areas implicated through epidemiological association between illness and shellfish consumption must be closed immediately to prevent additional implicated product from reaching the consumer. Broad closures of Growing Areas, in addition to reducing the chance of additional illnesses, will: improve identification of specific sites where harvesting is taking place; reduce the size of areas available to harvest; reduce the practice of mixing together shellstock from different growing areas; and reduce illegal harvesting because legitimate harvesters will self-police their ranks to prevent false tagging. In addition, shellfish product from the implicated growing areas should be detained and an effective recall of product initiated.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected.

@.02 Presence of Human Pathogens in Shellfish Meats.

Human pathogens have been found in shellfish in the absence of human illness. These pathogens can be present at levels below that of an infectious dose, and may originate either as naturally occurring organisms in the growing area or from contamination of the growing area or of the shellfish during its handling, storage, transport or processing. Continued finding of the presence of human pathogens in shellfish from a specific growing area with no evidence of illness in the consumers may or may not constitute a human health risk. In these circumstances, the shellfish control authority needs to act quickly to initiate a thorough investigation to determine if the pathogen source is either the growing area or the system used for distributing and processing the product. If the source can be determined, the authority needs to take immediate steps to correct the problem through appropriate actions such as eliminating the source, reclassifying the growing area or changing a distribution or processing procedure.

When the source of the organism cannot be identified or if the organism is naturally occurring, the authority should conduct a risk assessment using all available information to determine if the human consumer is at risk. When the risk is determined to be negligible, no further action is required. A determination that some risk exists may prompt further action to protect the consumer such as allowing the shellfish to be harvested with an advisory to immunologically compromised individuals, allowing shellfish to be used only for cooked product, or closing the growing area.

@.03 Presence of Toxic Substances in Shellfish Meats

Because shellfish are filter feeders, they can readily accumulate toxigenic micro-algae and other substances from the water column. These substances include heavy metals, chlorinated hydrocarbons and other poisonous or deleterious substances. The presence of these substances does not necessarily constitute a health risk, as toxicity is dependent on both concentration (dose) and length of exposure.

To protect the consumer, the shellfish control authority needs to evaluate the levels of toxic substances that may be present in the shellfish against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood*

(ISSC/FDA, 2002); and *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002).

Chapter III. Laboratory

Requirements for the Authority

@.01 Quality Assurance.

Laboratory results from the bacteriological and chemical testing of shellfish growing waters and meats are widely used in the National Shellfish Sanitation Program to determine the safety of shellfish for human consumption. Experience with the bacteriological and toxicological examination of shellfish and shellstock growing waters has indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory. The APHA *Recommended Procedures for the Examination of Seawater and Shellfish*, which are revised periodically, offer reliable information for minimizing these variations. Assuring uniformity nationwide in the application of a laboratory quality assurance program is necessary to substantiate the validity of analytical results. Integral to laboratory quality assurance is a strong program for the evaluation of laboratory performance.

@.02 Methods.

American Public Health Association (APHA) *Recommended Procedures for the Examination of Seawater and Shellfish* shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official reference of the NSSP for the examination of shellfish for *Vibrio cholerae, V. vulnificus, and V. parahaemolyticus* is the FDA *Bacteriological Analytical Manual*
(BAM). State laboratories should conduct the test for these organisms when routine tests of marine foods implicated in foodborne outbreaks fail to demonstrate other enteric pathogens or bacterial toxins.

Use of standardized laboratory methods and procedures produces results acceptable to all regulatory agencies and allows comparative evaluation of data across laboratories. The APHA reference and FDA's BAM contain procedures for the virological examination of seawater and shellfish. However, the use of these procedures should be limited to special studies such as the development of new approaches for assessing, controlling, or improving shellfish sanitary quality, investigation of shellfish-borne disease outbreaks and other research studies. Routine virus monitoring of shellfish or their waters is not recommended due to the technical complexity, time required, high cost, and limitations of the detection and recovery method. For methods used in the NSSP, see the NSSP Model Ordinance Guidance Documents: *Approved NSSP Laboratory Tests* (ISSC/FDA, 2002).

Chapter IV. Shellstock Growing Areas

Requirements for the Authority

@.01 Sanitary Survey

A. General. One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times. Shellfish-borne infectious diseases are generally transmitted via a fecal-oral

route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended.

Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc portions of water examined were positive for coliforms (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States, the National Shellfish Sanitation Program was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host. A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio*. The vibrios are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters. Among the marine vibrios classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus*. All three species have been recovered from coastal waters in the United States and other parts of the world. These and other vibrios have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform.

In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher. *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish. In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy. Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafoods, especially raw oysters. Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafoods are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm.

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions. The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing

areas.

The primary responsibility of the shellfish control authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one of five classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

B. Sanitary Survey Required.

The findings of the sanitary survey represent a comprehensive analysis of data from several sources used to determine the proper classification of a growing area. Therefore, the Authority is required to complete the survey before determining the classification of a growing area and the appropriate use of shellstock from the area. If no harvesting is to be permitted in a growing area, the sanitary survey is unnecessary.

C. Sanitary Survey Performance.

Since the sanitary survey must be kept current to routinely verify the classification of the growing area, specified frequencies for updating the various survey components are necessary. Lack of written documentation precludes accurate assessment on a routine basis, and requires that, to protect the public health, the growing area be placed in the prohibited classification or closed status of its classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

D. Shoreline Survey Requirements.

The shoreline survey (also known as the pollution source survey) is the sanitary survey component in which the actual and potential pollution sources that may adversely affect the growing area are identified. These sources may introduce infectious disease agents or poisonous and deleterious substances to the growing waters where they may be taken up and concentrated by shellfish. Detailed and accurate information concerning the pollution sources is necessary for a proper growing area classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The key to the accurate classification of shellfish growing areas is the sanitary survey. The principal components of a sanitary survey include: (1) an evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) a review of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality.

A pollution source survey should be conducted of the shoreline area and watershed to locate direct discharges (e.g., municipal and industrial waste discharges, package treatment units, and malfunctioning septic tanks) and non-point sources of pollution (e.g., storm water runoff and agricultural and wildlife area runoff). Municipal and industrial wastewater treatment facilities should be evaluated in terms of design capacity versus actual loading, type and concentration of pollutants discharged, and the type and effectiveness of pollution control devices.

Following these evaluations, hydrographic and meteorological characteristics that may affect the distribution of pollutants to the area should be determined. Examples of these are tidal amplitude and type, water circulation patterns, depth, salinity,

stratification characteristics, rainfall patterns and intensity, and prevailing winds.

Information from pollution source evaluations and hydrographic studies should be considered in developing an evaluation of the water quality in a growing area. The purpose of this evaluation is to develop specific information to assist in defining classification boundaries. In many instances, bacteriological and related salinity data can be used to develop information on hydrographic characteristics of the area.

In designing a water quality evaluation, the following should be considered. Most water samples should be collected from the surface, since pollution discharged into freshwater streams or brackish estuarine waters usually tends to remain near the surface or above the denser seawater. Sample collection should be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of bacteria in their surrounding waters. A sanitary survey report is needed to integrate data from several sources into a comprehensive analysis to determine the proper classification for the area. This report should include a compilation of relevant data, a data analysis utilizing recognized statistical techniques, conclusions as to the appropriate classification of the area, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of boundaries and open and closed periods for conditionally approved and restricted areas.

Maintaining the sanitary survey consists primarily of routinely evaluating major pollution sources, collecting water quality data from key stations under adverse conditions, and analyzing the data to assure that the sanitary survey continues to be representative of current sanitary conditions in the growing area. The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when routine monitoring reveals a substantial change in the sanitary conditions. A reevaluation report is then needed and a determination must be made as to the proper classification of the area.

Experience with the shellfish certification program indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all shellfish sanitary survey reports, maintenance data and analysis, and reevaluation reports is maintained. This is particularly true where responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file for all shellfish sanitary survey information will also simplify the appraisal of state programs by the FDA and will prevent loss of historical data which may be useful in evaluating the sanitary quality of an area.

@.02 Bacteriological Standards

A. General.

The NSSP recognizes the use of two different indicator organisms for evaluating shellfish growing water quality. The water quality standards for the two indicators are numerically different from one another but are believed to afford the same level of public health protection (Hunt and Springer, 1974). The Authority may use either indicator and its companion water quality standard in any growing area.

B. Water Sample Stations.

The location of water sample collection stations can markedly affect the water quality detected. The NSSP requires that stations be of sufficient number and located to capture the effect of pollution sources so that the water quality affecting the shellfish can be adequately evaluated.

C. Exceptions.

Application of the water quality standards under the NSSP is based on the collection of a specified minimum number of samples at a specified frequency over a 3-year period. When a new growing area is under evaluation for classification, 3 years of historic data may not exist. This section sets the minimum number of samples that must be collected as part of the

required sanitary survey to determine the appropriate growing area classification for these new growing areas. The requirements are more stringent for growing areas that have pollution sources that affect water quality. No water quality samples are required to place a growing area in the prohibited classification.

D. - F. Standards for the Approved Classification of Growing Areas in the Remote Status, Affected by Point Sources, or Affected by Nonpoint Sources.

Based on the information gathered in the sanitary survey, the shellfish authority determines the appropriate classification of the shellfish growing area. The shellfish authority makes a decision to place a growing area in either the approved, conditionally approved, restricted, or conditionally restricted growing area classification. The growing area classification determines how the shellstock may be used following harvest. Water samples collected as part of the sanitary survey or as a required update of the sanitary survey are used to determine if the water quality meets the water quality standards for the growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition sampling strategy to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the water sample monitoring strategy used dictate the frequency of samples that must be collected. If the water quality meets approved classification water quality standards, the growing area is placed in the approved classification. If the water quality does not meet the water quality standards for the approved classification or meets the water quality standards only under certain conditions, the Authority places the area in another more suitable classification. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy*, and *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2002).

A field sampling and data analysis design that employs a systematic random sampling plan, assumes that a statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set. Therefore, all shellfish growing area data collected shall be used during classification. This sampling and data analysis design may be applied to approved and restricted shellfish growing areas that are affected by only randomly occurring pollution events. Additionally, this sampling strategy may be used to classify shellfish growing areas where water quality is influenced by seasonal water uses or where harvesting is controlled by seasonal resource management restrictions.

Systematic random sampling cannot be applied to areas impacted by point source pollution. This field sampling and data analysis design presumes that if intermittent, unfavorable changes in water quality occur, they will be revealed in the bacteriological sampling results. These unfavorable sampling results will then contribute to the variation of the data set. Data sets displaying greater levels of variation will consequently exhibit an elevated estimated 90th percentile. The Authority's option to use a systematic random sampling strategy is therefore, contingent upon the acceptance of the estimated 90th percentile, as the statistic to measure the variance of a data set. This statistic shall, along with the geometric mean or median, be used when evaluating each sampling station for compliance with NSSP growing area criteria.

An example of an acceptable systematic sampling plan is one that documents a preestablished sampling schedule in the growing area central file. Monthly or bimonthly sampling regimes are acceptable as long as there is no avoidance of unfavorable conditions and a reasonable attempt is made to collect samples on the preestablished days. Field sampling crews will *not*
be required to take unnecessary risks to sample on any particular day. The sampling plan will address unsafe sampling (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

If the growing area is intended for year-round harvesting, the sampling regime should stipulate the collection of samples throughout the year. If the growing area is intended to be approved for direct harvest for only part of the year, the random sampling plan would need only to address that period when the area is available for harvest. The only exception to this obligation to a random sampling regime is that the Authority will direct sampling to a particular tidal condition, if that condition unfavorably impacts the quality of the growing area.

The estimated 90th percentile was suggested in ISSC issue 8109 and its addendum, to address the public health concerns associated with variation in shellfish growing water-monitoring data. The estimated 90th percentile will weigh every MPN value in the data set. This statistic will aid the evaluation of the growing water data by accurately describing the results of the field sampling. When environmental events (such as rainfall) produce unfavorable effects on water quality, a randomly collected set of growing water data may, while still meeting the "10 percent above 43" criterion, display a greater level of variance than that associated with NSSP criteria. The "percentage factor" was not intended to allow for variation in the data caused by changes in environmental conditions at the time of sampling. The "percentage factor" was intended for use with a normally distributed data set, and reflects the inherent variation of the MPN analytical method.

If growing water data collected following unfavorable pollution events are combined with data collected under normal conditions, variation is increased. The estimated 90th percentile will reflect this variation. Therefore, the estimated 90th percentile will facilitate the use of a systematic random sampling strategy, while protecting against the potential public health problems that may result when shellfish are consumed from growing waters that are adversely affected by intermittent pollution events. For more information on systematic random sampling, see the NSSP Model Ordinance Guidance Documents: *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

G. - H. Standard for the Restricted Classification of Growing Areas Affected by Point Sources or Nonpoint Sources and Used as a Shellstock Source for Depuration.

Classification as a restricted growing area used as a shellstock source for depuration is an option available to the Authority as an alternative to placing a growing area in the prohibited classification. Shellstock harvested from these waters are subjected to depuration, which is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment as a treatment process. Following successful depuration, the shellfish are safe to eat.

Water samples are collected to determine if the water quality meets the water quality standards for this growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition monitoring system to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the monitoring system used dictate the frequency of samples that must be collected for application of the water quality standards. If the water quality meets the water quality standard for this classification, the growing area is placed in the restricted classification. If the water quality does not meet this water quality standard, or meets the water quality standard only under certain conditions, the Authority places the area in either the prohibited or the conditionally restricted classifications. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy*, and *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2002).

@.03 Growing Area Classification

A. General.

The probable presence or absence of pathogenic microorganisms in shellfish waters is important in deciding how shellfish obtained from an area may be used. All actual and potential growing waters should thus be classified according to the information developed in the sanitary survey. Classification should not be revised upward without careful consideration of trends and currently available data. Included in the sanitary survey file should be a written report with analysis supporting the classification.

The classification in which a growing area is placed dictates how the shellstock from that area may be used i.e. sold directly to the consumer to eat or required to be subjected to natural or artificial cleansing prior to sale to the consumer. Therefore, the Authority must make every effort to use the sanitary survey information to determine the correct classification in which to place the growing area to minimize public health risk to the consumer. Any change from a more restrictive growing area classification to a less restrictive classification requires a written sanitary survey report that carefully and thoughtfully evaluates the changes in the information and data supporting the current classification to justify the less restrictive classification.

The status of a growing area is different from its classification. A growing area is generally in the open status for harvest subject to the limitations of its classification. When the conditions for the open status are not satisfied, the growing area may be placed in the closed status of its classification. For example, in a public health emergency such as deterioration of growing area water quality following a hurricane, a growing area in the approved classification would be placed in the closed status until the water quality is determined to meet the water quality standards for its classification. After a closure, a reevaluation must be made prior to reopening. The growing area would be returned to its open status when the water quality returns to normal provided it continues to meet all other criteria for the approved classification.

Some growing areas are so remote that there is no possibility of contamination. If an area qualifies for remote status, less restrictive monitoring requirements are imposed.

B. Approved Classification.

A review of epidemiological investigations of disease and marine biotoxin outbreaks attributable to the consumption of shellfish reveals that three general situations prevail insofar as contamination of approved growing areas are concerned.

Firstly, improperly conducted or outdated sanitary surveys or misapplication of approved area criteria have unwittingly allowed sewage contamination of approved areas. Such areas have been shown to be the source of shellfish involved in shellfish associated disease outbreaks. The misapplication of approved area criteria includes the improper interpretation of the upper 10 percentile criteria to permit an area that is contaminated 10 percent of the time to be classified as approved.

A report of a 1910 outbreak of typhoid fever involving 41 persons notes that raw sewage from a city with a population of 30,000 was discharged only a few hundred feet away from clam beds and floats. In 1947, a case of typhoid fever was attributed to clams harvested 200 yards from the outlet of a municipal sewage treatment plant. In the latter case, the coliform MPN of the harbor water exceeded 12,000 per 100 ml and the area had been posted as closed to shellfish harvesting. In 1961, clams were responsible for at least 15 cases of infectious hepatitis. Subsequent water quality samples from the area found total coliform levels ranged between 900 to 2,400 MPN per 100 ml. The highest fecal coliform level observed was 2,100 MPN per 100 ml.

In 1978, at least 2,000 persons were victims of oyster-associated food poisoning. The causative agent was determined to be the Norwalk virus. The oysters were contaminated by sewage and runoff during periods of heavy rainfall. In 1977, there were over 700 cases of viral gastroenteritis associated with the consumption of sewage-contaminated cockles. Between November 1, 1980 and April 30, 1981, 450 cases of infectious hepatitis A were reported from the consumption of cockles.

Secondly, shellfish associated illnesses have been caused by chance contamination of growing areas. These growing areas were contaminated by fresh fecal material, which was not diffused throughout the entire area and was not readily detectable by ordinary bacteriological sampling procedures. This possibility of chance contamination was recognized by Dr. Gurion in his report on a 1902 typhoid outbreak in which he noted "There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious."

In 1956, an outbreak of infectious hepatitis (691 cases) attributed to oysters, which were contaminated in a wet storage area, is another example of chance contamination. Similarly in 1939, 87 cases of typhoid were attributed to fecal contamination of a storage area by a typhoid carrier.

Finally, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. These areas should have been managed and classified as conditionally approved, or classified as restricted.

Shellfish from waters meeting approved area criteria are unlikely to be involved in the spread of disease that can be attributed to fecal contamination of the shellfish. This is because, in part, a total coliform MPN of 70/100 ml is equivalent to the fecal material contributed from one person diluted in about 2.27×10^8 liters (8 million cubic feet) of coliform-free water. In addition, such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance. This also means an element of time and distance to permit mixing of sewage or fecal material with large volumes of diluting water. An increasing amount of saltwater will increase the rate at which many terrestrial microorganisms die out. Many reports have been published on the natural die-off of microorganisms in the marine environment.

In general, microbial inactivation in seawater occurs by two different processes -physical dilution by diffusion and a process of biological inactivation. The inactivation process appears to be associated with the following factors: specific bacteriophages, sunlight and solar radiation, temperature, absorption and sedimentation, predation, antibiosis, action of inorganic salts, nutrient deficiencies, and action of heavy metals and other substances.

Studies have shown that enteric bacteria in seawater may survive from a few hours to five days and longer. Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to over 130 days. The survival of viruses in seawater becomes greatly prolonged once they become associated with sediments. Virus concentrations may be many-fold greater in sediments than in overlying water. In general, viruses survive longer at lower temperatures, at low salinity, and in waters contaminated by sewage. Evidence from many field studies indicates that a constant relationship does not exist between either pathogen (bacterial or viral) or coliform content of shellfish and overlying water.

The effectiveness of sewage treatment processes must be considered in evaluating the sanitary quality of a growing area since the bacterial and viral content of the effluent will be determined by the degree of treatment which is obtained. The results of bacteriological sampling must also be correlated with sewage treatment plant operation and evaluated in terms of the minimum treatment which can be expected with the possibility of malfunctioning, overloading, or poor operations.

The ability of shellfish to concentrate chemical pollutants from water and sediment may lead to accumulation of these poisonous and deleterious substances to levels that may constitute a public health hazard. The degree to which these added substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish. Concentration factors in oysters may range

from near unity for Strontium 90 to as high as 10^4
for DDT. Anatomical distribution in shellfish and biological half-life of the substances are also highly variable.

Although there have been at least nine closures of shellfish growing areas in the United States due to findings of added poisonous or deleterious substances, there have been no documented illnesses attributed to consumption of shellfish from these areas. The level of surveillance for these substances in a shellfish control program may vary widely. Review of existing background data derived from national and international monitoring programs and assessment of potential sources of the substances should enable program managers to determine if a potential problem exists that may indicate a need for further field study. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern due to lack of information.

Limiting maximum permissible concentrations of radioisotopes and unidentified mixtures in water and food has been established. Current standards should be consulted in evaluating public health significance in market shellfish. The NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances, and Guidance Levels for Poisonous or Deleterious Substances in Seafood*, (ISSC/FDA, 2002) contains current FDA action levels and tolerances for poisonous and deleterious substances in seafood. Existing data are insufficient to establish levels for other substances at this time. Information on procedures for developing action levels and guidelines may be found in the September 30, 1977 *Federal Register*. In the absence of specific levels, decisions must be made on a case-by-case basis utilizing the best available knowledge.

The approved classification for a growing area requires that the sanitary survey has determined that there are no unacceptable concentrations of fecal material, pathogenic microorganisms, or poisonous and deleterious substances. There are no NSSP limitations on the harvest of shellstock from growing areas placed in this classification.

C. Conditional Classification.

The basic concept of the NSSP is to control the safety of shellfish by preventing their harvest from contaminated growing areas. In reviewing growing area classifications and sanitary surveys conducted by national and international control officials, it appears that a common misinterpretation is the classification of an area as *approved* when in fact the area should have been classified as *conditionally approved*. Critical investigations usually reveal that the area is subject to intermittent pollution events. Careful consideration of an intermittent pollution event, development and application of a management plan, and cooperation and compliance by all parties may also allow upgrading of an area to a *conditionally approved* or *conditionally restricted* classification instead of requiring the area to be *restricted* or *prohibited* at all times.

Intermittent pollution to shellfish growing waters has been a significant cause of shellfish-borne infectious disease outbreaks worldwide. In 1978, at least 20,000 persons were involved in an outbreak of oyster-associated gastroenteritis attributed to Norwalk virus. The investigation of the outbreak indicated that a combination of meteorological and hydrographic events had caused inadequately treated and diluted sewage from a nearby municipal facility to reach the area. In an incident in 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters when a combination of raw sewage bypasses, high rainfall, strong winds, and abnormally low tides caused contamination of an area that was classified as approved. In both of these instances, application of the conditionally approved area concept probably could have prevented the outbreaks.

A common situation where this classification might be appropriate is when water quality is, to some degree, dependent upon the operation of a wastewater treatment plant. For example, the boundaries of an approved shellfish area might be improperly determined during a period when a wastewater treatment plant is operating at a satisfactory level. If there is some interruption in treatment, it follows that there will be some degradation of water quality in the growing area which may require a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the

pollution source and the growing area, hydrography, the amount of water, and the amount of pollution.

The concept is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples of such situations include:

The water quality in a growing area adjacent to a resort community may vary according to seasons of the year. During the summer months, when the community experiences a significant population increase, water quality may be adversely affected. However, during the winter when there are few people in the community, water quality might improve sufficiently to allow approval of the area. In some states, this is known as a seasonal closure.

The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet, several months a year might vary. When the fishing fleet is in, the harbor water might be of poor sanitary quality. However, during the remainder of the year the quality of the harbor water might be satisfactory. The area would be closed for shellfish harvesting when the fishing fleet is using the harbor.

The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants into the growing area. This type of pollution is often referred to as non-point pollution. During periods of low runoff, such an area might be of satisfactory quality and thus be approved for shellfish harvesting.

The first step in determining whether an area should be classified as conditionally approved or conditionally restricted is to determine whether sufficient state resources are available to manage, survey, monitor, control harvesting, affect closures, and reopen the area as required. It should be noted that sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. States electing to classify areas as conditionally approved have found the public resource investment to be substantial.

The second step in determining whether an area should be placed in the conditionally approved or conditionally restricted classification is to evaluate the potential sources of pollution in terms of their effect on water quality in the area. Some potential sources of pollution include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally used areas, animals, land runoff, and freshwater flows.

The third step in establishing a conditionally approved or conditionally restricted area is to evaluate each source of pollution in terms of the water quality standards to be maintained, and to formulate performance standards for each pollution source having a significant effect on the sanitary quality of the area. The following are examples of different types of performance standards that might be developed:

Performance standards or closure criteria may be based upon the bacteriological quality of effluent from sewage treatment plants. This might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard for an effluent discharge: "The median coliform MPN, in any one month, shall not exceed 500 per 100 ml, based on not less than 16 composite samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."

A performance standard may be based upon total quality of sewage, which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

A performance standard may be based upon the amount of vessel traffic in the area and the concomitant amount of sewage, which can be expected.

Performance standards may be based upon the amount of rainfall in the immediate area. An example could be: "The area will be closed when there has been 5 cm (2 inches) or more rainfall registered at a rain gauge at (specified area within a 24-hour period)."

Performance standards may be based upon the height of a river stage. An example could be: "When the river at (a specified area) reaches 3.66 meters (12 feet) or above, the area will be closed."

The design of a waste treatment plant and the plant effluent specifications may be critical to the designation of an area classified as conditionally approved or conditionally restricted. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (coliform) of sewage, predicted survival of coliform in seawater, effectiveness of chlorination and the total quality of clean dilution water in an area. Results of many studies on the survival of bacteria in seawater have been published.

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible, operations should be automatically recorded on charts. Requirements that might be imposed depend upon the importance of the unit's relationship to water quality. Important design features of a sanitary waste collection system that should be considered include:

Storm water should be excluded from the sanitary system. There should be stand-by equipment to insure that treatment or pumping will not be interrupted. It should be taken into account that interruptions may occur because of damage to a single unit or a power failure.

The pumps and critical units should be fitted with meters or gauges so the regulatory agency can monitor performance standards.

Installation of recording scales to indicate rate of chlorine use is helpful. Chlorine flow meters are available that integrate hydraulic flow with chlorine demand.

Liquid level recording gauges fitted with alarms and located in overflow channels of sewage treatment plants and wet wells of lift stations are useful. They can be set to indicate when overflow takes place. It is good operating procedure to date recording charts. Gauges should be calibrated and maintained so that indicated discharge rates are accurate.

Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants can be an important control.

Another factor to consider in developing a conditionally approved or conditionally restricted area is that a prohibited area must be interposed between the conditionally approved or restricted area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the state shellfish control agency, and for the latter agency to issue a notice to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The length of time a conditionally approved or conditionally restricted area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, shellfish activity and cleansing rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area.

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These optional classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection and the control of shellfish safety in the use of the conditional classifications are afforded through the use of a management plan. The management plan for each growing area placed in a conditional classification is based on the information gathered during the sanitary survey. The plan establishes a strict set of criteria that must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are: the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of compliance with the plan to assure public health protection. Use of the conditional classification requires more intense monitoring and more frequent reevaluation because of the intermittent nature of the pollution event.

When the Authority has sufficient resources to manage a conditional classification, the use of the conditional classification could allow the safe use of growing areas that might otherwise not be available to the shellfish industry. For a complete discussion of the conditional classification, see the NSSP Model Ordinance Guidance Documents: *Management Plans for Growing Areas in the Conditional Classification*
(ISSC/FDA, 2002). For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

D. Restricted Classification.

The restricted area classification is an option available to state shellfish control agencies to use instead of a prohibited classification. The establishment of a restricted area might be considered in instances where an area does not meet approved area criteria but is not grossly polluted. Another common situation where this classification might be appropriate is for areas affected by non-point pollution from either urban or rural sources that cause the water quality to fluctuate unpredictably or of sufficient frequency that a conditionally approved area is not feasible. In such instances, the state may, at its option, classify these areas as restricted and may limit the use of the shellfish to relaying, container relaying, or depuration operations.

Relaying is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The sanitary and bacteriological criteria to be applied by the state for classifying restricted areas are to be developed by the state shellfish control agency. The criteria may vary according to the use to be made of the shellfish and according to the effectiveness of the relay and/or depuration process to which the shellfish will be subjected. The effectiveness of the process is determined by a study as provided for in the Model Ordinance, Chapter V, Shellstock Relaying and Chapter XV, Depuration. The purpose of this study is to establish the bacteriological quality requirements for the shellfish processing. Effectiveness of the process is likely to vary from one cleansing area to another, from one species of shellfish to another, and from one depuration plant to another. The classification criteria may be based upon the quality of the shellfish or the water in the restricted area in addition to other sanitary parameters.

Before classifying an area as restricted, the state shellfish control agency should make a determination of whether sufficient state resources are available to monitor pollution sources; to provide coordination between state, local and industry officials; to issue special harvesting permits; and to supervise harvesting and transportation of shellfish to depuration facilities or relay sites. Some states that have classified areas as restricted have found the resource investment to be substantial. For a complete discussion of relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002). For a complete discussion of depuration, see the NSSP Model Ordinance Public Health Reasons and Explanations Chapter XV Depuration (ISSC/FDA, 2002).

E. Prohibited Classification.

The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification, used for areas subject to gross pollution. The use of this classification is also required, as a precautionary measure, for any growing area where the shellfish authority has not performed a sanitary survey, and for a growing area immediately adjacent to a sewage treatment plant outfall, irrespective of the level of effluent treatment provided. The harvesting of shellstock is not allowed for any human food use. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002)

@.04 Marine Biotoxin Control

Marine biotoxins may be ingested by molluscan shellfish feeding on toxic dinoflagellates. Dinoflagellates in their vegetative stage flourish seasonally when water conditions are favorable. Toxic blooms of dinoflagellates can occur unexpectedly or may follow predictable patterns. Paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and domoic acid poisoning, also known as amnesic shellfish poisoning (ASP) are the three types of poisonings most commonly associated with oysters, clams, mussels and scallops in the United States.

Cases of paralytic shellfish poisoning, including several fatalities resulting from poisonous shellfish, have been reported from both the Atlantic and Pacific coasts. The minimum quantity of poison, which will cause intoxication in the susceptible person, is not known. Epidemiological investigations of paralytic shellfish poisoning in Canada have indicated 200 to 600 micrograms of poison will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of poison. Investigations indicate that lesser amounts of the poison have no deleterious effects on humans. Growing areas should be closed at a level to provide an adequate margin of safety, since in many instances, toxicity levels will change rapidly.

A review of the literature and research dealing with the source of the poison, the occurrences and distribution of poisonous shellfish physiology and toxicology, characteristics of the poison, and prevention and control of poisoning has been prepared.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karemia breve* (formerly *Ptychodiscus brevis*). Toxic symptoms in mice suggest a type of neurotoxic shellfish poisoning rather than symptoms of paralytic shellfish poisoning. The most common public health problem associated with *Karemia breve* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karemia breve*
blooms have been reported in Florida. Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat.

Toxic dinoflagellates are indigenous to most coastal and estuarine waters on the Atlantic, Gulf, and Pacific coasts of

America, as well as in many other parts of the world. Blooms of these organisms can occur unexpectedly and rapidly. This phenomenon occurred in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses. During 1991 and 1992, there was a spread of domoic acid producing organisms throughout the world including the detection of high numbers of *Pseudonitzschia pseudodellcatissima* in Australia and *Pseudonitzschia pseudoseratia*
in California. Domoic acid was also recovered from shellfish in Washington and Oregon. All shellfish producing states or MOU countries must have a contingency plan that defines administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxins. A model state contingency plan for control of marine biotoxins is provided in the NSSP Model Ordinance Guidance Documents, A.2., *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002).

All states or MOU countries must monitor toxin levels to establish a baseline historical reference. Thereafter, states or MOU countries where shellfish toxins are likely to occur must monitor toxin levels on a routine basis to meet the approved area requirements for direct market harvesting. Experience with monitoring for shellfish toxins suggests that an effective program should include the following:

Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.

Samples should be collected of shellfish species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.

The frequency and period for collection of samples should be based upon historical patterns. This assumes several years of baseline data in order to establish stations and sampling plans.

An information network should be established between the health and marine resource communities and the state shellfish control agency. Any toxin-like illnesses related to shellfish and environmental phenomena such as dinoflagellate blooms, fish kills, or bird kills, which might indicate the early stages of an increase in toxin levels should be rapidly communicated over the network.

Sampling stations and frequency of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing.

Sample collection, sample transportation, and sample analysis procedures should be developed so that in an emergency sample results will be known within 12 hours.

When monitoring data or other information indicates that toxin levels have increased to the quarantine levels, growing area closures must be immediately implemented. The determination of which growing areas should be closed should include consideration of the rapidity with which toxin levels can increase to excessive levels and the inherent delays in the state sample collection procedures. It may be appropriate to close growing areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.

Shellfish growing areas closed because marine biotoxins have exceeded quarantine levels may be reopened for growing after a sufficient number of samples and other environmental indices, if used, have established that the level of toxin will remain below quarantine levels for an extended period. For example, experience has shown that appropriate reopening criteria include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams.

A. Contingency Plan.

The suitability of some areas for harvesting shellstock is periodically influenced by the presence of toxigenic micro-algae. Recent increases in toxigenic micro-algae distribution dictate that a more comprehensive series of public health controls be adopted. The need exists to make contingency plans to address the contamination of a growing area by toxigenic micro-algae or a disease outbreak caused by marine biotoxin. This contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of marine biotoxin in shellstock. The primary goal of this planning should be to ensure that maximum public health protection is provided in growing areas subject to marine biotoxin contamination. For a fuller discussion of marine biotoxin disease and its management in shellfish growing areas, see the NSSP Model Ordinance Guidance Documents: *Guidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

B. Marine Biotoxin Monitoring.

The primary purpose of a marine biotoxin-monitoring program is to prevent illness or death among the shellfish consuming public. The monitoring program should use the "indicator station" and "critical species" concepts to develop an early warning system to prevent harvest of biotoxin contaminated shellstock. For a full discussion, see the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

C. Closed Status of Growing Areas.

In the event of a toxigenic micro-algae bloom, shellstock-growing areas shall be placed in the closed status for harvesting to prevent human consumption of biotoxin-contaminated shellfish. The biotoxin level governing the need to place the growing area in the closed status will vary depending on the species of toxigenic micro-algae and the species of bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the Authority may permit the harvesting of one species with no adverse public health consequences while prohibiting the harvest of another species. In these situations, the Authority must closely monitor the growing area and develop a sufficient database for use in making this determination.

The Authority must develop criteria, which must be met before a growing area can be returned to the open status for harvesting. These criteria should integrate public health, conservation, and economic considerations. The criteria should also employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin will remain, for an extended period of time, at levels safe for human consumption. For additional discussion concerning biotoxin contamination of shellstock, see the NSSP Model Ordinance Guidance Documents:G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

D. Heat Processing.

Heat treatment can reduce the toxicity of some biotoxins. When heat treatment is used, the Authority must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.

E. Records.

Good record keeping is essential to the successful management of a marine biotoxin contingency plan. Appropriate records of monitoring data, evaluation reports, and closure and reopening notices should be compiled and maintained by the Authority. This information is important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

@.05 Marinas

A. Marina Proper.

Under the NSSP, any growing area within the confines of the marina proper is presumed to be contaminated for some period of time. Therefore, no growing area within the marina proper can be placed in the approved classification.

B. Adjacent Waters.

The microbiological and chemical contamination associated with marina facilities may result in the contamination of adjacent shellfish growing waters. The NSSP has developed a set of evaluation criteria to be used in determining if the growing waters adjacent to a marina are affected by microbiological contaminants associated with sewage. Since there are significant regional differences in all factors that affect pollution loading from marinas, sufficient flexibility must be allowed to account for these differences. The Authority has the option of applying the specified occupancy and discharge rates necessary to conduct a dilution analysis. The Authority may also opt to conduct studies to document different rates for specific areas. Best professional judgment of qualified individuals and best available technology must be applied to determine adequate restrictions on harvesting in and around marinas.

Chapter V. Shellstock Relaying

Requirements for the Authority

@.01 General.

Relaying is the practice of harvesting bivalve shellstock from polluted growing or growing areas and placing them in unpolluted bodies of water for a sufficient time for the shellstock to reduce contaminating microorganisms or chemicals to safe levels. Through the natural cleansing process in relaying, shellstock resource that would otherwise not be available for human consumption is made safe and becomes accessible to the shellfish industry and the consumer. As early as 1911, public health officials were investigating the use of natural cleansing through relaying to reduce pathogenic organism levels in oysters. For a complete discussion of relaying activities, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.02 Contaminant Reduction.

Research has shown that shellfish have the ability to purge themselves of certain microbial and chemical contaminants when placed in clean saline water. The rate of purging depends on the specific contaminants, species of shellfish, and environmental factors such as temperature and salinity. The shape of the containers used to hold the shellstock may also affect the purging rate. Because of the differences in purging rates among shellfish species and contaminants, a specific study must be performed in each growing area used for relaying to determine the purging rates, and the relay activity must be carried out in strict conformance with criteria established from the study. For a fuller discussion of the factors effecting contaminant reduction during relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.03 Licenses to Relay Shellstock.

Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas and transporting them to other growing areas for the purpose of natural cleansing. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.04 Management of Relaying Activities.

Because shellstock relaying involves the harvesting and transport of contaminated shellstock and its treatment to render it safe for human consumption, great care must be taken to assure that contaminated product does not inadvertently reach the consumer. This requires direct supervision of the operation and good enforcement by the shellfish authority. Techniques such as special licenses, testing of shellstock before and after relay activities, special tagging of shellstock during relay, special marking of the growing areas used for natural cleansing, record keeping, and additional patrol activities are used to ensure that effective contaminant purging is completed before the shellstock is marketed to the consumer. For additional information concerning the management of shellstock relaying, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

Requirements for Harvesters

.01 Harvester License Required.

Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Harvesters must work with the shellfish authority to foster the use and enforcement of special permits to prevent bypassing of the natural cleansing treatment process. Compliance with permit requirements is extremely important. Prevention of sale of contaminated shellstock to the consumer is the primary objective of the NSSP. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

Chapter VI. Shellfish Aquaculture

Oysters, clams, mussels and scallops are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, and poisonous or deleterious substances from the water column if these organisms or substances are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result. Poisonous or deleterious substances can induce illness or death immediately or through long-term exposure, may contribute to the development of cancer in humans. Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan, Sanitary Survey and the Classification of Growing Waters*, and *Shellstock Relay* (ISSC/FDA, 2002).

The culturing of molluscan shellfish in natural and artificial growing areas is known as aquaculture. This may include the cultivation of molluscan shellfish with non-molluscan species in a common aquaculture system known as polyculture. Oysters, clams, mussels and scallops raised in aquaculture operations are subject to the same potential for contamination as they are growing in the wild. In land-based operations, there may be some additional risk of accumulation in the shellstock of animal drugs used to stimulate growth and control mollusk diseases, or fish diseases in the case of polyculture. Since some components of aquaculture such as relaying, wet storage, depuration, growing water classification and tagging, are similar to other activities covered in the NSSP Model Ordinance, they are regulated under those Model Ordinance chapters. The shellfish authority must have an adequate legal basis and sufficient resources to regulate public health concerns pertinent to bivalve shellstock aquaculture.

Polyculture and land-based monoculture operations must be under adequate control to assure the shellstock product

harvested will be acceptable for human consumption. The shellstock authority must establish detailed procedures for issuing permits for shellfish aquaculture, approving culturing sites and boundaries, controlling of harvesting, sampling of shellstock, monitoring environmental parameters, keeping records, imposing quarantine measures, controlling the use of animal drugs to stimulate growth or treat diseases, and developing other control measures as may be necessary. The shellfish authority should work with FDA in its review of the plans for a land based aquaculture operation.

Of particular concern in land-based systems is the use of a closed or recirculating water system. Potential exists for shellstock contamination through the failure of the water treatment system to sufficiently disinfect the water to control levels of human pathogens that might be introduced through the water supply or other means. There is also potential for the increased concentration of poisonous and deleterious substances such as animal drugs or antifouling agents in the water supply and subsequently the shellstock over time.

Prior to its harvest for sale in interstate commerce, the aquaculturist must demonstrate that the water in the land-based system met the NSSP Model Ordinance criteria for direct sale of shellstock to the consumer. If the water supply does not meet those criteria, the aquaculturist must subject the shellstock to relaying or depuration prior to sale. Relay is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally over time as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The cultivation of shellfish with other species in a common aquaculture system is known as polyculture. There are some additional public health concerns related to polyculture. Greater potential may exist for contamination of oysters, clams, mussels and scallops with human pathogens and animal drugs in polyculture. However, the extent of that potential is not known. The extensive use of tanks, sea enclosures, floating rafts, ponds, etc. in polyculture makes the oysters, clams, mussels or scallops highly vulnerable to pollution from various sources, including their association with the other species present in the polyculture operation. The usage of anti-fouling agents (tributyltin, copper, etc.), hormones, and antibiotics in finfish aquaculture has evoked concern about its environmental effects and potential threat to human health through bioaccumulation in shellfish. Therefore, a conservative approach to polyculture is provided in the NSSP Model Ordinance requirements.

Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas

The purpose of wet storage is to improve palatability of shellfish by desanding or increasing their salt content, or to provide temporary storage for depurated shellfish or shellfish from approved or conditionally approved harvest areas. Wet storage facilities are not designed and operated to increase the safety of shellfish. Therefore, all controls pertaining to shellfish for direct consumption must be applied.

Effective control measures must be established and implemented by the Authority to ensure that wet stored shellfish are protected from becoming contaminated. These control measures include review of the plans for proposed wet storage areas or flats; review of the design and operating procedures for onshore facilities; periodic inspections of wet storage facilities; and, evaluation of the water quality for compliance with the requirements of the *Model Ordinance*.

The types, location, and uses of wet storage operations are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating natural or synthetic seawater for the purpose of desanding, temporary storage, or salt uptake. Consequently, it is not possible to provide detailed guidelines in the *Model Ordinance* and it is

necessary for each separate operation to be developed and evaluated on its own merit with respect to overall Program guidelines.

Removing shellfish from growing beds for storage in areas close to shore may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of health consequences due to such contamination is the outbreak (691cases) of infectious hepatitis in Sweden in 1956 attributed to oysters contaminated in a wet storage area.

Shellfish on floats near shore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to ensure that chance contamination does not occur.

Careful consideration must be given to designing and operating onshore wet storage tanks to ensure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity. Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during wet storage. Hence, washing and culling the shellfish prior to wet storage is essential.

Chapter VIII. Control of Shellfish Harvesting

Requirements for the Authority.
Other portions of this section of the Guide have described the public health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. Methods have been described for the evaluation and classification of such areas. However, classification is not effective unless the State can prevent illegal harvesting of shellfish from closed areas. For a full discussion of control activities, see the NSSP Model Ordinance Guidance Documents: *Growing Area Patrol and Enforcement* (ISSC/FDA, 2002).

For the most part, control of illegal harvesting depends upon the police activities as described in this chapter, @01.B. Adequate delineation of closed areas is fundamental to effective patrol. The type of area identification will be determined by the structure of the local shellfish industry and the legal requirements for each State to permit successful prosecution. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public health reasons.

Other methods for identification of closures include telephone, maps issued at checkpoints, or with harvesting licenses, direct mail, and news media. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that persons harvesting from closed areas can be successfully prosecuted.

The primary objective of the NSSP is to ensure that shellfish are only harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Growing areas may be classified as to their public-health suitability for shellfish harvesting on the basis of information obtained by sanitary surveys in accordance with Chapter IV., @01. However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from closed areas. *Thus, the patrol element of the NSSP is important to ensure compliance with the public-health safeguards resulting from the sanitary survey.* The fact that the law prohibits the removal of shellfish from certain areas will deter the majority of the population from attempting to harvest such shellfish, provided they are aware of

the law and of the areas which are closed. Where traditional gathering practices have prevailed, local public opinion may not support the need for such closures. In such cases, favorable opinion may be developed through an educational program or a locally demonstrated need resulting from an outbreak of shellfish-associated illness or intoxication.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons illegally harvesting shellfish in a closed area. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats capable of operating in open waters; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, undercover and surprise patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Complete removal of shellfish from polluted areas provides a safeguard against contaminated shellfish reaching the market. In some cases, depletion may be the method selected to eliminate an irresistible temptation for harvesters. Depletion may be more economical and effective than patrol of closed areas and will serve to protect public health.

Educational programs should be developed for both industry and the public describing the public health necessity for eliminating shellfish harvesting from closed areas. Programs developed specifically for participation of key industry people may be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to eliminate harvesting and marketing of shellfish from closed areas.

The adequacy of state laws as a basis for prosecution is an important component of this activity. Shellfish patrol will be ineffective and or compromised if State laws are so written or interpreted that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. It is important that periodic assessments are made by the State control or patrol agency of the degree of success of court actions taken in response to illegal harvesting. Information of this nature is necessary for both the analysis of the effectiveness of the program and for education purposes. Prosecution will be difficult where local public opinion does not support the need for the restriction or the courts are not fully aware of the public health hazards associated with the crime.

Requirements for Harvesters.

Precautions exercised in gathering shellfish from approved growing areas may be nullified if shellfish are contaminated with bilge water or polluted overboard water, or in the case of trucks, with contaminated water on the floor or hazardous materials on or adjacent to the shellstock. Also, several investigations have been conducted by States and the FDA regarding shipments of shellfish where product deterioration resulted when shellstock was held or shipped under adverse conditions such as direct sunlight and warm temperatures. These studies reaffirm the critical role that adequate shellstock protection and refrigeration plays when ambient temperatures are high. Product deterioration and bacterial growth occurs when shellstock is left exposed for several hours on harvest boats. If this shellstock is transported in trucks without adequate prechilling and in-transit refrigeration, product deterioration continues.

The majority of studies on microbiological quality of shellfish point up the need to refrigerate shellstock quickly after harvesting and maintain the product below 10°C (50°F) throughout processing, distribution and storage. It should be noted that a study by Cook and Ruple reported in 1989, showed that 10°C (50°F) storage of summer harvested Eastern oyster shellstock from the U.S. Gulf Coast, prevented the multiplication of fecal coliforms and vibrios, including *Vibrio vulnificus*. Universally, food control officials consider shellfish as a potentially hazardous food that is capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. Other foods in this category are milk, milk products, eggs,

meat, poultry and fish. Generally, FDA recommends that potentially hazardous food be held at 7.2°C (45°F) or below, and if large volumes are involved in processing, methods be employed to rapidly cool the product to an internal temperature of 7.2°C (45°F) within four hours (20).

Several studies have established that some pathogenic *Vibrio* species and other autochthonous bacteria may be present in marine sediments throughout the year. One study of *Vibrio* species and *Aeromonas hydrophila* in sediments of Apalachicola Bay, Florida, routinely detected *V. parahaemolyticus*, *V. alginolyticus*, and *A. hydrophila* and during some portions of the year at relatively high levels (up to 46,000 organisms per gram). Additionally, *V. vulnificus*, *V. cholerae*, *V. fluvialis* were detected at levels up to 2,400 organisms per gram of sediment.

Furthermore, there is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration. Vibrio species can also survive on inadequately cleaned equipment in a processing plant. Washing sediments from shellstock at the time of harvest helps to protect the shellfish and the processing equipment from becoming contaminated. Washing shellstock also helps to prevent quantities of mud and other bacteria from being mixed with the shucked shellfish, thereby contributing to high bacterial counts in the finished product. Muddy shellstock also makes it difficult to maintain shucking rooms in a clean, sanitary condition.

Water used for shellstock washing should be of good sanitary quality, to avoid possible contamination of the shellstock. There are instances when shellstock washing by the harvester might introduce a sanitary hazard because of the possible tendency of the harvester to wash the shellstock with polluted water from a harbor area, rather than with clean water from a growing area. Therefore, the Authority may waive the requirement for shellstock washing by the harvester when there are climatic, technical, or sanitary reasons for such action. In such event, the processor becomes responsible for washing shellstock.

It is necessary to protect the shellfish from pollution by disease-causing organisms that may be present in body wastes discharged from boats. This item is intended to protect the shellfish from chance pollution during harvesting. The likelihood of body wastes being discharged from boats will be considered in evaluating the sanitary quality of the harvesting area. If discharges are not adequately controlled, the area cannot meet the classification requirements for an approved harvesting area.

Licensing of each person who harvests shellfish for sale to a certified dealer is an important control measure to help protect against illegally harvested shellfish and to help maintain accurate source identity records. Harvesters must provide information necessary to create a record of the origin, quantity, and date of harvest that can be used to trace lots of questionable shellstock back to the source(s). Investigation of disease outbreaks can be severely hindered if the source of the shellfish cannot be readily identified. This can result in shellfish from the unacceptable source continuing to be used and continuing to cause illness. Health authorities may be forced to close safe areas, to ban safe shipments or to seize safe lots as a public health precaution if the source of contaminated shellfish cannot be accurately and rapidly determined.

Chapter IX. Transportation

Requirements for the Authority.

Studies conducted during the period from pre-1925 to 1989 showed that the bacteriological examination of shellfish is an important *tool*

in detecting: product mishandling; temperature abuse; and gross errors in growing area classification. The studies also

demonstrated that shellfish will generally reflect the bacteriological quality of the water in which they have grown. However, this relationship is not consistent. Variation reflects differences in species and product forms and seasonal conditions at the time of harvest. Some studies concluded that there is no single uniform bacteriological standard which could be applied to all species of shellfish.

Efforts to develop satisfactory bacteriological criteria for interstate shipments of shellfish (especially oysters) as received at the wholesale market level were begun in 1950. During the period from 1950 to 1964, there were many studies conducted to determine the bacteriological changes associated with shellfish harvesting, shucking - packing and marketing. Throughout this period various coliform and plate count standards were developed under the NSSP. However, it wasn't until 1965, that the fecal coliform and standard plate count criteria were applied to all species of shucked oysters at the "wholesale market level" (wholesale market level not defined). In 1968, the NSSP Workshop adopted these criteria, presumably for all species and product forms of oysters, clams and mussels.

Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained, and the sanitary practices applied during harvesting and shipping.

The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times. Because physiologically active shellfish pump and filter large quantities of water as part of their feeding process, rapid intake and concentration of bacteria, viruses, marine toxins, and other poisonous and deleterious substances may occur. Therefore, the shellfish may contain higher levels of chemical contaminants or pathogens than are found in the water in which they grow.

The shellfish-water bacteria ratio depends upon the shellfish species, water temperature, presence of certain chemicals, and varying physiological capabilities of the individual animals. If the water in which the shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man.

In addition, shellfish contaminated by added trace metals can result in illness to man if consumed in sufficient quantities. Health hazards also may result from the presence of naturally occurring biotoxins produced by certain marine dinoflagellates. The occurrence of these poisons is related to the concentration of toxic dinoflagellates in the growing area. The contamination of shellfish by these dinoflagellates usually occurs in well-defined areas and, in some instances, only during certain seasons not widespread over all shellfish producing areas.

Cooking does not necessarily ensure safety of contaminated shellfish since, in ordinary cooking processes; shellfish may not be heated sufficiently to ensure a kill of pathogenic organisms, although a considerable reduction will take place. Also, normal cooking processes cannot be relied upon to destroy paralytic shellfish poison.

Certified dealers have three principal responsibilities to assure that the consumer receives a safe product. The first is to purchase only safe and wholesome raw products. The second is to maintain the product in a sanitary manner. The final responsibility is to ship the product under sanitary conditions. The tagging and shipping records requirements, the sanitary shipping practices requirements, and the raw product inspection requirements are necessary to fulfill these responsibilities.

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements.

HACCP is a preventive system of hazard control. It consists first of an identification of the likely hazards that could be

presented by a specific product, followed by the identification of the critical control points in a specific production process where a failure to control would likely result in a hazard being created or allowed to persist. These critical control points (CCP) are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented when problems occur.

The application of HACCP controls by the molluscan shellfish industry, coupled with inspections by Shellfish Control Authorities based on the HACCP system, are a more effective and efficient system for ensuring the safety of molluscan shellfish products than the traditional Good Manufacturing Practices-based system. Adoption of HACCP controls by the molluscan shellfish industry will provide a basis for enhanced consumer confidence in the safety of molluscan shellfish.

The first step in the HACCP process, called Hazard Analysis, should include an assessment of both the likelihood that a food safety hazard will occur and its severity if it does occur. To be addressed by the HACCP system, the hazards must be such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food. Even factors beyond the control of the processor, such as how the food will be distributed and how it will be consumed, must be considered because these factors could influence how it should be processed. A hazard is a biological, chemical, or physical property that may cause a food to be unsafe.

All dealers must conduct a hazard analysis or have one conducted on their behalf. The hazard analysis need not be performed according to a standardized regime, nor must it be documented in writing for review by the State Shellfish Control Authority.

The hazard analysis must identify the hazard of pathogen contamination at the receiving CCP as a significant hazard for all raw, molluscan shellfish products. For this reason, all dealers must have and implement a written HACCP plan. Other hazards may also be identified (e.g., natural toxins, pesticides and environmental contaminants) at receiving and at other CCPs. In general, the CCPs identified in chapters XI.01, XII.01, XIII.01, and XIV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate, through the performance of a hazard analysis, that a particular hazard does not exist for a particular product or processing method, or that it can be controlled at another CCP in a manner that provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

In addition to listing the food safety hazards that are reasonably likely to occur in the food and the critical control points necessary to control these hazards, the HACCP plan must establish the critical limits for the preventive measures at each CCP. Critical limits can be thought of as boundaries of safety for each CCP. They may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies, and experts. In general, the critical limits listed in chapters XI.01, XII.01, XIII.01, and XIV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate that another critical limit provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

Monitoring procedures must also be included in the plan. Monitoring is a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for future use in verification. Monitoring: 1) tracks the system's operation so that a trend toward a loss of control can be recognized, and a process adjustment can be made before a deviation occurs; and 2) indicates when loss of control and a deviation has actually occurred, and corrective action must be taken. Monitoring intervals must be frequent enough to permit the dealer to determine whether the hazard is under control.

While the HACCP system is intended to prevent deviations from a planned process from occurring, perfection is rarely, if ever achievable. When a deviation from a critical limit occurs, corrective action must be sufficient to: 1) ensure that no

product enters commerce that is injurious to health or is otherwise adulterated as a result of the deviation; and 2) correct the cause of the deviation. These goals can be achieved by either predetermining what corrective actions will be taken when a critical limit failure occurs and then following those procedures, or following the minimum generic-type procedures described in X.01F(3).

The HACCP plan must also list the records that are necessary to document the result of monitoring at CCPs. These records must contain the actual values and observations obtained during monitoring. This requirement ensures that preventive monitoring is occurring in a systematic way.

.02 General Sanitation Requirements.

General Sanitation Requirements apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance: (1) Safety of Water for Processing and Ice Production; (2) Condition and Cleanliness of Food Contact Surfaces; (3) Prevention of Cross Contamination; (4) Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities; (5) Protection from Adulterants; (6) Proper Labeling, Storage, and Use of Toxin Compounds; (7) Control of Employees with Adverse Health Conditions; (8) Exclusion of Pests.

.03 Other Model Ordinance Requirements.

Other Model Ordinance Requirements apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted: (1) Plants and Grounds; (2) Plumbing and Related Facilities; (3) Utilities; (4) Insect and Vermin Control; (5) Disposal of Other Wastes; (6) Equipment Construction for Non-Food Contact Surfaces; (7) Cleaning and Sanitizing of Non-Food Contact Surfaces; (8) Shellfish Storage and Handling; (9) Heat Shock; (10) Post-Harvest Processing; (11) Toxic Materials; (12) Personnel; (13) Supervision.

.04 Certification Requirements.

A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. Although these requirements pertain only to interstate shipments, it is recommended that the same requirements be imposed on intrastate operations. To accomplish this, the NSSP includes criteria and procedures to assure that producing and processing states receive only product that has been grown, harvested, transported, processed, and/or shipped in compliance with NSSP guidelines. Certification is dependent on a dealer maintaining acceptable operational and sanitary conditions. The state must have adequate legal authority to regulate the sanitary requirements for harvesting, transporting, shucking-packing, and repacking of shellfish to be shipped interstate. This authority may be either a specific law or a regulation. The success with which the state is able to regulate all components of the shellfish industry provides a measure of the adequacy of the statutory authority.

The unique nature of shellfish as a food eaten whole and raw also makes it necessary that the Authority have authority to take immediate emergency action to halt sale and distribution of shellfish without recourse to lengthy administrative procedures. As an example, a state may find it necessary to detain lots of shellfish following reports of illness traced to a certain source of shellfish before confirmatory laboratory analysis can be conducted to document the causative agent. In taking such action, the responsible regulatory agency should be cognizant of the need to use rapid analytical methods for determining status of these highly perishable products. Periodic revisions of state shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments that have called for revision of state laws include the construction of depuration plants, changes in conservation laws, or the exploitation of a new resource.

State officials who certify dealers must fully comply with the requirements for certification for the process to remain viable.

Certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. For the certification process to be effective, certified dealers must fully comply with the applicable sanitation requirements pertaining to the type of operation involved.

The minimum plant sanitation and management guidelines for interstate shellfish shippers are described in Model Ordinance Chapters XI., XII., XIII., XIV., and XV. Only those shellfish firms that meet the guidelines are eligible for certification as Interstate Shellfish Shippers and may be listed in FDA's monthly publication of the ICSSL. Plants having major non-conformities should not be certified and certified plants found to have major non-conformities should have their license or permits suspended or certification canceled. This "List" is mailed to over 6,000 persons to inform them of approved sources of shellfish. Food control officials throughout the United States use the "List" to determine that shellfish offered for sale or used in food service establishments have been produced under the sanitary guidelines of the NSSP. These officials are asked to rely upon the certification process by not holding up shipments or sales of shellfish lots pending examination.

Inspections of certified shellfish dealers should be conducted at such frequency as is necessary to assure compliance with NSSP requirements. The recommended frequency of inspection for shucker packers, repackers, and depuration plants when operating is at least monthly and for shellstock shippers and reshippers at least quarterly. To conduct effective inspections, it is necessary that inspectors have adequate equipment and supplies to measure compliance with applicable requirements. Since the type of equipment and supplies required for an inspection will vary with the type of establishment, it is recommended that a checklist of equipment be developed for each dealer classification.

.05-.07 Shellstock Identification, Shucked Shellfish Labeling, Shipping Documents and Records.

The NSSP requires that the product be identified with certain information showing that the shellfish were harvested by licensed diggers and shipped and processed by certified dealers. This information assists in tracing the product back through the distribution system to the growing area in the event the shellfish are associated with a disease outbreak. The requirement for placing the certificate number and date marking on the sidewall or bottom of durable containers holding 1873 ml (64 fluid ounces) or more is to discourage re-use of these containers for illegal purposes.

In case of an outbreak of disease attributable to shellfish, it is necessary that health departments and other appropriate state and federal agencies be able to determine the source of contamination, and thereby to prevent any further outbreaks from this source. This can be done most effectively by following the course of a shipment, through all the various dealers who have handled it, back to the point of origin by means of records kept by the shellfish dealers. Maintaining adequate records is considered by some industry members to be a burden. This has resulted in various unacceptable practices being encountered by health officials, including no written records of purchase, undated shippers tags maintained in an unordered manner, new shipping tags being placed on a lot without records to correlate the original identity of the lot with the new identity, and shellfish on the premises with no tags. Although these dealers often have "records" in the most general sense, these records are not in the form that meets the intent of the NSSP certification requirement to provide traceability on a lot-by-lot basis. As a result, follow-up investigations of disease outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. The NSSP Guide Section V, Suggested Forms, contains an example of a typical ledger that may be used to provide the required information.

An example where the failure to maintain adequate records was identified as one of the principal contributing factors to a series of continuing disease outbreaks was in 1981 and 1982. The outbreaks continued for several months and affected thousands of people. An investigation by the states involved and FDA revealed that some states were unable to enforce the record keeping and tagging requirements of the NSSP. FDA found in one state that approximately one-third or the certified dealers inspected failed to maintain adequate records. State officials realized that an improved labeling or manifest system

was needed to track shellfish in the marketplace back to the distributor and to the digger. However, they also recognized that no single source identity and record keeping system would be applicable to all situations in each state. Therefore, specific requirements should be developed by each state to achieve the NSSP requirements.

Additionally, the Federal Food, Drug and Cosmetic Act requires that food labels provide an accurate statement which includes the name and address of either the manufacturer, packer, or distributor; the net amount of food in the package; the common or usual name of the food; and the ingredients, unless the product conforms to standard of identity requirements. Foods shipped in interstate commerce having labels that do not meet these requirements are deemed misbranded and in violation of Section 405 of the Food, Drug and Cosmetic Act.

.08 Wet Storage in Artificial Bodies of Water.

The purposes of wet storage are the temporary storage of approved shellfish, desanding and improving palatability. Wet storage facilities are not designed and operated to increase safety of the shellfish. Therefore, all controls pertaining to shellfish for direct consumption should be applied.

The types, locations, and purposes of wet storage operation are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating, synthetic seawater for the purpose of desanding and salt uptake. Consequently, it is not possible to provide detailed guidelines in the Model Ordinance and it is necessary for each separate operation to be developed and evaluated on its own merit with respect to overall program guidelines.

Removing shellfish from growing beds to storage areas close to shore and habitations may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of such contamination is the 1956 outbreak of infectious hepatitis in Sweden (691 cases) attributed to oysters contaminated in a wet storage area.

Shellfish on floats nearshore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to assure that chance contamination does not occur.

Careful consideration must be given to designing and operating onshore wet storage tanks to assure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity. Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during storage. Hence, washing and culling the shellfish prior to storage is essential.

Proper hydraulic design of the tank is important to assure an adequate quantity and quality of water with minimum turbulence at suitable temperatures to achieve the intended purpose of the storage operation. Inadequate flow or "dead spots" can lead to oxygen deficiency and shellfish mortality if the shellfish are physiologically active. Minimum turbulence will permit feces and pseudo feces generated by active shellfish to settle out without being resuspended and ingested. Tanks fabricated with safe material, which are easily cleanable, will prevent possible adulteration with chemicals migrating from the tank into the water and will facilitate cleaning and sanitizing.

Commingling of bivalve mollusks with other species in tanks may subject the bivalve mollusks to contamination from pathogenic organisms from the non-molluscan animals. Fish, crabs, lobsters, and other marine species may be harvested from polluted areas and may have ingested pathogens or accumulated them on their body surfaces. Therefore, holding such animals in the same tank with bivalve mollusks presents a risk of cross contamination. This risk can be avoided by using

separate tanks for non-bivalve molluscan species. Where the same water is used for all tanks, effective disinfection must be provided prior to entering the tank holding the bivalve species.

Chapters XI, XII, XIII, and XIV. - SHELLFISH PROCESSING AND HANDLING

Requirements for Dealers.

.01 Critical Control Points.

[NOTE: these Critical Control Points apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Receiving Critical Control Point.

Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained and the sanitary practices applied during harvesting and shipping. The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times. If the water in which shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man. Harvesters and shippers must provide information necessary to create a record of the origin, quantity, and date of harvest, which can be used to trace lots of questionable shellfish back to the sources(s).

B. Shellstock Storage Critical Control Point.

There is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration.

C. Processing Critical Control Point.

The bacteria count of the final pack is related to the elapsed time after shucking when the shellfish are held at temperatures favorable to the rapid growth of bacteria. Factors which influence the length of time required to lower the temperature of shucked shellfish to 7.2°C (45°F) include the temperature of blower or other process water, the speed of the individual shucker or shucking machinery, the frequency with which the shucking containers are delivered to the packing room, ambient air temperature in the plant, and the temperature of the shellstock being shucked. To maintain optimum bacteriological quality, it is preferable that the elapsed time between shucking and cooling to a temperature of 7.2°C (45°F) does not exceed four hours. More rapid processing is very desirable.

D. Shucked Meat Storage Critical Control Point. Shucked shellfish are an excellent medium for the growth of bacteria. Thus, it is very important that the packaged shellfish be cooled and refrigerated promptly so that bacteria growth is minimized. Studies have shown that bacterial growth is significantly reduced at storage temperatures of less than 7.2°C (45°F) and that storage in wet ice is the most effective method for refrigeration of shucked meats.

.02 Sanitation Requirements.

[NOTE: these General Sanitation Requirements apply to chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Safety of Water for Processing and Ice Production. Water should be safe and sanitary to avoid contamination of food-contact surfaces and the product. Ice may become contaminated by non-potable water or may become contaminated during freezing or in subsequent storage or handling. When non-hermetically sealed containers of shellfish are stored in unsanitary ice, a partial vacuum may form within the containers and draw water from the melting ice into the container and

contaminate packed shellfish. Special attention should be given to ice used for direct contact chilling of shellfish meats to assure that the ice is of acceptable quality. Water used for shellstock washing should be of good quality, to avoid possible contamination of the shellstock. The organisms causing typhoid fever, hepatitis, and other gastrointestinal diseases may be present in the body discharges of cases or carriers, and thus be present in the drainpipes in the plants. Correctly installed plumbing protects the water supplies against cross connections and back siphonage.

B. Condition and Cleanliness of Food Contact Surfaces. Colanders, shucking pails, skimmers, blowers, and other equipment or utensils which come into contact with the shucked shellfish and which have cracked, rough, or inaccessible surfaces or are easily cracked or chipped, or which are made of improper material, are apt to harbor accumulations of organic material in which bacteria or other microorganisms may grow. These microorganisms may later cause illness among those who eat the shellfish, or spoilage in the shucked shellfish. Slime and foreign material, which accumulate in blower pipes below the liquid level, afford an excellent breeding place for bacteria. This material may be dislodged and forced into the batch of shellfish in the blower, thus increasing the bacterial content of the shellfish. Cleaned and sanitized equipment and utensils reduce the chance of contaminating shellfish during shucking and processing. Shellfish furnish an excellent growth medium for spoilage microorganisms, and small numbers of these microorganisms on improperly sanitized equipment may multiply to very high levels in the finished pack. Use of sanitizers is not effective unless the equipment is first thoroughly cleaned and rinsed.

C. Prevention of Cross Contamination.

The nature of shellfish operations is such that the shellfish require protection from undesirable microorganisms, chemicals, filth, or other extraneous materials. This protection is achieved by properly selecting the plant location so that it is not contaminated by floodwaters. It is normal during shucking operations for shucker's clothing to become very soiled. If shuckers enter the packing room, shucked stock, cans, and other equipment may become contaminated. A delivery window has proven to be an effective means of keeping shuckers out of the packing room. If shellstock are stored where polluted ground or surface water or floor drainage can accumulate, the shellstock may become contaminated.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands. Disease-causing microorganisms may be present in body discharges of employees that are cases or carriers of communicable disease organisms. When sewage disposal facilities are of a satisfactory type, there is less possibility that the shellfish being processed may become contaminated with fecal material carried by flies, rodents, or by other means.

E. Protection from Adulterants.

Shielded light fixtures help protect the food, equipment, and employees from glass fragments should the fixture break. Ventilation, plumbing, and air intakes for blowers can all introduce adulterants into the area where shellfish are stored or processed. Care must be exercised to prevent the entrance or leakage of adulterants. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants in these items from contacting shellfish.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the establishment. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, to be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests.

Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from being contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter.

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons, and gloves to eliminate the tendency to store such articles on the shucking benches or in packing rooms, where they interfere with plant clean up and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and are, therefore, more likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous materials. Miscellaneous equipment and articles may interfere with plant operations and make clean up more difficult.

B. Plumbing and Related Facilities.

Adequate toilet and Hand washing facilities, including running water, soap, and sanitary drying facilities also are essential to personal cleanliness of the workers.

C. Utilities.

Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Excessive temperatures also promote growth of spoilage microorganisms in shellfish and on food-contact surfaces.

D. Insect and Vermin Control.

Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from becoming contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter. Fly control measures, such as insecticide spraying, may also be necessary on the shell pile.

E. Disposal of Other Wastes.

Shellstock shipping and shucking facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the buildings or on the grounds. Removing shell and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Methods found to be suitable for removing these materials without contaminating the shucked product include conveyors,

baskets, barrels, wheelbarrows, and shell drop-holes. When shells are to be temporarily piled or stored on the premises, special controls may be needed. Organic wastes, including culled shellfish, clam siphons, and surf and ocean quahog viscera, need to be discarded into separate containers from the shells in the plant during shucking. These wastes can then be disposed of separately from the shell at, for example, a landfill. Proper disposal and prompt removal of shell and non-edible wastes from the plant also makes it possible to keep the premises clean, and decreases the likelihood that any product or food-contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless shucking benches, stands, blocks, and stalls are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces.

Determining an adequate cleaning procedure for facilities and equipment will depend upon which method of sanitizing is selected and what equipment and utensils are identified to be washed in a sink or washed "in place." Detergents and brushes, including special brushes that may be needed for cleaning equipment, such as blower lines, should be available. Cleaning and sanitizing of equipment and utensils should be initiated immediately after processing operations are finished. Postponing clean-up operations results in more difficult cleaning, creates conditions conducive to growth of bacteria and mold, which may not be completely removed, and may result in product contamination.

H. Shellfish Storage and Handling.

The sanitary requirements for individual shellfish dealers are variable since they may engage in several different phases of processing and distribution. Some shellstock shippers may have only a truck that is used to ship shellstock from a harvester to a processor or the market. Other shippers must have a building where shellstock is stored, repacked, or labeled. Consequently, the applicable sanitary controls must be based on an evaluation of the individual characteristics of the operation. Single-service and single-use containers, which have not been stored and handled in a sanitary manner, may become contaminated and thus may contaminate the packaged shellfish. Unacceptable practices that can interfere with the prompt handling, packing, and refrigerating of shellfish include holding shucked meats at the shucking station for prolonged periods, return of overage to the shucker, and bench grading of shucked meat. Another frequently encountered unacceptable practice is soaking of shucked meats for prolonged periods in water for the purpose of increasing yield through uptake of fresh water by the shellfish.

I. Heat Shock.

The primary objective of heat shock is to facilitate shucking of shellfish. Due consideration in developing the scheduled process must be given to a large number of factors which affect the heat shock process. Heat penetration into the shellfish will vary with species and size. Even regional variations in shell thickness and shape may affect the length of time required to reach the desired internal temperature. The temperature and time of exposure must be such that the adductor muscle is sufficiently relaxed to open easily but must allow the shellfish to remain alive. The scheduled process may be developed from studies conducted by the state, by a knowledgeable processor in cooperation with state shellfish control authorities, by shellfish experts such as university biologists, or by any other person with adequate knowledge of the technical control procedures. The person responsible for developing the scheduled process should retain all records of process operations so the FDA may review them and state shellfish control authority if questions arise regarding the adequacy of the scheduled process or its use.

J. Post-Harvest Processing. *Vibrio vulnificus*

has been identified as an organism of concern to at-risk consumers of shellfish. Post-harvest treatments which can demonstrate that the process achieves end point criteria of non-detectable (<30 MPN/gram) for *Vibrio vulnificus* can provide a product that has a reduced level of risk for these at-risk consumers. Applying those processes enables the dealer to label

treated products "Processed to reduce *Vibrio vulnificus* to non-detectable levels."

K. Toxic Materials.

Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to ensure the safety of workers and the consumer.

L. Personnel.

Disease producing agents may be carried on the hands of shuckers and packers unless proper Hand washing is practiced. Finger cots, gloves, and shields, unless effectively sanitized periodically, will accumulate bacteria that may contaminate the shucked shellfish. Employees handling shucked shellfish need to sanitize their hands as an added public health control practice.

M. Supervision.

Hand washing by employees is an important public health measure. Unless someone is made specifically responsible for this practice, it is apt to be forgotten or overlooked. Similarly, one person must be responsible for plant clean up. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for assuring compliance by all personnel with all requirements.

Chapter XV. Depuration

Requirements for the Authority

@.01 Administration

Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish harvested from moderately polluted (restricted) waters to such levels that the shellfish will be acceptable for human consumption without further processing. The process is not intended for shellfish from heavily polluted (prohibited) waters nor to reduce the levels of poisonous or deleterious substances that the shellfish may have accumulated from their environment. The acceptability of the depuration process is contingent upon the Authority exercising very stringent supervision over all phases of the process.

The depuration process shall be under the effective supervision of the Authority. The Authority shall have a management plan which details procedures for regulating the harvesting from restricted areas; controlling the transport of shellfish between the harvest area and to the depuration plant; approving plant design and operation, including subsequent changes; certifying and inspecting plants in accordance with the requirements of the *Model Ordinance*; and, prohibiting interstate shipments in the event that nonconformities are found which compromise the validity of the process. A Memorandum of Understanding (MOU) shall be developed between appropriate Authorities when more than one Authority is involved in the management plan.

Extensive administrative procedures are essential if the Authority is to adequately control a very complex operation such as depuration. There are numerous critical control points where significant deviation can result in the distribution of contaminated shellfish. Control over the harvesting areas is needed to ensure that the shellfish are not so contaminated that cleansing will be inadequate. Adequate control measures must be taken to prevent diversion of undepurated shellfish into the marketplace. Shellstock delivered to the depuration plant must be properly identified with information necessary to trace each harvest lot back to the harvest area, date of harvest, and harvester or group of harvesters.

Shellfish destined for depuration plants shall be protected as necessary during harvesting and transporting to prevent further contamination and undue physiological stress that could reduce the effectiveness of the depuration process. Thermal and physical shock can adversely affect the pumping action of shellfish and reduce the rate of elimination of microorganisms. Additional contamination of the shellfish during harvest could raise bacterial levels to such a point that adequate depuration will not occur. Thermal abuse may also cause bacterial levels to reach the point that depuration may not be effective in 48 hours. The types of protection that may be provided to prevent thermal abuse include; but, are not limited to: furnishing shade in warm weather; providing refrigeration in transit; ensuring rapid transit to the depuration plant; preventing freezing in cold weather; preventing breakage of shells; and, optimizing holding or storage time before depuration.

Depurated shellfish require an increased level of control compared to shellfish from approved areas because of the increased potential for contamination. These controls must include packaging and labeling that will serve to help identify the deputation cycle of each harvest lot and to deter illegal commingling of undepurated shellfish with depurated shellfish. Such controls include prohibition against commingling of harvest lots during packing, tags that identify the shellfish as being depurated, and a prohibition against repackaging after the shellfish leave the depuration plant. It is recommended that tamper-evident seals be used on the packages as a further deterrent. Design, construction and operation of the plant must adhere to guidelines established in the *Model Ordinance*. Finally, the inspection program must be adequate to detect critical deviations and to effect immediate correction or prevent the sale of suspect shellfish.

Requirements for the Depuration Processor

.01 Critical Control Points

A. Receiving Critical Control Point

Shellfish intended for deputation must be harvested only from growing areas meeting the water quality requirements for approved, conditionally approved, restricted, or conditionally restricted areas in the open status.

It has been amply demonstrated that shellfish harvested from prohibited areas should not be used for depuration. Depuration studies have been conducted on the relationship of initial levels of indicator bacteria and viruses to the levels of these indicators after varying lengths of time. These studies have indicated that consistent reductions of both bacteria and viruses to low levels can be achieved with moderately polluted shellfish, but satisfactory results cannot be obtained with heavily contaminated shellfish.

It is also essential that shellfish harvested from restricted or conditionally restricted areas be controlled so these shellfish are not illegally diverted and sold. This usually necessitates special procedures for monitoring harvest operations and tagging the shellfish. Methods that may be employed include the use of specially designed, labeled, or colored containers; or the use of colored or distinctly shaped tags. If shellfish are transported in bulk, other methods to distinguish the shellfish as originating from restricted or conditionally restricted areas may need to be employed. Recommended measures include continuous surveillance of the boat or truck, transporting in trucks sealed with a serially numbered, tamper-evident seal, or a count by the Authority of the quantity shipped and quantity received at the depuration plant.

B. Processing Critical Control Points

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design. Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is

accomplished by comparing the means and variability of end-product data from consecutive harvest lots for each species of shellfish harvested with species-specific critical limits for these parameters established empirically through extensive field work. The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets these established species-specific critical limits. New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subject to addition, more rigorous requirements under the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the marketplace.

C. Finished Shellstock Storage Critical Control Point

Depurated shellfish must be stored in a manner that maintains quality and prevents the shellfish from becoming contaminated. Two options are available to meet this requirement. The first is to bring and maintain the product under appropriate temperature control (45°F) by icing or refrigeration. In this way any low levels of bacteria that remain in the shellfish after depuration will be prevented from growing and reaching the point at which they may become harmful. The second option is to wet store depurated shellfish in waters of appropriate sanitary quality which meet the requirements of Chapters VII or X in the *Model Ordinance*.

.02 Sanitation

A. Safety of Water for Processing and Ice Production. The source of the process water and the water treatment system must be such that an adequate volume and quality of process water can be provided to accomplish effective depuration. Currently all plants in the United States use ultraviolet light (UV) for disinfection of process water. Numerous studies have shown UV treatment to be highly effective for inactivating bacteria and viruses provided the units are properly operated and maintained. In choosing a UV treatment system, consideration should be given as to whether the process water will be recirculating or flow through and whether the type of plant and flow rate are compatible with the UV treatment system.

As with any disinfection system, microbial inactivation is strongly dependent on the dose-time relationship which, for UV treatment is primarily a function of water depth and turbidity. Contact time is a function of the flow rate of the water and cross-sectional area or volume of the unit. In order for the UV lights to remain effective, the tubes must be kept clean to prevent build-up of materials which reduce radiation intensity. The amount of radiation must be monitored and the UV tubes replaced when they are no longer effective.

Ozone has been used for many years in Europe for treating depuration process water. Care must be taken in using ozone or other chemicals which may react with organic and inorganic components in the water to form compounds which adversely affect physiological activity. Disinfection with ozone and other chemicals could constitute a food additive situation requiring FDA approval before use.

Ice should be produced using potable water to avoid contamination. Care should also be exercised to avoid contamination of the ice during freezing or in subsequent storage and handling.

Shellfish washing should make use of water of good sanitary quality to avoid possible contamination or added contamination of the shellfish. Whatever the source, shellfish wash water must be of the sanitary quality of potable or drinking water .

B. Condition and Cleanliness of Food Contact Surfaces. The need to effectively clean and sanitize processing tanks, containers and pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment

can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur.

Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Uncleanable surfaces can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish.

C. Prevention of Cross Contamination.
Shellfish must be stored in a manner that will protect them from contamination while in dry storage and at transfer points. Employees should be encouraged to practice good personal hygiene, as they may be a source of cross-contamination.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Adequate toilet, hand washing and sanitizing facilities must be provided. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash their hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands.

E. Protection from Adulterants. Shielded light fixtures help protect the shellfish from contamination with glass fragments should the fixture break. Ventilation, plumbing, and air intakes can all introduce adulterants into the area where shellfish are stored or processed. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants from any source from contacting the shellfish or shellfish contact surfaces.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the plant. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer. Only those chemical agents necessary for plant operations shall be present in the plant and shall be used only in accordance with labeling.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of shellfish, shellfish contact surfaces, or shellfish packaging materials becoming contaminated, to be excluded from any operations which could be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests.
Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from being contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

. 03 Other Model Ordinance Requirements.

A. Plants and Grounds.

Physical facilities of the plant including the processing system shall be kept in good repair, and are cleaned and sanitized as necessary. No miscellaneous equipment is stored in processing or holding areas. The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons and gloves to eliminate the tendency to store such articles where they may interfere with plant cleanup and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and, therefore, are more likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous materials. Miscellaneous equipment and articles may interfere with plant operations and make cleanup more difficult.

The grounds about a depuration plant must be free from conditions that may result in contamination of shellfish at any time during processing and storage. The plant building or structure shall be suitable in size, construction, and design to prevent contamination of shellfish by animals and other pests; to keep untreated and treated shellfish separate; and to facilitate adequate cleaning, sanitizing, operation, and maintenance of the depuration facilities. Processing tanks, containers, piping and conveyances must be enclosed within a protective structure.

It is essential that depuration plants be designed and constructed so shellfish will be adequately protected and consistently depurated. Research on the depuration process and experience gained in commercial facilities has led to some generally accepted standards that are critical for effective depuration. Other design and construction criteria are less clearly defined, and only general guidance is available. Additionally, the plant must be designed and constructed so adequate cleaning and sanitizing can be accomplished (36), and to facilitate proper operation.

B. Plumbing and Related Facilities.

Adequate toilet and hand washing facilities, including running water, soap, and sanitary drying facilities are essential to personal cleanliness of the workers. Adequate floor drainage and backflow preventers are installed where appropriate. Drainage or waste pipes are not installed over shellfish processing or storage areas; nor, are they installed in areas in which shellfish containers and utensils are stored. Such precautions will minimize the potential for cross contamination.

C. Utilities.

Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Adequate ambient temperature control prevents excessive temperatures that promote growth of spoilage microorganisms and potential pathogens in shellfish and on shellfish contact surfaces.

D. Insect and Vermin Control.

Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from becoming contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

E. Disposal of Wastes.

Depuration facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the plant or on the grounds. Removing shell culled shellfish and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Proper

disposal and prompt removal of shell and non-edible wastes from the plant make it possible to keep the premises clean and decreases the likelihood that any shellfish or shellfish contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless storage and handling equipment are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces. Cleaning of the depuration tanks and equipment must be performed in a manner and at a frequency that will preclude the potential for contamination of the shellfish or shellfish contact surfaces.

H. Shellfish Storage and Handling. Washing of shellfish prior to depuration rids shells of sand, mud, and detritus that may interfere with depuration and may make tank cleaning difficult. The type of harvest method may negate the need for additional washing however. At other times, thorough washing at the plant may be necessary to adequately remove mud. Depurated shellfish shall be washed and culled after depuration and packaged in clean containers fabricated from safe materials. Different harvest lots of shellfish must not be commingled during packing. After depuration, washing removes feces and pseudo-feces that may cling to shells and may recontaminate the shellfish meats during processing or consumption.
Non-depurated shellfish must be stored in a manner that maintains their physiological ability to cleanse themselves and prevents post harvest contamination. Otherwise, depuration may not be effective. Depurated shellfish must be stored in a manner that will maintain their quality and prevent recontamination.

I. Personnel.
Personnel are not allowed to store clothing or other belongings, eat, drink or smoke in areas where shellfish are processed or stored. Such activities could lead to cross contamination of the shellfish or shellfish contact surfaces.

J. Supervision.
Management shall clearly designate a knowledgeable and competent individual to be present at the plant and be accountable that appropriate operating procedures and proper personal hygiene practices are followed. The supervisor will also maintain complete and accurate records that will permit each batch of depurated shellfish to be traced back to its source, and will account for all product sample results and measurements of critical parameters for each cycle. One person must be responsible for plant cleanup. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for ensuring compliance by all personnel with all requirements.

K. Plant Operating Manual.
The plant must prepare a written Depuration Plant Operations Manual (DPOM). A copy of this Manual must be kept in a location that is accessible to plant personnel responsible for the depuration activity. The DPOM will be kept current and contain all the information and records relevant to the operation of the depuration plant, and will be formatted to include the following:

(1) Introduction.

The introduction must contain information relative to the current status of the DPOM (create, revise, update, etc.), ownership of the plant, proposed schedule of operation, potential harvest areas and plant capacity.

(2) Description of the Facility.

The DPOM must contain site plan drawings for the plant, the facility layout including a detailed schematic of the entire depuration system, a schematic drawing of the process, shellfish flow diagram showing the movement of the shellfish throughout the plant, and a schematic of the process water delivery and distribution system. Essentially, the

documentation provided should show that the plant has the capability to achieve effective depuration of the shellfish, provide adequate storage before and after depuration, and prevent commingling of both depurated and undepurated shellfish and treated shellfish from different harvest lots.

(3) Design Specifications of the Depuration Unit.

During design and construction of depuration systems, careful consideration must be given to hydraulic flow through the tank. Non-uniform flow may result in dead spots and oxygen depletion that lead to inadequate depuration at some locations in the tank. Choice of' design criteria may be based on existing studies or new studies which verify effectiveness of any new designs. Furfari reports accepted design criteria for tank loading rates, water flow, and container arrangement. Tank water volume is recommended to be at least 6,400 liters per cubic meter of shellfish (8 cubic feet of water per U.S. bushel) for hard clams and eastern oysters and 4,000 liters per cubic meter of shellfish (5 cubic feet per bushel) for soft clams. A minimum flow rate of 107 liters per minute per cubic meter of shellfish (1 gallon per bushel) is recommended to maintain adequate oxygen levels. A clearance space of at least 7.6 cm (3 inches) is recommended for separating containers of shellfish in the tanks and between the shellfish containers and the bottom and sides of the tanks.

(4) Laboratory to be Utilized for Microbial Analyses.

Sample analyses shall be conducted by a laboratory approved by the Authority pursuant to the requirements of Chapter III in the *Model Ordinance*. Use of an approved laboratory ensures the quality and reliability of the analytical results.

(5) Depuration Process Monitoring.

If shellfish are released for sale before they are adequately depurated, adulterated shellfish may reach the market. It is essential; therefore, to implement an adequate sampling program designed to determine if critical environmental conditions are being met and if the shellfish being released to the market meet accepted criteria. Extensive field-testing has resulted in a set of species-specific critical limits being established which indicate the effectiveness of depuration process. These limits are referred to as the Critical Limits for the Indices of Depuration Plant Performance.

(6) Standard Operating Procedures.

Since effective depuration is dependent upon the control of a wide range of interrelated variables, it is essential that a set of standard operating procedures (SOPs) be developed which specify the exact procedures to be used for every aspect of the depuration process from receipt of the shellfish to data analysis, labeling and tagging. Use of SOPs help to ensure that appropriate actions are taken at each stage in the depuration process. By so doing, the probability that effective depuration and safe handling will be achieved is considerably increased and the incidence of processing mistakes is minimized.

(7)Record Keeping.

It is essential that detailed identification information be maintained on all harvest lots and shipping containers of depurated shellfish. In the events that an outbreak of illness occurs, or a question arises concerning the product, responsible state and federal authorities must be able to trace the implicated shellfish back to a specific depuration cycle, and to the harvest area. Additionally, maintaining complete and accurate records of all transactions serves to promote business integrity wherein all harvesters, processors, and dealers are fully accountable for their product. Records of product samples and critical parameters within the plant are necessary to determine if the plant is operating in accordance with the DPOM. Plant records should be kept for at least two (2) years in order that adequate investigations can be conducted in the event of a suspected illness and in order that the Authority can make process reviews.

L. Process Verification

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design. Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is accomplished by comparing the means and variability of end-product data for consecutive harvest lots for each species of shellfish with species-specific critical limits for these parameters established empirically through extensive fieldwork and referred to as the Critical Limits for the Indices of Depuration Plant Performance. The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets the established species-specific critical limits for the Indices of Depuration Plant Performance.

New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subjected to additional, more rigorous requirements under what is known as the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the market.

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IV. Guidance Documents
Chapter I. General

(.01 Evaluation Standards | .02 Procedures for Initiating a New State Program Under the National Shellfish Sanitation Program)

.01 EVALUATION STANDARDS

Background: 1995 Evaluation Standards Committee
As the result of an issue submitted at the 1994 ISSC annual meeting, the 1995 ISSC Evaluation Standards Committee was created. The Committee was charged with reviewing the standards of the Evaluation Research Society and making a recommendation to the ISSC as to whether these standards should be included in the NSSP and the form the inclusion should take. The Committee reviewed these standards as well as the American Evaluation Association's (AEA) *Guiding Principles for Evaluators*. The Committee recommended that the ISSC adopt the five principles of the AEA. The Committee consensus was that these principles should apply to all participants of the ISSC and should be included in the FDA state program evaluation manual currently in development. The Committee also submitted a resolution to the ISSC voting delegates recommending that the principles be adopted by the ISSC and that FDA incorporate these principles into its state program evaluation manual. The ISSC adopted the both the Committee's recommendation and resolution at its 1995 Annual meeting for use in the NSSP.

Evaluation Standards
In 1995, at its Annual Meeting, the ISSC adopted the following principles of the American Evaluation Association and requested that the Food and Drug Administration conduct its evaluations consistent with these principles.

- *Systematic Inquiry:* Evaluators conduct systematic, databased inquiries about whatever is being evaluated.
- *Competence*: Evaluators provide competent performance to stakeholders.
- *Integrity/Honesty:* Evaluators ensure the honesty and integrity of the entire evaluation process.
- *Respect for People:*
  Evaluators respect the security, dignity and self-worth of the respondents, program participants, clients, and other stakeholders with whom they interact.
- *Responsibilities for General and Public Welfare:*
  Evaluators articulate and take into account the diversity of interest and values that may be related to the general and public welfare.

.02 PROCEDURES FOR INITIATING A NEW STATE PROGRAM UNDER THE NATIONAL SHELLFISH SANITATION PROGRAM

The requirements of the NSSP are contained in its Model Ordinance. Implementation of the Model Ordinance is a shared responsibility of federal, state, tribal and local governments and the shellfish industry. The Model Ordinance establishes the minimum requirements necessary to effectively manage and enforce an interstate program, and is written for ease of legal adoption at all levels of government. It is intended to be adopted by state and tribal regulators to address the interstate movement of shellfish. The Model Ordinance provides a uniform legal instrument for enforcement, better nationwide public health protection, and facilitates the shipment of high quality shellfish in interstate commerce.

The ISSC provides the formal structure wherein state regulatory authorities, with FDA concurrence, can change the Model Ordinance and establish other guidelines and procedures for the sanitary control of the shellfish industry. For additional Information concerning the origin of the Model Ordinance and the ISSC, see the historical overview by Clem (1994) and the NSSP Guide for the Control of Molluscan Shellfish (ISSC/FDA, 2002).

To ensure uniformity in the administration and implementation of the requirements of the NSSP Model Ordinance at the state and tribal regulatory agency level, the FDA reviews their programs on an annual basis. New state or tribal regulatory programs under the NSSP are required to have their proposed program reviewed prior to its initiation to assure that any shellstock produced under the state or tribal program for movement in interstate commerce meets the requirements of the Model Ordinance.

New State or Tribal Program
The Authority must apply to the FDA for evaluation and be found in conformity with the NSSP before initiating a state or

tribal shellfish sanitation program or a new program element within an existing state or tribal program. The FDA will act on any application submitted by the Authority within 30 days. If the FDA has not acted within 30 days, the Authority may proceed with the new shellfish sanitation program.

When two or more State or tribal agencies will be involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

States and tribes are responsible for maintaining shellfish programs that conform to the requirements contained in the Model Ordinance. These requirements should be mandatory within each State program.

References

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IV. Guidance Documents
Chapter II. Growing Areas

.01 Total Coliform Standards

@.02 Bacteriological Standards

Note: The National Shellfish Sanitation Program (NSSP) allows growing areas 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. Once properly classified applying either standard for classification, the NSSP allows the use of the adverse pollution condition or the systematic random sampling strategy for routine classification monitoring as appropriate to the situation in the growing area. For maximum flexibility, a state may wish to adopt the use of both standards and both monitoring strategies as appropriate with each standard. At the Interstate Shellfish Sanitation Conference's annual meeting in 1992, Task Force II recommended that this portion of the *Model Ordinance* be codified according to the standard used and the monitoring strategy employed. The *Model Ordinance* has subsequently been recodified in this manner. This codification represents the delineation of the standards based on total coliforms. The division of the standards based on fecal coliforms is outlined in the main body of the *Model Ordinance* (Chapter IV).

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.

B. Sampling Stations. The Authority shall ensure that the number and location of sampling stations is adequate to effectively evaluate all pollution inputs into the growing area.

C. Exceptions.

(1) Except for growing areas classified as prohibited, in any growing area where there are nonpoint pollution sources which impact the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify a growing area not previously classified under Chapter IV @ .03.

(2) Except for growing areas classified as prohibited or when systematic random sampling is applied in growing areas where there are no pollution sources having an effect on the water quality, a minimum of 15 samples shall be required to classify any growing area not previously classified under Chapter IV @ .03 when there are no pollution sources impacting the water quality.

(3) The Authority is not required to apply the total coliform standard if a detailed study verified by laboratory findings demonstrates that the coliforms recovered from the growing area are not of direct fecal origin and do not indicate a public health hazard.

D. Standard for the Approved Growing Area Classification in the Remote Status.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard below.

(2) Total Coliform Standard for the Remote Status. The total coliform geometric mean MPN of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml; and not more than 10% of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for the 12-tube, single dilution test.

(3) Required Sample Collection.

(a) A minimum of 2 samples per sampling station shall be collected annually.

(b) A minimum of the most recent 15 samples collected per sampling station shall be used to calculate the geometric mean and 10% criteria of the data 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 Source Pollution.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard in
E §.(2)

(2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water quality sample results for each sampling station shall not exceed 70 per 100 ml, and, not more than 10 % of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for the 12-tube, single dilution test.

(3) Required Sample Collection.

(a) A minimum of 5 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 geometric mean and 10% criteria of the data to determine compliance with this standard.

(c) Sampling station locations shall be adjacent to actual or potential sources of pollution.

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Source Pollution.

(1) Exception. If the tidal stage increases the total coliform concentration, the Authority shall use sample results collected during that tidal stage to classify the area.

(2) Pollution Sources. Harvest waters shall be:

(a) Impacted only by randomly occurring, intermittent environmental 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 total coliform standard in §F (4) or §F (6) as appropriate to the monitoring strategy being used.

(4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml and the estimated 90^{th} percentile shall not exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

(a) Determining the geometric mean and logarithmic (base 10) standard deviation for the sample result from each sampling station; then

(b) Multiplying the log standard deviation in (a) by 1.28; and

(c) Adding the product from (b) to the log mean of sample results, and;

(d) Taking the antilog of the results in (c) to get the estimated 90th percentile.

(e) MPN values that signify the upper or lower range of sensitivity of the MPN test used in the 90th percentile calculation shall be increased or decreased by one significant digit.

(6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each sample station shall not exceed 70 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test; or

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for a 12-tube, single dilution test.

(7) Required Sample Collection.

(a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. (3) for application of the standard under §E. (2).

(b) Systematic Random Sample Monitoring. The requirement for systematic random sample monitoring 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 adhered to. If conditions at the time of scheduled sample collection are hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled in accordance with provisions in the sampling schedule;

(iii) A minimum of 6 random samples shall be collected annually from each sampling station in the growing area; and

(iv) A minimum of the 30 most recent randomly collected samples from each sampling station shall be used to calculate the geometric mean and 90th percentile to determine compliance with this standard.

(c) Transition from Adverse Pollution Condition Monitoring to Systematic Random Sample Monitoring. 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 requirements for a transition period not to exceed 3 years; and

(ii) Uses the transition period described in (i), as additional random samples are collected, the random samples shall chronologically replace 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 Source Pollution and Used as a Shellfish Source for Shellfish Depuration.

(1) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the total coliform standard in §G. (2).

(2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or

(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 1,386 MPN per 100 ml for a 12-tube, single dilution 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 Source Pollution and Used as a Shellfish Source for Shellfish Depuration.

(1) Exception. If the tidal stage increases the total 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 total coliform standard in §H. (4) or §H. (6) as appropriate to the monitoring strategy being used.

(4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean MPN of the water sample results for each sample shall not exceed 700 per 100 ml and the estimated 90^{th} percentile shall not exceed:

(a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or

(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test.

(5) Estimated 90^{th} percentile. The estimated 90^{th} percentile shall be calculated by the same method described in §F. (5).

(6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or

(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.

(7) Required Sample Collection.

(a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. (3). for application of the standard under §H. (6).

(b) Systematic Random Sample Monitoring. The Authority shall collect samples in the same manner and at the same frequency as specified in §F. (7)(b) for application of the standard under §H. (4).

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IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Contingency Plans

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP *Model Ordinance* requirements apply only to interstate
commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Introduction

Shellfish are filter feeders and, therefore, they have the ability to concentrate toxigenic dinoflagellates from the water column when present in shellfish growing waters. The toxins produced by these dinoflagellates can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and are transferred to humans when the shellfish are eaten (Gordan et al, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. Most of these toxins are detected through animal testing. However, some involve the use of instrument based or biochemical analyses for detection. Since the dinoflagellates are naturally occurring, their presence in the water column or traces of their toxin in shellfish meat does not necessarily constitute a health risk, as toxicity is dependent on concentration (dose) in the shellfish. To protect the consumer, the Authority must evaluate the concentration of toxin present in the shellfish or the dinoflagellate concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.

There are three types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and amnesic shellfish poisoning (ASP), also known as domoic acid poisoning. All three are dangerous toxins, and PSP and ASP or domoic acid can cause death at sufficiently high concentrations. In addition, ASP can cause lasting neurological damage. PSP is caused by dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karenia* (formerly *Gymnodinium*). Both of these dinoflagellates can produce "red tides", i.e. discolorations of seawater caused by blooms of the algae. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictably in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm.1973). Historically, *Alexandrium*
blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of clams which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. NSP, which is less common, has occurred from the Carolinas and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994).

The minimum concentration of PSP toxin that will cause intoxication in susceptible persons is not known. Epidemiological investigations of PSP in Canada, however, have indicated 200 to 600 micrograms of PSP toxin will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterious effects on humans. Shellfish growing areas should be closed at a PSP toxin level, which provides an adequate margin of safety, since in many instances PSP toxicity levels can change rapidly. The NSSP Model Ordinance requires that growing areas be placed in the closed status when the PSP toxin concentration is equal to or exceeds the action level of 80 micrograms per 100 grams of edible portion of raw shellfish (FDA, 1977; FDA, 1985).

In shellfish growing areas where low levels of PSP routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce but not entirely destroy the PSP content of the shellfish. If thermal processing is practiced, the Authority must develop and

implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat, or when the cell counts for members of the genus *Karenia* in the water column exceed 5,000 cells per liter of water.

ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudonitzachia*. Blooms of *Pseudonitzachia* are of relatively short duration. However, during the 1991-1992 incident in Washington, high toxin levels persisted for several months (Liston, 1994). The NSSP Model Ordinance requires that growing areas be placed in the closed status when the domoic acid concentration is equal to or exceeds 20 parts per million in the edible portion of raw shellfish.

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of PSP, NSP, domoic acid, or other marine biotoxins. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries having shellfish sanitation Memoranda of Understanding (MOU) agreements with the United States. As a result, states or countries with MOUs with the U.S. need to make contingency plans to address shellfish-borne intoxications.

Controlling Marine Biotoxins in Shellfish

The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxicity (Wilt, 1974). The primary goal of this planning should be to ensure that maximum public health protection is provided. To achieve this goal the following objectives should be met:

* An early warning system should be developed and implemented.

* Procedures should be established to define the severity of occurrences.

* The state or MOU country should be able to respond effectively to minimize illness.

* Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.

* Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.

Under the certification provisions of the NSSP, FDA and receiver states should have the assurance that shellfish producing states or MOU countries are taking and can take adequate measures to prevent harvesting, shipping, and consumption of toxic shellfish. To provide this assurance, the NSSP requires the Authority to develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The Authority's plan should specify how each of the objectives listed above will be accomplished. This document provides recommended guidelines to be used in preparing a plan to meet these objectives.

Recommended Contingency Plan Guidelines

** Provide an early warning system:*

1. Communication procedures should be established with other appropriate agencies to rapidly report to the Authority any abnormal environmental phenomenon that might be associated with shellfish growing areas such as bird or fish kills, water discoloration or abnormal behavior of shellfish or marine scavengers.

2. The Authorities should establish procedures for health agencies to report any toxin-like illnesses.

3. An early warning phytoplankton and/or shellfish-monitoring program should be implemented. These monitoring programs should use the "key station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).

* Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.

* When monitoring shellfish, samples should be collected of species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.

* The frequencies and periods for collection of samples should be established recognizing the randomness of PSP blooms. This assumes several years of baseline data in order to establish stations and sampling plans.

* Frequency of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations.

4. Channels of communication concerning shellfish toxicity should be established with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine biotoxin control official should be designated by the Authority to receive and distribute all marine biotoxin related information. Consultation with adjacent jurisdictions, marine biologists and other environmental officials might also be useful (Felsing, 1966; Quayle, 1969; Prakash et al., 1971)

* *Define the severity of the problem:*

1. A procedure should be established to promptly expand the sampling program for marine biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

2. Information should be available concerning the location of commercial shellfish resource areas in the state.

3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.

4. Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.

* *Respond effectively to minimize illness:*

1. A summary should be provided citing the laws and regulations in the state (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine biotoxin episode. The plan should clearly define the timeframe involved in taking appropriate legal action.

2. The administrative procedures necessary to place growing areas in the closed status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accomplish these actions should also be specified.

3. A plan should be developed which will define what type of patrol program is necessary to properly control harvesting in toxin contaminated growing areas. The program should be tested to ensure prompt implementation in the event it is needed.

4. Procedures should be developed to promptly disseminate information on the occurrences of toxic phytoplankton blooms to the industry and local health agencies.

5. Procedures should be established to coordinate control activities taken by state and federal agencies or departments and district, regional, or local health authorities.

* *Gather follow-up data:*

1. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

2. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.

* *Return growing areas to the open status of their NSSP classification:*

1. Once a growing area is placed in the closed status because of marine biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.

2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health, conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.

3. A program of consumer education should be continued as long as any area remains in the closed status because of marine biotoxin contamination.

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IV. Guidance Documents
Chapter II. Growing Areas

.03 Sanitary Survey and the Classification of Growing Waters

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Oysters, clams, mussels and scallops are filter feeders that pump large quantities of water through their bodies when actively feeding. During this process, molluscan shellfish can concentrate microorganisms, toxigenic micro-algae and poisonous or deleterious substances from the water column when they are present in the growing waters (Kennedy *et al.*, 1996). Concentrations in the shellfish may be as much as 100 times that found in the water column. If human pathogens are concentrated to an infective dose, and if the shellfish are consumed raw or partially cooked, human disease can result. If toxigenic micro-algae are present and producing toxin, human illness or death can occur, and cooking is not reliable as an effective barrier against intoxication.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing harvest from contaminated growing waters. In implementing this concept, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. Conformance with a classification's requirements is established through the sanitary survey.

The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times (Rippey [a] and [b], 1994). Shellfish-borne infectious diseases are generally transmitted through a fecal-oral route (i.e., the shellfish become contaminated by sewage and are eaten by humans). The pathway can be quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via storm water runoff or collected wastes can be discharged directly into a waterway. The runoff or discharge may go directly into the growing area or indirectly as is the case with wastes transported by freshwater streams to estuarine or marine waters. Information concerning the relationship between sewage pollution of bivalve shellfish growing areas and human disease is available in several good summaries (Hackney and Potter 1994 [a] and [b]; Jaykus *et al*, 1994; Stelma and McCabe, 1990).

Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct cause and effect between a numerical correlation and pollution source strength, bacteriological quality of water, and the degree of hazard to health. Tidal fluctuations and pollution source variations contribute to a high degree of variability in water quality. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc (cubic centimeter) portions of water examined were positive for the coliform group (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which could not be detected by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States (Lumsden, 1925), the National Shellfish Certification Program, now the National Shellfish Sanitation Program (NSSP), was initiated by the states, the Public Health Service, and the shellfish industry (Frost, 1925). The 1925 criteria for safe growing areas were stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilutions of the growing area water. The collective application of these criteria was known as the sanitary survey, which was used to determine if an area was safe for shellfish harvesting for human

consumption. These criteria were adopted in the United States in 1925. Reliance on these criteria and others to measure excess variability in water quality were combined together with sanitary reconnaissance (shoreline survey), hydrographic and meteorological considerations, and patrol of closed harvest areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. For a complete discussion of the history of the NSSP, see the historical overview by David Clem (1994) and the NSSP Guidance Document, *History of the Interstate Shellfish Sanitation Program* (ISSC/FDA, 2002).

The ability of shellfish to concentrate chemical pollutants from water and sediment can lead to accumulation of these poisonous and deleterious substances to levels that constitute a public health hazard (Kurland *et al.*, 1960; Texas Dept. Of Health, 1977). These poisonous or deleterious substances may enter shellfish growing areas through industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land, geochemical reactions, or naturally occurring toxigenic micro-algae (O'Connor and Beliaeff, 1995; Liston, 1994). The degree to which these substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish (Capuzzo, 1996; Roderick and Schneider, 1994; Rosijadi, 1996). The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

For a full discussion of the public health risk associated with micro-toxigenic algae, see the NSSP Guidance Document, *Guidelines for Developing a Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

Components of the Sanitary Survey

A review of epidemiological investigations of disease outbreaks attributable to the consumption of bivalve shellfish reveals that three general situations occur in the contamination of growing areas placed improperly in the approved classification. First, improperly conducted or outdated sanitary surveys or misapplication of water quality data have unwittingly allowed harvesting from sewage contaminated growing areas. Second, fresh fecal material present and not diluted, diffused, or not detected by ordinary bacteriological sampling procedures caused shellstock contamination (Lumsden, 1925). Dr. Gurion recognized the possibility of chance contamination as early as 1902 in his report on a typhoid outbreak:

"There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious (Gurion, 1917)."

Third, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. Some of these areas could have been placed in the conditionally approved classification and managed to avoid harvest of polluted shellstock, provided the occurrences of the sources of pollution could be predicted and the boundaries of their effects determined. For a full discussion of the use of the conditional classifications, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

The first critical control point in preventing food-borne illness from shellfish consumption is identifying growing areas of acceptable sanitary quality. The completion of a sanitary survey is of paramount importance in making the distinction between acceptable and unacceptable growing areas, and is the key to accurate growing area classification as approved, conditionally approved, restricted, conditionally restricted, or prohibited. Under the NSSP Model Ordinance, a sanitary survey is required for each growing area prior to its approval by the state as a source of shellfish for human consumption or as a source for shellfish to be used in a depuration or relay operation. A sanitary survey is an in-depth evaluation of all environmental factors that have a bearing on the water quality in a shellfish growing area. The environmental factors include both actual and potential pollution sources, whether natural or man-made, and meteorological and hydrographic characteristics of the growing area. The principal components of a sanitary survey are: (1) identification and evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) an evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality. For a complete discussion of the sanitary survey, see *Sanitary Surveys of Growing Waters* (Garreis, 1994).

(1) An evaluation of the pollution sources that may affect the growing areas. A pollution source survey (also known as a shoreline survey) must be conducted of the growing area shoreline and watershed to locate direct discharges (e.g., municipal and private sewage and industrial waste discharges, sewage package treatment units, malfunctioning septic tanks and animal manure treatment lagoons) and non-point sources of pollution (e.g., storm water runoff, and runoff from agricultural and wildlife areas). Municipal and industrial wastewater treatment facilities should be evaluated in terms of actual loading versus design capacity, type and concentration of pollutants discharged, effectiveness of their treatment processes and pollution control devices. For additional information concerning sewage treatment plant discharges and their control, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002) and the U.S. Environmental Protection Agency documents concerning increasing reliability of sewage treatment plants (USEPA [a] and [b], 1974).

The following survey procedures should be followed in the shoreline survey.

● *Survey Assignment*

Each shoreline survey area must be determined and assigned by the Authority. Each survey area must be identified by a unique designation. All survey data must be identified by this unique designation that allows for tracking of all forms used in the survey. All shoreline survey data must be documented and filed promptly.

● *Examination of Individual Properties for Pollution Sources*

* The boundaries of the shoreline survey area must be determined by an in-field investigation of the area topography and the proximity of individual properties to the growing area. Those properties with the potential to impact growing water quality must be included within the boundaries of the shoreline survey area. Once the boundaries of the shoreline survey area have been determined, all businesses and residences must be examined and all potential discharges of wastes (raw sewage, kitchen wastes, laundry wastes, agricultural wastes, etc.) must be evaluated.

* The location of each property with a pollution source adversely impacting the growing area must be provided.

* If the property has a pollution source adversely impacting a growing area, one of the two notations listed below must be made concerning its impact on water quality.

a) Direct Impact: A pollution source having direct impact is defined as any waste discharge which has immediate impact on the growing area. An attempt should be made to quantify the volume of the discharge.

b) Indirect Impact: A pollution source having an indirect impact is defined as any waste discharge which reaches the growing area in a roundabout way. An attempt should be made to quantify the volume of the discharge.

* All sanitary, industrial, or agricultural pollution sources must be located on a map of the survey area.

* All animal farms must be evaluated. Evaluation must include the number and type of animals.

* All marinas must be evaluated in accordance with the requirements of the Model Ordinance.

* Notations must be made of any flocks of waterfowl and an estimation of their number given. Populations of wild animals such as deer and muskrat should be noted and where possible an estimation of their number given.

* Drainage ditches must be evaluated.

* Any other potential source of pollution, which in the surveyor's opinion might influence water quality, must be noted.

* At the end of each shoreline survey, the surveyor must write a summation. The surveyor must also provide a comprehensive map of the survey area identifying the location of each pollution source found.

The level of surveillance for poisonous and deleterious substances in a shellfish control program may vary widely. The intensity of the surveillance is frequently driven by a history of marine biotoxin contamination, sanitary survey findings, or findings from investigations by other state or federal agencies or academia. Review of existing background data derived from national and international monitoring programs can also be useful (O'Connor, 1996; Beliaeff *et al*, 1997). An assessment of possible sources in the sanitary survey should enable shellfish control program managers to determine if a potential problem exists and whether a need for further field study exists. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern because of a lack of information.

When poisonous or deleterious substances are found in shellstock, the Authority must evaluate the levels that may be present against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Guidance Documents: *FDA Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2002); *Shellstock Relay* (ISSC/FDA, 2002); and *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002). In the absence of specific tolerance or action levels, decisions must be made on a case-by-case basis using the best available knowledge.

(2) An evaluation of meteorological factors.
Climate and weather can affect the distribution of pollutants or can be the cause of pollutant delivery to a growing area. Prevailing winds can determine the distribution of pollutants in a growing area. Rainfall patterns and intensity can affect water quality through pollutant delivery in runoff or cause flooding which can affect the volume and duration of pollutant delivery. An example of the effects of meteorology occurred in 1982. In the late fall, the arrival of cold fronts caused strong winds, abnormally low tides and high rainfall which resulted in raw sewage bypasses from overloaded sewage treatment plants. This combination of meteorological events resulted in raw sewage reaching a growing area causing shellfish- borne illness in 471 persons (Casper, 1982).

(3) An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area. Examples of hydrographic factors are tidal amplitude and type, water circulation patterns, and the amount of fresh water. These factors, along with water depths and stratification caused by density (salinity and temperature) differences, and wastewater and other waste flow rates are used to determine dilution, and time of transport. Tracer dye studies provide site-specific dilution, dispersion and time of travel information, and can be used in calibration of site-specific hydrodynamic models.

(4) An assessment of water quality.
In general, microbial reduction in seawater occurs by two different processes - physical dilution by advection and diffusion, and a process of biological inactivation. Dilution factors are physical and predictable with a direct relationship between pollution loads and dilution water available. The inactivation process is more variable and appears to be associated with the following factors: sunlight and solar radiation, absorption and sedimentation, temperature, predation, antibiosis, action of inorganic salts, nutrient deficiencies, the action of heavy metals and other substances, and effects of specific bacteriophage. Kator (1994) has provided a good summary of current knowledge concerning inactivation of bacteriological and chemical indicators caused by the effects of environmental factors.

Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to several months (Jaykus, 1994). In general, viruses survive longer at lower temperatures, at low salinity and when bound to sediments.

Evidence from many field studies indicates that a constant relationship does not exist between the bacterial pathogen, viral pathogen or coliform group levels in shellstock and the presence of these organisms in the overlying water column (Kator, 1994; Jaykus *et al*, 1994). Experience in the NSSP, however, has shown that shellstock from waters meeting the water quality standards for the approved classification are unlikely to be involved in shellfish-associated disease outbreaks attributed to fecal contamination of the growing area. In part, this is because the coliform group (total coliform) water quality standard of 70 MPN per 100 milliliters of growing water is equivalent to the fecal material contributed from one person diluted in about 2.27×10^8
liters (8 million cubic feet) of water free from the coliform group. Such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance.

The NSSP in its Model Ordinance allows for the Authority to classify a growing area using either a total coliform group or fecal coliform MPN standard as part if its sanitary survey. The two standards are believed to afford the same level of public health protection (Hunt and Springer, 1974). The NSSP Model Ordinance further allows the application of either standard to different water bodies within the state. The NSSP Model Ordinance also recognizes two distinct water quality monitoring strategies to collect the total coliform group or fecal coliform monitoring data for application of the standards: Adverse pollution conditions are to be established for initial classification, but if no point source pollution source impact is found the systematic random sampling monitoring strategy can be used for monitoring. The Authority may adopt the use of both the total coliform group and fecal coliform standards and both monitoring strategies, if applicable, for each standard.

The difference between the adverse pollution condition monitoring strategy and the systematic random sampling monitoring strategy is determined by 3 factors:

(1) The presence or absence of point source impact in the growing area;

(2) The timing of water sample collection; and

(3) The way in which the MPN data are calculated for comparison to the standard.

An adverse pollution condition (APC) is a state or situation, caused by meteorological, hydrological or seasonal events or point source discharges, that has historically resulted in elevated total coliform group or fecal coliform levels in a particular growing area. In using this monitoring strategy, sample collection must be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of microorganisms in their surrounding waters. The APC monitoring strategy must be used in initial growing area classification to assess the impact by sewage treatment

facilities, combined sewer overflows, or other point source discharges and to evaluate the impact of nonpoint pollution. The results of bacteriological sampling must be correlated with sewage treatment plant operation and evaluated in terms of treatment and nonpoint pollution contributions at the time of sampling. These results, combined with considerations for malfunctions, overloads, poor operation, and nonpoint triggering conditions are used in the initial classification.

The systematic random sampling monitoring strategy can be used in approved or restricted growing areas except those that are affected by point source pollution. This strategy assumes that monitoring conductedon a pre-established schedule at anadequate frequency willcapture weather or rainfall conditions that trigger nonpoint pollution contribution. For a full discussion of this strategy, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

Total coliform group or fecal coliform data collected under either the APC or the systematic random sampling monitoring strategy are reported as a MPN i.e. a statistical estimate of the number of bacteria per unit volume of water and is determined from the number of positive results in a series of fermentation tubes used in a particular laboratory test. A complete discussion of the MPN test can be found in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1985). In the APC monitoring strategy, the application of the two-part water quality standards for both total coliform group and fecal coliform involves use of a median or geometric mean and a "percentage factor". The "percentage factor" corrects for the inherent variation of the MPN analytical method when used with a normally distributed data set. In the systematic random sampling strategy, the application of the two part water quality standards for both the total coliform group and fecal coliform involves use of a median or geometric mean and an estimated 90th percentile as the statistic to measure the variance of the data set. The use of the strategy requires that the times of samples be scheduled in advance, so monitoring runs are made with no consideration for meteorological conditions. For a more in-depth explanation, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

A written sanitary survey report is needed to integrate the data from the pollution source survey, the hydrographic and meteorological investigations, and the water sampling into a comprehensive information analysis. The purpose of this analysis is to determine the appropriate classification for the growing area and the geographic boundaries of the classification. This report must include a compilation of relevant data, a water sample data analysis using appropriate data sorting to determine adverse pollution conditions and recognized statistical techniques, conclusions as to the appropriate growing area classification, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of the classification boundaries, when and the time periods for the open and closed status when conditionally approved and conditionally restricted classifications are proposed. Pollution conditions that cause closure, and conditions and time periods for seasonal openings must be included in the management plan.

Keeping the sanitary survey current consists primarily of routinely evaluating major pollution sources, collecting water quality data from sampling stations under the selected NSSP water quality monitoring strategy, and analyzing the data to assure that the classification continues to represent current sanitary conditions in the growing area. The sanitary survey must be repeated fully every 12 years. In the interim, the sanitary quality of each growing area must be reviewed as often as is necessary to ensure that the classification is appropriate. Certain sanitary survey components are required by the Model Ordinance to be updated annually and triennially (every third year). The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when monitoring or other informationreveals a substantial change in the sanitary conditions. A reevaluation report is required and must include a determination as to whether a change in growing area classification is necessary.

The Authority is required to collect and maintain survey data and information for each growing area in a centrally located file. Experience with the sanitary survey program for determining the appropriate classification for each growing area indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all sanitary survey reports, update information, and reevaluation reports is maintained. This is particularly true when responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file also simplifies the appraisal of state programs by the FDA and prevents loss of useful historical data.

Minimum Requirements of the Sanitary Survey Report

The following outline contains the minimum requirements for the written growing area sanitary survey report required in the NSSP Model Ordinance.

A. Executive Summary

B. Description of Growing Area

(1) Location map or chart showing growing area

(2) Description of area and its boundaries

(3) History of growing area classification

* Date of last sanitary survey

* Previous classification(s) map(s)

C. Pollution Source Survey

(1) Summary of Sources and Location

* Information gathered under the shoreline survey procedures outlined above.

* Map or chart showing the location of major sources of actual or potential pollution in the survey area.

* Table of sources of pollution cross-referenced to the survey area map.

(2) Identification and evaluation of pollution sources

* Domestic wastes (discussion and maps)

* Storm water

* Agricultural waste (farms, feedlots, & slaughterhouse operations)

* Wildlife areas

* Industrial wastes

D. Hydrographic and Meteorological Characteristics

(1) Tides (type and amplitude), and currents (velocity and direction)

(2) Rainfall

* Amount

* When (e.g. time of year)

* Frequency of significant rainfalls

* Winds (Seasonality and effects on pollution dispersion)

(4) River discharges (volume and seasonality)

(5) Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout the growing area

* Salinity, depth, and stratification characteristics

* Computer model verification if used for classification.

E. Water Quality Studies

(1) Map of sampling stations

(2) Sampling plan and justification

* Adverse condition sampling

* Random sampling

(3) Sample Data Analysis and Presentation: Tables containing the basic NSSP statistics (number of samples, median or geometric mean, and the respective variability factors)

* Station by station monitoring data array collected under the adverse condition or systematic random sampling monitoring strategy

* Daily sampling results and number of samples collected for survey

* Overall compliance with NSSP criteria

* Sorting of data by environmental pollution condition

* Classification assigned to each station

F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:

(1) Effects of meteorological and hydrographic conditions on bacterial loading

(2) Variability in the bacteriological data and causes

G. Conclusions

(1) Map or chart showing classification assigned to growing area(s) (closure lines, boundary lines separating various classifications)

(2) Legal description of growing area boundaries

(3) Management plan for growing area if in the conditionally approved or conditionally restricted classification

(4) Recommendations for sanitary survey improvement

* Changes in monitoring schedules, addition of sampling stations or station relocation, etc.

* Comments

Growing Area Classifications

As a result of the information gathered during the sanitary survey, the Authority should be able to distinguish those growing areas suitable for harvest of shellstock for direct human consumption, those growing areas where the shellfish will require treatment to make them safe for human consumption, and those growing areas unsuitable to harvest for human consumption. The probable presence or absence of pathogenic microorganisms, marine biotoxin or other poisonous or deleterious substances in growing area waters is important to the Authority in deciding how the shellfish obtained from the growing area should be used. The Authority's decision, based on the sanitary survey information, will place all actual and potential growing areas in one of the five possible NSSP growing area classifications.

The five growing area classifications are approved, conditionally approved, restricted, conditionally restricted and prohibited. Except for an emergency situation such as conditions following a hurricane when a growing area in the approved classification may be placed temporarily in the closed status, a growing area in the approved classification is always in the open status. The remaining four growing area classifications all place some type of restriction on shellstock harvesting. For more information concerning the enforcement of these restrictions, see the NSSP Guidance Document, *Growing Area Patrol and Enforcement of Growing Area Restrictions* (ISSC/FDA, 2002).

Growing areas are placed in the approved classification when the sanitary survey information and marine biotoxin surveillance data indicate that fecal material, pathogenic microorganisms, poisonous, or deleterious substances are not present in the growing area in unacceptable concentrations. Shellstock harvested from these growing areas may be sold directly to the public for consumption raw or cooked.

Use of the conditionally approved and conditionally restricted classifications by the Authority is optional. The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when, during certain times of the year or under certain conditions, the shellstock from the growing area may be safely

harvested. The concept also applies to situations where conditions are acceptable for harvest when wastewater treatment plant operation is satisfactory, but not when a malfunction occurs. A management plan is required that describes the controls to provide public health protection in the use of the conditional classifications. For a full explanation of the conditional classifications and their use, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

A growing area may be placed in the restricted classification instead of the prohibited classification when the sanitary survey indicates a limited degree of pollution. This option may be used when the sanitary survey for the growing area indicates that the levels of fecal material or poisonous or deleterious substances in the growing area are such that additional treatment through depuration or relay can render the shellstock safe for human consumption. A common situation in the use of the restricted classification occurs when a growing area is affected by non-point source pollution from either urban or rural sources. In this situation, the water quality fluctuates unpredictably or with sufficient frequency that the use of the conditionally approved classification is precluded. The Authority should use the restricted classification only when sufficient depuration or relay studies have been conducted to establish raw product quality requirements at the harvest level; and when the Authority has sufficient administrative and technical resources to properly administer this classification. These resources include monitoring of pollution sources; providing coordination between state, local and industry officials; issuing special harvesting permits; and supervising the harvesting and transport of shellstock to relay sites or depuration facilities. For a complete discussion of the supervision requirements at the harvest level, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Use of the restricted classification requires the Authority to develop the controls necessary to assure that the shellfish are relayed or depurated prior to consumption. Bacteriological water quality standards are applied on a growing area specific basis. The criteria may vary according to the use to be made of the shellstock and the effectiveness of the relay or depuration process used to cleanse the shellstock. Process effectiveness is determined through a study, which establishes the fecal coliform density in the shellstock at the time of harvest, and the density that can be achieved at the completion of the process. Effectiveness of the process is likely to vary between growing areas used for natural cleansing treatment in relay operations and between depuration facilities used for controlled cleansing treatment. The species of shellstock may also affect the effectiveness of the relay or depuration process. For a complete discussion of relay, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

A growing area is placed in the prohibited classification when the sanitary survey or marine biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area for any human food purpose is not allowed.

Depletion of prohibited areas can be an effective deterrent to illegal harvesting as it provides a safeguard against contaminated shellfish reaching the market and eliminates a temptation for harvesters. Depletion may be more economical and effective than patrol of prohibited areas in protecting public health. In a depletion operation, all market sized shellstock and as many of the smaller sized shellstock as can be gathered by reasonable methods are removed from the growing area. To be effective, depletion operations should be conducted at sufficient intervals to keep growing areas free of commercial quantities of market-sized shellstock. When commercial harvesters conduct depletion operations, the Authority or the Patrol Authority must provide effective supervision.

The NSSP Model Ordinance also requires that an area in the prohibited classification (closed safety zone) must be established between any sewage treatment plants or other waste discharge of public health significance and any growing area placed in the approved, conditionally approved, restricted, or conditionally restricted classification. The size of the prohibited area should be based on the effectiveness and level of sewage treatment; the location of the shellstock resource that would be affected; the classification of adjacent waters, the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; the time it would take the Authority to issue a notice to stop shellstock harvesting, and the degree of effluent dilution. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night.

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IV. Guidance Documents
Chapter II. Growing Areas

.04 Action Levels, Tolerances And Guidance levels for Poisonous or Deleterious Substances in Seafood

Because shellfish are filter feeders, they can readily accumulate substances from the water column. The types of poisonous or deleterious substances that have been recovered from shellfish include heavy metals, pesticides, petroleum products, polychlorinated biphenyls, and naturally occurring marine biotoxins. The source of these contaminants may be industrial, agricultural, mining, spillage, sewage, dredging operations, sludge dumps, and naturally occurring toxigenic marine organisms.

The FDA has established action levels, tolerances and guidance levels for poisonous or deleterious substances to control the levels of contaminants in human food including seafood (FDA Federal Register, 1977; FDA, 1985). Action levels are established and revised according to criteria specified in the ***Code of Federal Regulations*** (21 CFR 109 and 509), and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective. Action levels and tolerance represent limits at or above which FDA will take legal action to remove adulterated products, including shellfish, from the market. Action levels and tolerances, are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. Guidance levels are used to assess the public health impact of the specified contaminant.

Table 1 lists action levels, tolerances and guidance levels established by the FDA for poisonous or deleterious substances in seafood including shellfish. Notices are published in the ***Federal Register*** as new action levels are established or as existing action levels are revised or revoked. Should any of these notices affect Table 1, FDA will issue an interpretation advising NSSP participants of this revision or addition.

Table 1
Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Class of Substance	Substance	Level	Food Commodity[a]	Reference
Deleterious Substance	Aldrin/Dieldrin[c]	0.3 ppm	All Fish	CPG sec 575.100[b]
	Chlordane	0.3 ppm	All Fish	CPG sec 575.100[b]
	Chlordecone[d]	0.3 ppm	All Fish	CPG sec 575.100[b]
		0.4 ppm	Crabmeat	CPG sec 575.100[b]
	DDT, DDE, TDE[e]	5.0 ppm	All Fish	CPG sec 575.100[b]
	Diquat[g]	0.1 ppm	All Fish	40 CFR 180.226
	Glyphosate[g]	0.25 ppm	Fin Fish	40 CFR 180.364
		3.0 ppm	Shellfish	40 CFR 180.364
Toxic Elements	Arsenic	76 ppm	Crustacea	FDA Guidance Document
		86 ppm	Molluscan Shellfish	FDA Guidance Document
	Cadmium	3 ppm	Crustacea	FDA Guidance Document
		4 ppm	Molluscan Shellfish	FDA Guidance Document
	Chromium	12 ppm	Crustacea	FDA Guidance Document
		13 ppm	Molluscan Shellfish	FDA Guidance Document
	Lead	1.5 ppm	Crustacea	FDA Guidance Document
		1.7 ppm	Molluscan Shellfish	FDA Guidance Document
	Nickel	70 ppm	Crustacea	FDA Guidance Document
		80 ppm	Molluscan Shellfish	FDA Guidance Document
	Methyl Mercury	1.0 ppm	All Fish	CPG sec 540.600
	Heptachlor / Heptachlor Epoxide[f]	0.3 ppm	All Fish	CPG sec 575.100
	Mirex	0.1 ppm	All Fish	CPG sec 575.100
	Polychlorinated Biphenyls (PCBs)[g]	2.0 ppm	All Fish	21 CFR 109.30
	2,4-D[g]	1.0 ppm	All Fish	40 CFR 180.142
Natural Toxins	Paralytic Shellfish Poison (PSP)	80 µg/100g	All Fish	CPG sec 540.250
	Neurotoxic Shellfish Poison (NSP)	<20 MU/100 g	Clams, mussels, Oysters, fresh frozen or canned	NSSP MO
	Amnesic Shellfish Poison (ASP)	20 ppm	All Fish (except in the viscera of Dungeness crab where 30 ppm is permitted	Compliance Program 7303.842

Note:
the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals and all mollusks as defined in *21 CFR 123.3(d)*.

Footnotes for Table 1

a) Unless otherwise specified, the action levels, tolerances and other values listed apply to both the raw and processed food commodity. Procedures for sample collection and analyses are specified in Sections 420 and 450 of the ***FDA Investigations Operation Manual***; ***FDA Pesticide Analytical Manual (PAM)*** Volume I or II; ***AOAC Official Methods of Analysis***; ***APHA Recommended Procedures for the Examination of Sea Water and Shellfish***, Fourth Edition, 1970; or, peer reviewed literature for domoic acid (ASP) methodologies.

b) References designated as CPG represent the FDA Compliance Policy Guides and all associated numbers as they appear in appropriate sections of FDA's Compliance Policy Guides Manual.

c) The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at the level below 0.1 ppm for fish.

d) Previously listed as Kepone, the tradename for chlordecone.

e) The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE do not count any of the three found below 0.2 ppm for fish.

f) The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.

g) The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

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IV. Guidance Documents
Chapter II. Growing Areas

.05 Management Plans for Growing Areas in the Conditional Classification

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate
commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. In implementing this goal, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. For a full explanation of this concept, see the public health explanation in NSSP Guidance Document, Sanitary *Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection from unsafe shellfish in the use of the conditional classifications is afforded through the use of a management plan. Using a thorough investigation conducted as part of the sanitary survey, the Authority determines that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the factors which determine this period of time are known, predictable and are not so complex that the factors cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. The plan establishes a strict set of criteria, which must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of the compliance with the plan to assure public health protection.

The criteria for the approved classification of the NSSP require that the growing area be not subject to human or animal fecal matter at levels that present an actual or potential public health risk, and not be contaminated with pathogenic organisms, poisonous or deleterious substances or marine biotoxin. From the review of growing area classifications and sanitary surveys conducted by national and international Authorities, it appears that a common misuse of the approved classification is the placement of a growing area in the approved classification when the use of the conditionally approved classification would have been more appropriate. Critical investigation usually reveals that the growing area is improperly classified because it is subject to intermittent pollution events, which is a contravention of the criteria for the approved classification.

Intermittent pollution events have been identified as a significant cause of shellfish-borne infectious disease outbreaks worldwide. As an example, in the fall of 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters from a growing area that had been placed in the approved classification (Casper, 1982). An investigation into the outbreak demonstrated that the growing area could probably be safely open to harvesting in the summer when the prevailing winds are southerly and tides are high. In the late fall, the arrival of cold fronts can cause high rainfall, strong winds and abnormally low tides and raw sewage bypasses from overloaded

sewage treatment plants. Under these conditions, sewage reached the growing area causing the outbreak. As a result of the investigation, the Authority learned that it should have placed the growing area in the conditionally approved classification and developed a management plan to automatically close the area in the late fall through spring when climatic conditions were likely to render the growing area unsafe. Under the management plan, the area would be reopened to harvesting in the summer when favorable conditions prevailed and would be intensively monitored to ensure that the summer conditions were met. In this instance, application of the conditionally approved area concept probably could have prevented the outbreak.

Use of the Conditional Classification

Use of the conditional classifications is a voluntary option for the Authority. There are two types of conditional areas: conditionally approved and conditionally restricted. Any growing area in the conditionally approved classification must meet the criteria for the approved classification when it is in the open status of this classification. When the growing area is in the closed status of this classification, it may be used for relaying or depuration if it meets the requirements for the restricted classification and if this use is specified in its management plan, or it may be closed to any use. Any growing area in the conditionally restricted classification must meet the criteria for the restricted classification when it is in the open status of this classification and no harvesting is permitted when it is in its closed status.

Growing areas that are subject to intermittent microbiological pollution from predictable pollution events may be placed in the conditionally approved or conditionally restricted classification under the NSSP. Examples of predictable pollution events include the failure of wastewater treatment facilities to maintain a performance standard needed to maintain an established effluent quality; changes in seasonal populations affecting growing area water quality; and nonpoint source pollution events such as caused by as certain rainfall intensities. Conditional classifications may also be used to manage growing areas affected by toxigenic micro-algae that produce marine biotoxins.

An example of a common situation where use of the conditionally approved classification might be appropriate is when water quality is dependent upon the operation and performance of a sewage treatment plant. In this example, the growing area would meet the criteria for the approved classification when the sewage treatment plant is performing satisfactorily. If there is some interruption in sewage treatment, the likely result will be degradation of water quality in the growing area. This degradation would require the establishment of a prohibited area large enough to dilute and assimilate the effluent discharged during the interruption in treatment. If an interruption can be predicted and is at a manageable frequency necessitating repeated closings (e.g. one or two times a year), the Authority may consider a conditionally approved classification for a portion of the growing area classified as prohibited. Interruptions could include a disinfection failure or certain climatic conditions which are known to affect the wastewater treatment facility's performance). Although many Authorities are burdened by administrative procedures, the use of a management plan for the conditional classification allows the Authority to act quickly to implement closures, and avoid unnecessary delays in returning the conditionally approved portion of the growing area to the open status. The added administrative burden might be offset by the shellfish resource gained by upgrading a prohibited portion of a growing area to the conditionally approved classification.

The concept of the conditionally approved classification is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples include:

* The water quality in a growing area adjacent to a resort community may vary according to seasons of the year. During the summer months, when the community experiences a significant population increase, water quality may be adversely affected. However, during the winter when there are few people in the community, water quality might improve sufficiently to allow the growing area to be placed in the open status. In some states, this is known as a seasonal closure.

* The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet several months a year, might vary. When the fishing fleet is in the harbor, the water might be of poor sanitary quality. The area would be closed for shellstock harvesting when the fishing fleet is using the harbor. During the remainder of the year, however, the quality of the harbor water might meet the criteria for the approved classification and be opened to shellstock harvesting.

* The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants from adjacent land surfaces (non-point pollution) into the growing area. During periods of low

runoff or river discharge, the area might meet the criteria for the approved classification.

The use of the conditional classification option offers the Authority the ability to increase the availability of water for shellfishing that would otherwise be closed. The management plan dictates the circumstances and procedures for immediate response to situations requiring closure. The administrative procedures included in the management plan allows the Authority to reopen the area to harvesting as soon as the pollution condition is over and the water quality and shellstock have returned to acceptable quality.

Suitability of the Conditional Classification

The first step is to determine, through a thorough investigation conducted as part of the sanitary survey, if the growing area is suitable for conditional management by evaluating the potential sources of pollution in terms of their effect on water quality. Information must be gathered to support the supposition that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the pollution events which determine this period of time are known, predictable and are not so complex that the factors of these events cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The investigation may also consider relevant resource management, social, economic, or political factors that may influence the open and closed periods, and the establishment of boundaries, for the conditional classification of a growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. Some potential sources of pollution which could be managed under a conditional classification management plan include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally related pollution occurrences, animals, land runoff, and freshwater flows.

The second step in determining the suitability of conditional classifications is to determine whether the Authority has sufficient resources available to survey, manage, monitor, control harvesting, close and reopen the area as required. Use of these classifications imposes additional manpower and resource burdens on the Authority. For example sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. Any Authority that has elected to use the conditionally approved or conditionally restricted classifications has found the resource investment to be substantial and this investment must be balanced against the benefit of the additional shellfish resource available.

The third step is to evaluate each source of pollution in terms of the pollution load and to determine if performance standards can be formulated for each pollution source having a significant effect on the sanitary quality of the growing area. The conditional classification management plan must establish a strict set of criteria, which must be met for the growing area to remain in the open status. The following are examples of different types of performance standards that could be used:

* Performance standards might stipulate the bacteriological quality of effluent from sewage treatment plants. The microbiological quality can be monitored in terms of disinfection residual or dosage for ultraviolet light disinfection. An example of a performance standard for an effluent discharge is: "The median fecal coliform MPN, in any one month, shall not exceed 200 per 100 ml, based on not less than 16 samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 1,000 per 100 ml. This fecal coliform limit shall be presumed to be met if the chlorine residual in the effluent is at least 1.0 ppm and the chlorine residual in the effluent is continuously recorded on a chart by chlorine residual analyzer or is measured hourly and recorded in the daily monitoring records as required for the plant's NPDES permit."

* For disinfection by ultraviolet (UV) light, the disinfection is based on dosage. An example of a performance standard is, "A minimum UV dose of 37 mW-Sec/cm^2 is to be maintained. The calculation of intensity of the UV light is to include factors for effluent quality, including turbidity, suspended solids, and transmittance. The effluent factors contributing to the dose, including turbidity, suspended solids, transmittance, and flow will be continuously measured and recorded. An alarm will be activated if any of the factors are above design limits."

* Performance standards might be based upon the amount of vessel traffic in the area and the concomitant amount of sewage that can be expected.

* Performance standards might be based upon the amount of rainfall in the immediate area. An example is: "The growing area will be closed to harvesting for (number of days) when there has been 2 inches or more rainfall

registered at a rain gauge at (specified location) within a 24-hour period."

* Performance standards might be based upon the height of a river stage. An example could be: "When the river at (a specified area) reaches 3.66 meters (12 feet) or higher, the growing area will be closed."

The design of a waste treatment plant and the plant effluent specifications are critical to the use of the conditional classifications. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (fecal coliform) of sewage, predicted survival of fecalcoliform in seawater, effectiveness of disinfection and the amount of clean dilution water in an area.

The mechanical equipment at critical sewage treatment or plant components should be such that interruptions will be minimized. Requirements, which might be imposed, depend upon the importance of the unit's relationship to maintenance of water quality in the growing area. Important design features, which should be considered in the design of the sewage collection system, include:

* Exclusion of storm water runoff from sewer collection systems and use of devices such as flow equalization tanks to control effects of storm water infiltration on treatment plant performance;

* Provision of stand by power at critical sewage pumping stations through the use of on-site emergency generators, or other alternate power sources;

* Use of gauges, charts and other recording devices to monitor flows and performance standards; and

* Use of alarms, telemetering or other devices to report immediately failure of any critical components at the wastewater treatment plant and in the collection system at sewage pumping stations.

A detailed discussion of ways to increase the reliability of sewage treatment plants can be found in *Protection of Shellfish Waters* (USEPA, 1974) and *Design Criteria for Mechanical, Electric and Fluid System Component Reliability* (USEPA, 1974).

The fourth step is to determine the water quality, which will occur in the growing area when the performance standards are not met, and what portion of the growing area will be affected. Once these determinations are made, the Authority can select the appropriate management strategy for the portion of the growing area that will be placed in the closed status when performance standards are not met, and can select the boundaries for the closed status. The boundaries of that portion of the growing area to be placed in the closed status would depend upon such items as the distance and travel time from the pollution source to the area, the concentration of pollutants in the discharge during the breakdown condition, amount of effluent and hydrographic factors including dilution available in the receiving water.

The use of the conditional classification where a sewage treatment plant is the pollution source being managed requires a fifth step. An area in the prohibited classification (closed safety zone) must be established between the sewage treatment plant and the growing area placed in the conditionally approved or conditionally restricted classification. The size of the prohibited area should be based on the level of sewage treatment; the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; and the time it would take the Authority to issue a notice to stop shellstock harvesting. The size of the area in the prohibited classification should allow for a effluent travel time through the prohibited area that is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night. A minimum effluent dilution is to be determined at the prohibited boundary and can be the controlling factor in situations where there is efficient detection and notification of breakdowns.

The length of time that a growing area should be in the closed status of its conditional classification will depend upon several factors. These factors include the degree of pollution in the growing area and flushing capacity of the estuary, the species of shellfish, water temperature, shellstock activity and cleansing rates, and presence of silt or other chemicals that might interfere with the physiological activity of the shellstock. Additional information on the natural cleansing of shellstock is provided in the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Minimum Requirements for a Conditional Area Management Plan

The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are:

A. An understanding of and agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved;

B. A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C through H;.

C. A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data.

D. A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including:

(1) For a wastewater treatment facility, the performance standard should be based on:

* Peak effluent flow

* Bacteriological quality of the effluent

* Physical and chemical quality of the effluent

* Bypasses from the treatment plant or its collection system

* Design, construction, and maintenance to minimize mechanical failure or overloading (i.e. The reliability of the treatment system and collection system components)

* Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.

* Identification of conditions that lead to wastewater treatment plant failure and closure of the conditionally approved area.

(2) For meteorological or hydrological events, the performance standard should be based on:

* Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;

* Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and

* The predicted number of times, based on historical findings, that the pollution event will occur within one year.

(3) For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance standard should be based on:

* Identification of the seasonal event that will cause the growing area to be placed in the closed status,

including its estimated duration; and

* Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification;

E. A description of the plan for monitoring water quality including numbers and frequency;

F. A description of how the closed status for the conditional classification will be implemented, which must include:

(1) A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status;

(2) A requirement to notify the Authority or Authorities that the management plan performance standards have not been met, including:.

* The name of the agency or other party responsible for notifying the Authority;

* The anticipated response time between the performance standards not being met and notification of the Authority; and

* The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel;

(3) A description of the implementation and enforcement, including:

* The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority;

* The procedures and methods to be used to notify the shellfish industry; and

* The procedures and methods to be used to notify the patrol agency (enforcement agency) including:

- The name of the responsible patrol agency;

- The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and

- A description of the patrol agencies anticipated activities to enforce the closed status.

G. A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:

(1) The performance standards established in the management plan are again fully met;

(2) The flushing time for pollution dissipation is adequate;

(3) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;

(4) Where necessary, the bacteriological quality of the water must be verified; and

(5) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

H. A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance.

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IV. Guidance Documents
Chapter II. Growing Areas

.06 Shellstock Relay

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Relaying is the practice of harvesting shellstock from polluted growing areas and placing them in unpolluted bodies of water for a sufficient time for the shellstock to reduce contaminating microorganisms and chemical contaminants to safe levels. When adequate controls are used during the relay process, shellstock resources that would otherwise not be available for human consumption are made safe through natural cleansing, and become accessible to the shellfish industry and the consumer.

Research has shown that shellstock has the ability to purge itself of certain microbial and chemical contaminants when placed in clean saline water. The rate of purging depends on the specific contaminants, species of shellstock, and several environmental factors. As early as 1911, public health officials were investigating the use of natural cleansing through relaying to reduce pathogenic organism levels in oysters (Clem, 1994).

Factors Affecting Natural Cleansing

Shellstock, which is heavily contaminated with microorganisms, may require additional time for natural cleansing. (Metcalf and Stiles, 1968; Canzonier, 1971; Metcalfe, 1979) The length of time required for the cleansing process is influenced by many factors including level of pollution in the shellstock when it is removed from the polluted waters. Roderick and Schneider (1994) have prepared an excellent summary of the current knowledge concerning depuration and relaying of shellstock. Their work identifies four critical factors that affect the physiological activity, pumping rate and behavioral responses of shellstock: water temperature, salinity, dissolved oxygen, and turbidity and suspended solids. Shumway (1996) reports that temperature is the most important factor affecting the eastern oyster. Both temperature and salinity have an important effect on eastern oyster pumping rates, which is important for natural cleansing, with temperature being the most important parameter.

Investigations by marine biologists have confirmed that the physiological activities of shellstock are reduced when the water temperature falls below a certain value. This finding is important because viruses, other pathogens and chemical contaminants cannot be eliminated from shellstock if the shellstock is not actively pumping water. Loosenoff (1958) showed that pumping rates in the eastern oyster rose steadily as water temperature climbed from 8°C to 28°C. Pumping was reported as severely reduced or non-existent below 2°C. Generally investigators agree that the pumping rates in the eastern oyster are reduced at less than 10°C (50°F) (Shumay, 1996).

Cabelli (1971) reported that few coliform organisms were recovered from the northern quahog (*Mercenaria mercenaria*) when the temperature was below 10^0 C (50°F), even though they were collected from heavily polluted waters. Cabelli (1970) also reported the lower limit of the water temperature of the water acceptable for cleansing of soft clams is about 10°C (50°F). Burkhardt et al (1992) found that hibernating shellfish become very active after the threshold temperature is reached, and that bacterial and viral indicators accumulate and eliminate differently.

Jaykus *et al* (1994) have prepared a good summary of the current knowledge concerning the viruses associated with shellstock and their elimination through relaying and depuration. In their discussion of the relationship between viruses in shellstock and the coliform indicators used as bacteriological standards, the investigators report "no meaningful relationships have been found between virus presence in clams and oysters and a variety of bacteriological and physicochemical parameters for water and

shellfish."

There is considerable information available, particularly for the eastern oyster *(Crassostrea virginica)*, concerning the bioaccumulation and elimination of metals and lipophilic organic contaminants from shellstock (Roesijadi, 1996; Capuzzo, 1996). Pringle (1968) showed that different species of shellstock accumulate varying levels of heavy metals depending upon the pollution level. The chemicals become incorporated into the tissues of the various organs. The rate of release of metals depends on initial levels and species of shellstock. Some metals in some species of shellstock took up to 84 days to deplete. Morrison (1979) reported that the slower depletion of metals as compared to microbiological contaminants indicates that the 14-day cleansing period traditionally used in relaying is not appropriate for removal of metals and their isotopes.

Similarly, most chemicals are not significantly reduced by depuration. It has been found that in soft shell clams, reduction of benzo-a-pyrene to its biological half-life (50% removal) took up to 11 days, depending on temperature and initial level (Jackim, 1977). Removal of over 90% of the polynuclear aromatic (PNA) hydrocarbons took more than over 5 1/2 weeks in the same series of experiments. In depuration studies of the pesticide kepone in oysters relayed from the James River to non-kepone contaminated waters of the York and Rappahannock Rivers in Virginia, Bender (1977) found dramatic effects of temperature on the depuration rates. In the summer, the biological half-life of kepone was about one week, while during the winter about 40 days were required for residue levels to decline by the same amount.

Use of containers to hold shellstock during the natural cleansing process may have some effect on rate of contaminant elimination. Quayle (1976) demonstrated rapid purging rates of *E. coli* from Pacific oysters held in wire mesh baskets. Within 48 hours, the level of bacteria in the oysters was the same as the level in oysters harvested from local areas in the approved classification. Becker (1977) reported depth of oysters in baskets was a critical factor. Full baskets did not show effective cleansing in 96 hours, while single layers were effectively cleansed in 48-96 hours.

When use of containers is proposed to hold shellstock during the natural cleansing process, special studies should be made to evaluate the design of the container, and its effect on the rate of natural cleansing. Such studies should be conducted for each container relay operation, each harvesting area, and each relay site.

Relaying Operations

The NSSP recognizes two methods of handling the shellstock during the natural cleansing process: (1) replanting the shellstock directly on the bottom in clean waters; and (2) placing the shellstock in containers (container relaying) which are then floated, suspended from racks, or placed on the bottom in clean waters.

Shellstock may be harvested and transferred for natural biological cleansing from growing areas in the restricted classification, in the closed status of the conditionally approved classification, or in the open status of the conditionally restricted classification. All growing areas used for natural cleansing must be in the approved classification or in the open status of the conditionally approved classification. For more information concerning the classification of growing waters, see the NSSP Guidance Document: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

Prior to the initiation of the relaying operation, a decision is required as to whether the purpose of the operation is natural shellstock cleansing to remove microbial or poisonous and deleterious substances or both. Requirements, particularly the time allotted for natural cleansing, may differ depending on the type of contaminant. If the intent of the relay operation is to reduce shellstock microbial contaminants, the shellstock must not also be contaminated with poisonous or deleterious substances that would not be effectively reduced to acceptable levels during the cleansing period. For more information concerning acceptable levels of poisonous and deleterious substances in shellstock, see the NSSP Guidance Document: *FDA Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2002).

Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. This is particularly important when harvesters are transporting contaminated shellstock as part of a relay operation. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas and transporting them to other growing areas for the purpose of natural cleansing. The permits must be good for no more than one year, must be issued only for a specific relay operation, and must specify any limitations and conditions for harvesting.

The water quality in the harvest area to which the shellstock are relayed and the bacteriological and/or chemical quality of the relayed lots of shellstock to be subjected to natural cleansing must be verified throughout the relay process. In addition, the identity of the relayed shellstock should be maintained throughout harvesting, transport, processing, packaging, and distribution in the event the shellfish needs to be traced back to its source.

The generally accepted minimum time period for elimination of microbial contaminants from shellstock is 14 days when environmental conditions are suitable for natural cleansing. Longer periods may be required if environmental conditions are not optimum. Shorter time periods may be permitted at some locations or during some periods of the year if there is an adequate study to support the reduced time frame and there is intensive monitoring during the process. Container relaying is particularly amenable to shorter time periods for microbial elimination.

The Authority or the shellfish industry may conduct relay operations. The relay operation must be effectively supervised by the Authority to assure that all the shellstock are actually relayed to harvest areas in the approved classification or in the open status of the conditionally approved classification and sufficiently cleansed. Relay control procedures should preclude any opportunity for shellstock to be inadvertently diverted to sale for human consumption before the natural cleansing process is completed. Controls must be applied to all phases of the operation including initial harvesting, transportation, replanting, the cleansing period, and final harvesting for marketing.

Control procedures must, at a minimum:

(1) Require that the source and species of shellstock being relayed be identified;

(2) Require information concerning:

(a) The quality (bacteriological or chemical) of the water and the shellstock prior to harvest for relay;

(b) The quality of the water and the shellstock indigenous to the area to be used for natural cleansing; and

(c) The quality of the shellstock when the required period of natural cleansing has ended;

(3) Specify the time period of the year when relaying may be conducted;

(4) Use special markings to designate portions of harvest areas where relayed shellstock may be placed for natural cleansing;

(5) Require special harvesting permits for relay operations;

(6) Specify the method of shellstock transportation to the site of natural cleansing, the shellstock deposition method and the method by which different lots of shellstock will be separated during cleansing;

(7) Specify the records to be maintained and filed with the Authority; and

(8) Meet the requirements of the NSSP Model Ordinance.

Control procedures may include monitoring environmental parameters, establishing interagency agreements, imposing quarantine measures, increasing patrols, and developing unique control measures as may be necessary.

A record of water temperature, salinity, and other critical variables must be maintained when it is known that the limiting values of environmental factors may be approached and when minimum relay times are being used.

When container relaying is used, a system of container identification is necessary to locate and avoid re-harvesting of shellfish from containers that have not been left in place long enough for sufficient cleansing.

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IV. Guidance Documents
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.07 Systematic Random Sampling Monitoring Strategy

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to Interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the *Model Ordinance.*

The first critical control point in preventing food-borne illness from shellfish consumption is identifying shellfish growing areas of acceptable sanitary quality. The completion of a sanitary survey is of paramount importance in making the distinction between acceptable and unacceptable growing areas, and is the key to accurate growing area classification as approved, conditionally approved, restricted, conditionally restricted, or prohibited. A sanitary survey is required under the National Shellfish Sanitation Program's (NSSP) *Model Ordinance* for each growing area prior to its approval by the state as a source of shellfish for human consumption or as a source for shellfish to be used in a depuration or relay operation. The principal components of a sanitary survey are: (1) identification and evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) an evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality. For an in depth discussion of the sanitary survey, see the NSSP Guidance Document, *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The NSSP in its *Model Ordinance*
allows the Authority to classify a growing area using either a total or fecal coliform standard as part if its sanitary survey. The two standards are believed to afford the same level of public health protection. The NSSP *Model Ordinance* also recognizes two distinct water quality monitoring strategies to obtain total coliform or fecal coliform monitoring data: the adverse pollution condition strategy to be used for initial classification and for monitoring; and, the systematic random sampling strategy that can be used only for monitoring if no input from point source pollution is present.

Total coliform or fecal coliform monitoring data collected under either the adverse pollution condition or the systematic random sampling strategy and the data collected for initial classification are reported as MPN values. An MPN or most probable number is a statistically derived estimate of the number of bacteria per unit volume of water sampled. The value of the MPN is determined from the combination of positive and negative results obtained from a series of fermentation tubes used in a particular laboratory test. A complete discussion of the MPN test can be found in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1985).

NSSP water quality standards for growing area classification have two components. The first component establishes a median MPN value. The second component intended for use with data collected under uniform conditions represents the variability inherent in the testing procedure and a small allowance for some additional variability peculiar to the changing conditions in the water being sampled. The original NSSP "variability factor" for the total coliform group, an MPN of 230 per 100 milliliters of sample was developed to include 90% of the samples collected under uniform conditions in which the only sources of variability operational are due to the test procedure and the allowance for some additional variability arising from changing conditions in the water being sampled. Therefore, if only these two sources of variability are active in the sample data, then no more than 10% of the samples derived under these conditions will exceed an MPN value of 230 per 100 milliliters of sample when the 5-tube, decimal dilution MPN procedure is used. This is referred to in the NSSP as the 10% criteria where no more than 10% of the samples should exceed the variability factor established for the standard and the testing procedure being used.

This same type of reasoning has been applied to both the total and fecal coliform groups and appropriate 10% criteria developed for the MPN test employed (330 and 140 MPN per 100 milliliters for the total coliform group tested by the 3-tube, decimal dilution and the 12-tube, single dilution MPN procedures, respectively, and 43, 49 and 28 MPN per 100 milliliters for the fecal coliform group tested by the 5 and 3 -tube, decimal dilution and 12-tube, single dilution MPN procedures, respectively. Because these variability factors were derived for use with data sets collected under uniform

conditions, they do not address wide swings in water quality that result from changing environmental conditions driven by random pollution events such as runoff carried pollutants following rainfall. Therefore, the 10% criteria is not considered sufficient to protect public health when shellfish are taken from growing area waters adversely affected by known meteorological or hydrological events, that occur intermittently, and are shown to degrade water quality.

While many growing area waters may meet the NSSP median value and 10% criteria, some shellfish growing area sampling stations still display a considerable level of variation in the MPN sample results. Sampling data of this type may indicate that the shellfish growing areas are intermittently polluted during adverse pollution conditions and pose a risk to the shellfish consuming public. The NSSP has never intended to place a growing area that is polluted 10% of the time in the approved classification. The dilemma facing the Authority, therefore, is how to distinguish between the inherent variation of the MPN test and the variability resulting from intermittent environmental conditions that degrade water quality. When environmental events (such as rainfall) produce unfavorable effects on water quality, the data may contain data points that vary widely from the median value of the established classification. Such a data set would probably contain upper outliers that represent periods when the shellfish may be exposed to significantly greater quantities of pollution. In this situation, the determination of NSSP conformity to the established classification standard for a set of growing water samples from a particular station may become an arbitrary function of the mechanics of sampling (timing and/or frequency) rather than an actual characteristic of the growing area. Use of a statistical method, the estimated ninetieth percentile, will detect these random pollution events that may cause a data set to be skewed because of a few high MPN values.

When shellfish water sampling data collected following intermittent pollution events are combined with data collected under normal conditions, variability is increased. The estimated ninetieth percentile will reflect this increased variability. Therefore, use of the estimated ninetieth percentile will protect against the potential public health problems that may result when shellfish are consumed from growing waters that are adversely affected by intermittent pollution events and improperly classified.

The method for calculating the ninetieth percentile for use in evaluating growing water bacteriological data was suggested by the Georgia Department of Natural Resources, as an addendum to Interstate Shellfish Sanitation Conference (ISSC) in issue 8109. The ISSC adopted the systematic random sampling monitoring strategy and the method recommended for calculating the ninetieth percentile at its 1989 ISSC Annual Meeting

Water Quality Assessment

In the adverse pollution condition monitoring strategy, the water quality standards for both total and fecal coliforms use the 10% criteria, the variability portion of the standard to adjust for the inherent variability of the MPN testing procedure in data with uniform bacterial densities. In the systematic random sampling strategy, the application of the water quality standard employs the variability portion of the standard to detect the impact of intermittent environmental events on water quality above and beyond those attributed by the MPN testing procedure alone.

A field sampling and data analysis design that employs a systematic random sampling plan for routine monitoring assumes that a statistically representative cross section of all meteorological, hydrographic, or other pollution events will be included in the data set. Therefore, all shellfish growing area data collected under the systematic random sampling plan are used to determine compliance with the appropriate total coliform or fecal coliform water quality standard. This sample collection and data analysis design may be applied only to growing areas that are affected by randomly occurring pollution events triggered by rainfall and runoff and that meet the standard for the approved or restricted classification. This sampling strategy may also be used to monitor growing areas where water quality is influenced by seasonal water uses or where harvesting is controlled by seasonal resource management restrictions. In this situation, monitoring must be done during the season when the growing waters are open. Systematic random sampling is not intended to nor should it be applied to areas impacted by point source pollution.

The systematic random sampling monitoring strategy and data analysis design presumes that if intermittent, unfavorable changes in water quality occur, they will be revealed in the bacteriological sampling results. These unfavorable sampling results will contribute to the variability of the data set. Data sets displaying high levels of variability will consequently exhibit an elevated estimated ninetieth percentile. The Authority's option to use the systematic random sampling strategy is, therefore, contingent upon acceptance of the estimated ninetieth percentile as the statistic used to measure the variability of the data set. Also required is that timing of monitoring runs be preplanned far in advance so that effects of random nonpoint pollution events will be captured if they occur. This statistic, along with the geometric mean of the data set, can be used when evaluating each sampling station for compliance with the NSSP water quality standards.

An example of an acceptable systematic sampling plan is one that documents a pre-established sampling schedule in the growing area central file. Monthly or bimonthly sampling regimes are acceptable and the schedule is maintained so there is no avoidance of unfavorable conditions. A reasonable attempt must be made to collect samples on the pre-established days regardless of navigational conditions. Field sampling crews, however, are not required to take unnecessary risks to sample on any particular day. The sampling plan must address unsafe sample collection (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

If the growing area is to be used year-round for harvesting, the random sampling plan should stipulate the collection of samples throughout the year. If the growing area is intended to be approved for direct harvest for only part of the year, the random sampling plan would need only to address that period when the area is available for harvest. The only exception to this obligation in a random sampling regime is that the Authority will require sampling during a particular tidal condition, if that condition unfavorably impacts the water quality of the growing area.

Estimating the Ninetieth Percentile

Use of the systematic random sampling strategy involves calculating the estimated ninetieth percentile of the data. This statistic measures variability in the data and should not be exceeded by random pollution events if the growing area is properly classified. When the Authority elects to employ the systematic random sampling strategy, the following guideline must be used to calculate the estimated ninetieth percentile.

The estimated ninetieth percentile must be obtained using the following equation:

Est. 90th percentile value = Antilog $[(S_{log})1.28^{A} + \bar{x}_{log}]$

Where

S_{log} = base 10 logarithmic standard deviation.

$\bar{x}_{log}$ = base 10 log mean

[A] The value 1.28 is obtained from the standard normal distribution

Other:

* For the purpose of mathematical calculations, MPN values that signify the upper or lower range of sensitivity for that test shall be increased or decreased one significant number. (MPN counts are reported in the form of two significant numbers.) For example, an MPN value of 'less than 2' shall be decreased by one to 1.9 to indicate the lower level of sensitivity of the five tube, decimal dilution MPN test. In a similar manner, 2.9 shall be used to indicate the MPN value of 'less than 3' for the three tube, decimal dilution MPN test. Therefore it would follow that a MPN value of 1700 shall be used to indicate the MPN value 'greater than 1600' for the five tube MPN test.

* Logarithms may be rounded to three decimal places.

* Antilogs of log MPN calculations may be rounded to the ***next lower integer*** (zero decimal places) [example - antilog (0.556) = 3]

* The standard deviation of the log MPN data shall be calculated in the following manner:

$$S_{log} = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

Application of the Guideline:

Example 1

(1) Convert MPN values to base 10 logarithms.

Obs	MP	Log_{10}	Obs	MPN	Log_{10}
1	2.9	0.462	16	3.6	0.556
2	2.9	0.462	17	3.6	0.556
3	2.9	0.462	18	3.6	0.556
4	2.9	0.462	19	9.1	0.959
5	2.9	0.462	20	9.1	0.959
6	2.9	0.462	21	9.1	0.959
7	2.9	0.462	22	9.1	0.959
8	2.9	0.462	23	9.1	0.959
9	3.6	0.556	24	9.1	0.959
10	3.6	0.556	25	23	1.362
11	3.6	0.556	26	23	1.362
12	3.6	0.556	27	23	1.362
13	3.6	0.556	28	43	1.633
14	3.6	0.556	29	43	1.633
15	3.6	0.556	30	460	2.663

(2) Calculate Geometric Mean and Standard Deviation.

Median - 3.6

Percentage greater than 43 - 3.3 %

Geometric Mean (Antilog $\overline{x}_{log}$) - (Antilog 0.834) or 6

Log Standard Deviation (S_{log}) - 0.506

(3) Calculate Estimated 90th Percentile using above equation.

Est. 90^{th} = Antilog [$(S_{log})1.28 + \overline{x}_{log}$]

= Antilog [(0.506)1.28 + 0.834]

Est. 90^{th} = Antilog [1.482] or 30

(4) Interpret.

The geometric mean of the data set is less than 14 and the estimated 90th percentile is less than 49 (three tube, decimal dilution test). This station meets the NSSP fecal coliform water quality standard for the approved classification.

Example 2

(1) Convert MPN values to base 10 logarithms.

Obs	MPN	Log_{10}	Obs	MPN	Log_{10}
1	1.9	0.279	16	2.0	0.301
2	1.9	0.279	17	4.5	0.653
3	1.9	0.279	18	4.5	0.653
4	1.9	0.279	19	7.8	0.892
5	1.9	0.279	20	7.8	0.892
6	1.9	0.279	21	7.8	0.892
7	1.9	0.279	22	11	1.041
8	1.9	0.279	23	11	1.041
9	2.0	0.301	24	23	1.362
10	2.0	0.301	25	23	1.362

11	2.0	0.301	26	23	1.362
12	2.0	0.301	27	23	1.362
13	2.0	0.301	28	33	1.519
14	2.0	0.301	29	540	2.732
15	2.0	0.301	30	1700	3.230

(2) Calculate Geometric Mean and Standard Deviation.

Median - 2.0

Percentage greater than 43 - 6.6 %

Geometric Mean (Antilog $\overline{x}_{log}$) - (Antilog 0.788) or 6

Log Standard Deviation (S_{log}) - 0.737

(3) Calculate Estimated 90th Percentile using above equation -

Est. 90^{th} = Antilog $[(S_{log})1.28 + \overline{x}_{log}]$

= Antilog [(.737)1.28 + .788]

Est. 90^{th} = Antilog [1.731] or 53

(4) Interpret.

While this station's geometric mean is less than 14, the standard deviation that resulted from the high values in this data set, would lead one to conclude that water quality may have been adversely affected by storm water runoff or another intermittent pollution event. The estimated 90th percentile was 53 (greater than 43 - for the five tube, decimal dilution MPN test). Therefore this station ***would not meet***
the NSSP fecal coliform water quality standard for the approved classification.

References

U.S. Food and Drug Administration (FDA). 1965. National Shellfish Sanitation Program Manual of Operations, Part I. FDA, Washington, D.C., p. 11, footnote 6.

Interstate Shellfish Sanitation Conference. 2002. Sanitary Survey and the Classification of Growing Waters. *In* ISSC (ed.), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

American Public Health Association. 1985. *Standard Methods for the Examination of Water and Wastewater*, 16th Ed. American Public Health Association, American Water Works Association, Water Pollution Control Federation, Washington D.C.

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IV. Guidance Documents
Chapter II. Growing Areas

.08 Growing Area Patrol and Enforcement

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to Interstate commerce although many states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

The primary objective of the NSSP is to ensure that shellstock is only harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Under the NSSP, growing areas, based on their public-health suitability for shellstock harvesting, are placed in one of five shellstock harvesting classifications. Information obtained from sanitary surveys sets the basis to determine the appropriate growing area classification. All classifications, except for the approved classification, place some type of restriction on harvesting. For more information concerning growing area classification, see the NSSP Guidance Document, *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

If harvesters are not convinced of the need for the restrictions, shellstock may be harvested surreptitiously from areas in the closed status or the in prohibited classification. Therefore, the patrol element of the NSSP is vital to ensure compliance with the public-health safeguards resulting from the classification of growing waters. The fact that the law prohibits the removal of shellstock from contaminated areas will deter the majority of the population from attempting to harvest the shellstock.

Patrol Activity

Control procedures are necessary in a comprehensive shellfish sanitation program to assure that shellstock are harvested only from growing areas in the approved classification or the open status of the conditionally approved classification. Under special permits and close supervision of the Patrol Authority, shellstock may also be harvested from growing areas in the restricted or conditionally restricted classification for cleansing treatment through relay or depuration prior to sale to the consumer.

The Patrol Authority is responsible to provide sufficient personnel and equipment that will act as a deterrent to illegal shellstock harvesting from growing areas in the closed status or in the prohibited classification. In addition, the Patrol Authority must have sufficient legal authority to apprehend and to effectively prosecute persons apprehended harvesting shellstock illegally. Penalties for such violations must be sufficient to discourage illegal harvesting.

Specific patrol requirements applicable to technical and administrative situations vary from state to state. Consequently, the NSSP requires each Patrol Authority to develop a patrol policy document and to keep it current. This policy document must fully describe the Patrol Authority's organization and its activities to deter illegal harvesting. In addition, it must include information concerning the Patrol Authority's legal basis and the laws and regulations to be enforced, personnel, equipment, training in shellfish patrol techniques, patrol activities and record keeping. The NSSP requires the policy document to be updated and reviewed annually.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment allows the officers to apprehend persons illegally harvesting shellstock. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes. Organization of the patrol activity must take into consideration the need for night, weekend, holiday, and undercover patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Adequate delineation of growing areas in the closed status or prohibited classification is fundamental to effective patrol enforcement. The type of growing area identification used will be determined by the structure of the local shellfish industry

and the legal requirements that permit successful prosecution in each state or local jurisdiction. Posting a warning sign is one method of informing shellstock harvesters that an area is off-limits to the taking of shellstock for public health reasons. Other identification methods for off-limit growing areas include information access through toll free or other telephone systems, maps issued at checkpoints or with harvesting licenses, direct mail, and news media. The Patrol Authority or other appropriate Authority should seek the advice of the state's legal counsel to ensure that the marking of growing areas in the closed status or prohibited classification and notifications to shellstock harvesters are sufficient to provide for the successful prosecution of persons harvesting from these areas.

Application of legal penalties sufficient to defer the taking of shellstock from growing areas in the closed status or the prohibited classification is a necessary component for effective enforcement in a shellfish sanitation program. The adequacy of state or local laws as a basis for prosecution is an important to this activity. The Patrol Authority will be ineffective or compromised if state or local laws are written or interpreted so that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. Periodic assessments, by the Patrol Authority or another appropriate Authority, of the degree of success of court actions taken in response to illegal harvesting is necessary for both the analysis of the effectiveness of the program. Prosecution will be difficult if the courts are not fully aware of the public-health hazards associated with the crime. Written policies or guidelines that are used to recommend penalties on specific cases to the courts must be developed by the Patrol Authority or another appropriate Authority. Courts should be encouraged to apply effective penalties, and records should be kept to determine the effectiveness of the penalty system.

Licensing shellstock harvesters is an important control measure to help protect against illegally harvested shellstock. The appropriate Authority shall license each person who harvests shellstock. In the case of leased land, either the lessee or the person who harvests from the lease must be licensed. The appropriate Authority must maintain a record of all licenses granted. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas for use in relay or depuration operations.

Depletion of prohibited areas can be an effective deterrent to illegal harvesting, and may be more economical and effective in protecting public health than patrol of prohibited areas. Complete removal of shellstock from prohibited areas provides a safeguard against contaminated shellstock reaching the market and eliminates a temptation for harvesters. In a depletion operation, all market sized shellstock and as many of the smaller sized shellstock as can be gathered by reasonable methods are removed from the growing area. To be effective, depletion operations should be conducted at sufficient intervals to keep growing areas free of commercial quantities of market-sized shellstock. When commercial harvesters conduct depletion operations, the Authority or the Patrol Authority must provide effective supervision.

All relay operations must be under the effective supervision of the Patrol Authority or other appropriate Authority. Supervision must ensure that shellstock harvested for relay cannot be illegally diverted to the market and only shellstock that have completed the required period of treatment are marketed. The supervising official must be authorized and equipped to enforce the relay operation procedures and to supervise the harvest, transport, and re-deposition of the shellstock. The Patrol Authority must also provide effective supervision of the relay area until completion of the relaying operation. For additional information concerning relay operations, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

All shellstock harvested for depuration must also be under the effective supervision of the Patrol Authority or other appropriate Authority so that the shellstock cannot be illegally diverted to the market before depuration. The supervising official must be authorized and equipped to enforce the depuration operation procedures and to supervise the harvest and transport of shellstock to the depuration operation. For a complete discussion of depuration, see the NSSP Model Ordinance Public Health Reasons and Explanations Chapter XV Depuration (ISSC/FDA, 2002).

Recommendations for FDA Evaluation of State Program Patrol Element

The NSSP requires the FDA to evaluate the patrol of growing areas and its enforcement component on an annual basis. Technical assistance may be provided to FDA by a representative of a patrol agency(ies) through use of these procedures that have been agreed to by the FDA and the ISSC. Both FDA and the ISSC have agreed that these procedures do not apply to special investigations by either party.

The following procedures should be used in conducting patrol evaluations:

A. The person in charge of the patrol agency must be advised of the intent to conduct patrol evaluations, approximate patrol dates desired, recommended patrol areas or districts, and other pertinent information.

B. If requested by the state shellfish patrol agency, FDA will meet with the person in charge or his designee prior to participating in patrols to gain a better understanding of patrol program activities.

C. Agency patrol documents and past FDA reports of areas to be evaluated should be reviewed.

D. The FDA Standardized Patrol Evaluation Format must be used in conducting patrol evaluations.

E. FDA evaluators must allow adequate time in the field with primary patrol officers to fully evaluate an area.

Following individual patrol evaluations, the FDA evaluator must:

A. Prepare draft reports for the individual patrol areas evaluated and an overall draft patrol evaluation report and promptly send them for review to the technical advisor who participated in the evaluation.

B. Send copies of draft reports to the person in charge of the patrol agency for comment prior to finalizing evaluation reports.

C. Meet with the person in charge of the Patrol Authority, if requested by the Patrol Authority to further qualify the accuracy of the final report.

When an FDA evaluator, in the field and unaccompanied by a patrol officer, observes an alleged violation, the FDA evaluator must immediately report the alleged violation to the Patrol Authority.

FDA Standardized Patrol Evaluation

When an FDA evaluator conducts an evaluation of a patrol area, the following information must be collected:

1. Background information such as:

* Patrol evaluation date and time

* Accompanying officer(s)

* Patrol area name and/or number

* Weather, tide, and other pertinent information

* Type of harvest (recreational or commercial)

2. Agency and patrol area organization including identification of:

* Laws, regulations and policies which apply to shellfish control activities

* Number and positions of personnel within the region and within the patrol area

* Supervision for that patrol area and region

3. Patrol area information including:

* An officer's or officers' knowledge of the area and experience within the agency and related agencies

* Variations in patrol area coverage (days, nights, weekends, and holidays)

* Transplants, relay, or aquaculture operations in the patrol area (if appropriate)

* Coverage of adjacent areas, and back-up to primary officer(s) for this patrol area

* Equipment used for patrolling the area including the primary vehicle, boats and motors, radios, visual assisting tools and other equipment.

4. Coverage of markets and retail stores as appropriate.

5. Other responsibilities of officer or officers while on patrol.

6. Records of enforcement activities for the area during the last year.

7. Problems unique to the patrol area.

To comply with Standardized Evaluation Criteria, the authority shall:

1. Have a patrol policy document	CRITICAL item
2. Update patrol policy document every year.	KEY item
3. Meet the NSSP patrol training requirements.	KEY item
4. Patrol all areas that require patrol	CRITICAL item
5. Meet NSSP requirements for frequency of patrol	KEY item
6. Have formalized MOA with other agency per Chapter VIII@.01.B(5).	KEY item
7. Have a risk management plan per Chapter VIII@.01.B(3)(b)(c)(d).	CRITICAL item
8. Have a complete risk management plan per Chapter VIII@.01.B(3)(b)(c)(d).	Other item

The authority shall ensure the following COMPLIANCE CRITERIA procedures are implemented when an FDA evaluation identifies deficiencies with NSSO MO criteria.

(a) During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;

(b) Within 15 days of the closeout meeting, the Shellfish Specialist should provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;

(c) Within 30 days of receiving the PEER, the State patrol agency should provide a written response that indicates:

- The item(s) was corrected;
- A correction plan has been developed with a completion date; or,
- The reasons why the State disagrees with FDA's finding(s).

(d) Within 15 days of receipt FDA should review the State response, and respond to the State;

(e) Any CRITICAL item deficiency should be corrected within 30 days of acceptance by FDA of the correction plan;

(f) Any KEY item deficiency should be corrected within one year of acceptance by FDA of the correction plan.

(g) An OTHER item deficiency should be corrected within 60 days of acceptance by FDA of the correction plan.

FDA shellfish specialists shall be responsible for monitoring the progress of state action plans.

References

Interstate Shellfish Sanitation Conference (ISSC). 2002. Sanitary Surveys and the Classification of Growing Waters. In ISSC (ed), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

Interstate Shellfish Sanitation Conference (ISSC). 2002. Shellstock Relay. In ISSC (ed), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

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.09 Control of Shellfish Harvesting

Requirements for the Authority.
Other portions of this section of the Guide have described the public health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. For a full discussion of control activities, see the NSSP guidance document, *Growing Area Patrol and Enforcement of Growing Area Restrictions* (ISSC/FDA, 2001).

For the most part, control of illegal harvesting depends upon the patrol activities as described in this chapter, @01.B. Adequate delineation of closed areas is fundamental to effective patrol. The type of area identification will be determined by the structure of the local shellfish industry and the legal requirements for each State to permit successful prosecution. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public health reasons.

Other methods for identification of closures include telephone, maps issued at checkpoints, or with harvesting licenses, direct mail, and news media. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that persons harvesting from closed areas can be successfully prosecuted.

However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from closed areas.
Thus, the patrol element of the NSSP is important to ensure compliance with the public-health safeguards resulting from the sanitary survey.
The fact that the law prohibits the removal of shellfish from certain areas will deter the majority of the population from attempting to harvest such shellfish, provided they are aware of the law and of the areas which are closed.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons illegally harvesting shellfish in a closed area. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats capable of operating in open waters; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, undercover and surprise patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Complete removal of shellfish from polluted areas provides a safeguard against contaminated shellfish reaching the market. In some cases, depletion may be the method selected to eliminate an irresistible temptation for harvesters. Depletion may be more economical and effective than patrol of closed areas and will serve to protect public health.

Educational programs should be developed for both industry and the public describing the public health necessity for eliminating shellfish harvesting from closed areas. Programs developed specifically for participation of key industry people may be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to eliminate harvesting and marketing of shellfish from closed areas.

The adequacy of state laws as a basis for prosecution is an important component of this activity. Shellfish patrol will be ineffective and or compromised if State laws are so written or interpreted that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. It is important that periodic assessments are made by the State control or patrol agency of the degree of success of court actions taken in response to illegal harvesting. Information of this nature is necessary for both the analysis of the effectiveness of the program and for education purposes. Prosecution will be difficult where courts are not fully aware of the public-health hazards associated with the crime.

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.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods

1. Microbiological Methods

Application	Sample Type	Total Coliform[1]			Fecal Coliform[2]						Standard Plate Count[3]
					A1M		APHA			ETCP	
		APHA Decimal Dilution MPN	12 tube single dilution MPN	Other	Decimal dilution MPN	12 tube single dilution MPN	Decimal dilution MPN	12 tube single dilution MPN	mTEC		
Growing Area Survey & Classification	Seawater	X	X		X[4]	X[4]	X	X	X		
Controlled Relaying	Seawater	X	X		X[4]	X[4]	X	X	X		
	Shellfish						X				
Wet Storage	Seawater			X					X		
	Shellfish						X				
Controlled Purification	UV Effluent			X					X		
	Shellfish						X	X		X	
Market Shellfish	Shellstock						X				X
	Shucked						X				X

References

1. Total Coliform Methods
   - American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N. Y. [Decimal Dilution MPN test]
   - American Public Health Association, American Water Works Association, and Water Environmental Federation. 1992. Section 9221. Examination of a 100 ml aliquot by the Multiple Tube Fermentation Method (MTF). *Standards Methods for the Examination of Water and Wastewater*, 18th Edition, APHA/AWWA/WEF. Washington, D.C. [Decimal Dilution MPN test]
   - Redman, J. H. 1974. A simpler multiple fermentation tube test for monitoring the bacteriological quality of shellfish harvest waters; the examination of twelve 1.0 ml sample portions, p.123-124. *In* Wilt, D. S. (ed.), *Proceedings 8th National Shellfish Sanitation Workshop,*. U.S. Food and Drug Administration, Washington,

D.C. [12-tube, Single Dilution MPN test]
- Springer, J. A. 1974. Statistical considerations in using the twelve-tube MPN test for routine monitoring of shellfish waters, p.125-126. *In* Wilt, D. S. (ed.), *Proceedings 8th National Shellfish Sanitation Workshop*. U.S. Food and Drug Administration, Washington, D.C. [12-tube, Single Dilution MPN test]

2. Fecal Coliform Methods
   - 40 CFR 136.3 Table I-A. List of Approved Microbiological Methods
   - A-1M, 1990 AOAC International - *Official Methods of Analysis*, 15th Edition. Association of Official Analytical Chemists. Washington, D.C. [A-1 Modified MPN test]
   - APHA. 1998. Standard Methods for the Examination of Water and Wastewater APHA, 20th Edition, APHA, Washington, DC
   - American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y.
   - Rippy, Scott, et. al, Enumeration of Fecal Coliforms and E. coli in marine and estuarine waters: an alternative to the APHA-MPN approach. Journal Water Pollution Control Federation. August 1987, pg. 795-798.
   - U.S. Food and Drug Administration. 2001. (Revised 12-8-02). NSSP Interpretation, 03-III-@.02-100, Options for the use of the 12-tube, single dilution MPN test. [12-tube, Single Dilution MPN test for seawater]
   - U.S. Food and Drug Administration. 2001 (Revised 12-8-02). NSSP Interpretation 03-XV-.03-100, Method for determining fecal coliform levels in end product depurated shellfish. [12-tube, single dilution MPN test for the controlled purification of shellfish]
   - Cabelli, V. J. and W. P. Heffernan. 1970. Accumulation of *Escherichia coli* by the northern quahog. Appl. Microbiol. 19:239-244. [ETCP for the controlled purification of hard- and soft-shelled clams]
3. Standard Plate Count Method
   - American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N. Y.

Footnote:

4

The use of A-1 Medium Minus Salicin is optional with the following condition. Any State that eliminates Salicin must show equivalency with a minimum of 30 samples seasonally (4 sets of 30 samples). The samples must generate results and the results must not be significantly different as shown by using a T test. The data generated to support the elimination of Salicin must be submitted to FDA for review and concurrence prior to State action to eliminate the use of Salicin.

2. Marine Biotoxin Method

Application	Sample Type	Paralytic Shellfish Poison (PSP)	Neurotoxic Shellfish Poison (NSP)
Growing Area Survey & Classification	**Shellfish**	X	X
Controlled Relaying	**Shellfish**	X	X

References:

1. Paralytic Shellfish Poison (PSP) and Neurotoxic Shellfish Poison (NSP) Methods
   American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y.

3. Type III and Type IV Microbiological Test Methods

Application	Sample Type	Total Coliform	Fecal Coliform	Other
Growing Area Survey & Classification	**Seawater**			

Controlled Relaying	**Seawater**			
	Shellfish			
Wet Storage	**Seawater**			
	Shellfish			
Controlled Purification	**UV Effluent**	Type III[1]		
	Shellfish			
Market Shellfish	**Shellstock**			
	Shucked			

Footnotes:

1. Single step direct mEndo-LES Membrane Filter Technique used in the Newburyport Depuration Plant, Massachusetts.

4. Type III and Type IV Marine Biotoxin Test Method

Application	Sample Type	NSP	PSP	DSP	AS	Other
Growing Area Survey & Classification	**Shellfish**		Type III[2]		Type III[1]	
Controlled Relaying	**Shellfish**				Type III[1]	

Footnotes:

1. Peer recognized HPLC Methods with or without clean up.
2. Jellett Rapid Test for PSP
    i. Method can be used to determine when to perform a mouse bioassay in a previously closed area.
    ii. A negative result can be substituted for a mouse bioassay to maintain an area in the open status.
    iii. A positive result shall be used for a precautionary closure.

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.11 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

NSSP Guidance Documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Laboratory results from the bacteriological and marine toxin testing of shellfish growing waters and meats are widely used in the National Shellfish Sanitation Program (NSSP) to aid in determining the safety of shellfish for human consumption. Experience with the bacteriological and marine biotoxin analyses of shellfish and shellfish waters have indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory. To ensure uniformity nationwide in the application of standards for shellfish and shellfish growing waters, a laboratory quality assurance program is necessary to substantiate the validity of analytical results. A laboratory quality assurance program is the systematic application of the practices essential to remove or minimize errors that may occur in any laboratory operation caused by personnel, apparatus, equipment, media, reagents, sampling procedures, and analytical methodology (APHA, 1985). Integral to laboratory quality assurance is a strong program for the external assessment or evaluation of laboratory performance.

Requirements for evaluating laboratories that analyze samples under the NSSP have increased significantly since the 1970's. The number of laboratories participating in the shellfish program has also increased. Several states now have multiple laboratories that provide these analyses. Some states have officially designated city, county or private laboratories to conduct analyses supporting their shellfish sanitation programs. Some states are also authorizing the use of private laboratories to monitor depuration operations. More states are maintaining a marine biotoxin analytical capability in their laboratories; and more foreign laboratories are involved in the NSSP. Historically, FDA has evaluated all these laboratories. Reduction in FDA staffing has made it difficult to evaluate the many state, county, municipal, and foreign shellfish laboratories operating in support of the NSSP. If states with multiple laboratory support would exercise their option to accept responsibility for evaluating their laboratories by employing a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO), FDA would be able to better meet its NSSP responsibilities.

Selection of State Shellfish LEOs should be based on the following criteria:

(1) The individual must be administratively attached to a State central shellfish sanitation laboratory that has been found by the FDA to be in full conformance with NSSP requirements. To avoid the appearance of impropriety and maintain objectivity in the evaluation process, individuals certified as State Shellfish LEOs will not be allowed to evaluate their own laboratories. FDA will maintain the responsibility for evaluating these laboratories.

(2) The individual must be an experienced analyst and should have laboratory supervision experience. To maintain the integrity of the evaluation process, this individual should not, however, have overall supervisory responsibility for the laboratory or laboratories to be evaluated If deemed necessary by an FDA Laboratory Evaluation Officer, the individual must conduct several laboratory evaluations jointly with the FDA Laboratory Evaluation Officer.

(3) During the joint on-site laboratory evaluations with an FDA Laboratory Evaluation Officer, the individual must demonstrate competence in evaluating the laboratory's capability to support the NSSP. The evaluation will be performed and documented using the most current version of the applicable FDA Shellfish Laboratory Evaluation Checklist.

(4) The individual must submit a written narrative report of the joint on-site evaluation to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in this evaluation write-up; and, where relevant an explanation provided relating the potential impact of the deficiency on the analytical results. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations must also be included in this write-up.

The FDA will issue a letter certifying each individual who successfully completes the certification process and will clear the evaluation report(s) for distribution to the laboratories evaluated with copies to the appropriate Shellfish Specialist. Certification is normally effective for a period of three (3) years. Once certified, the individual is then expected to assume the following responsibilities:

* Conduct on-site laboratory evaluations at least every three (3) years. However, more frequent evaluations are strongly encouraged and may be required with marginally performing laboratories, or when major changes in workloads or priorities have occurred or when there has been a substantial turnover of personnel, or, at the specific request of State Shellfish Control Authorities;

* Provide appropriate post-evaluation follow-up for each laboratory evaluated;

* Prepare timely narrative evaluation reports for all laboratories evaluated incorporating the requirements specified in 4 above;

* Distribute completed evaluation reports to the appropriate FDA Laboratory Evaluation Officer and Regional Shellfish Specialist;

* Inform the appropriate FDA Laboratory Evaluation Officer when a laboratory has been found to be nonconforming;

* Develop/coordinate/implement/conduct yearly proficiency testing for all laboratories in the state supporting the NSSP; and,

* Prepare at least annually (in December) a summary list of qualified analysts for each laboratory supporting the NSSP in the state and transmit it to the appropriate FDA Laboratory Evaluation Officer.

Recertification of State Shellfish LEOs will normally occur triennially and will be based on satisfactorily meeting the following criteria:

(1) The individual must continue to be administratively attached to a central state shellfish laboratory which is in full conformance with NSSP requirements;

(2) The individual is not the supervisor of any of the laboratories to be evaluated;

(3) The individual must demonstrate continued competence in evaluating the capability of laboratories to support the NSSP. If considered necessary, the individual will be required to perform one to several joint evaluations with the FDA Laboratory Evaluation Officer;

(4) The individual must submit a written narrative report of the joint evaluation(s) to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and the narrative portion should be prepared as described above;

(5) The individual must have all state laboratory evaluations, split-sample (proficiency) test examinations, and reports current;

(6) The individual should receive training, as necessary, in laboratory evaluations and analytical procedures to remain proficient.

State Shellfish LEOs who successfully complete this process will be issued a letter of recertification by FDA and be cleared to distribute the evaluation reports to the laboratories evaluated with a copy to the appropriate Regional Shellfish Specialist. Normally recertification is effective for a period of three (3) years. Individuals who fail to meet the requirements for recertification will lose their certification until it is demonstrated that all requirements including adequate training are met.

References

American Public Health Association. 1985. *Standard Methods for the Examination of Water and Wastewater.* 16th Ed. American Public Health Association, American Water Works Association, Water Pollution Control Federation. Washington, D.C.

Food and Drug Administration. 1994. *Standard Procedures for State Shellfish Laboratory Evaluation Officers*. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Cooperative Programs, Shellfish Safety Branch, Washington, D.C.

Laboratory Evaluation Checklist - Microbiology

PUBLIC HEALTH SERVICE		
SHELLFISH LABORATORY EVALUATION CHECKLIST		
LABORATORY:		
ADDRESS:		
TELEPHONE: **FAX:** **EMAIL:**		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**

LABORATORY REPRESENTED BY:	**TITLE:**
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**
OTHER OFFICIALS PRESENT:	**TITLE:**

Items which do not conform are noted by:
C- Critical K - Key O - Other NA- Not Applicable Conformity is noted by a "√"

Check the applicable analytical methods:	
☐	Multiple Tube Fermentation Technique for Seawater (APHA)[PART II]
☐	Multiple Tube Fermentation Technique for Seawater using MA-1 [PART II]
☐	Membrane Filtration Technique for Seawater using mTEC [PART II]
☐	Multiple Tube Fermentation Technique for Shellfish Meats (APHA)[PART III]
☐	Standard Plate Count for Shellfish Meats [Part III]
☐	Elevated Temperature Coliform Plate Method for Shellfish Meats [PART III]

PART 1 - QUALITY ASSURANCE

CODE	REF.		ITEM
K	8, 11		**Quality Assurance (QA) Plan**
			1. Written Plan (Check those items which apply.)
		☐	a. Organization of the laboratory
		☐	b. Staff training requirements
		☐	c. Standard operating procedures
		☐	d. Internal quality control measures for equipment, calibration, maintenance, repair and for performance checks.
		☐	e. Laboratory safety.
		☐	f. Internal performance assessment.
		☐	g. External performance assessment.
C	State's Human Resources Department	☐	2. In state laboratories, the supervisor meets the state educational and experience requirements for managing a public health laboratory
K	State's Human Resources Department	☐	3. In state laboratories, the analyst(s) meets the state educational and experience requirements for processing samples in a public health laboratory.

C	USDA Microbiology & EELAP	☐	4. In private laboratories, the supervisor must have at least a bachelor's degree in microbiology, biology, or equivalent discipline with at least two years of laboratory experience.
K	USDA Microbiology & EELAP	☐	5. In private laboratories, the analyst(s) must have at least a high school diploma and shall have at least three months of experience in laboratory sciences.
C	8	☐	6. QA Plan Implemented.
K	11	☐	7. Participates in a proficiency testing program annually. Specify Program(s)_____
CODE	**REF.**	**Work Area**	
O	8,11	☐	1. Adequate for workload and storage.
K	11	☐	2. Clean, well lighted.
K	11	☐	3. Adequate temperature control.
O	11	☐	4. All work surfaces are nonporous, easily cleaned and disinfected.
K	11	☐	5. Microbiological quality and density of air is < 15 colonies/plate in a 15 minute exposure determined monthly and results recorded.
O	11	☐	6. Pipette aid used, mouth pipetting not permitted.
CODE	**REF.**	**Equipment**	
O	9	☐	1. To determine the pH of prepared media, the pH meter has a standard accuracy of 0.1 units.
O	14	☐	2. pH electrodes, consisting of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier preventing passage of Ag ions into the medium which may effect the accuracy of the pH reading).
K	11	☐	3. The effect of temperature on the pH is compensated for by an ATC probe or by manual adjustment.
K	8	☐	4. pH meter is calibrated daily or with each use and records are maintained.
K	11	☐	5. A minimum of two standard buffer solutions is used to calibrate the pH meter. The first must be near the electrode isopotential point (pH 7). The second near the expected sample pH (i.e. pH 4 or pH 10). (Standard buffer solutions are used once daily and discarded.
O	8,15	☐	6. Electrode effectiveness is determined daily or with each use. Method of determination_____.
K	9	☐	7. Balance provides a sensitivity of at least 0.1 g at a load of 150 g.
K	11,13	☐	8. Balance checked monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent and records are maintained.
K	11	☐	9. Refrigerator temperature(s) monitored at least once daily and recorded.
K	1	☐	10. Refrigerator temperature maintained at 0° to 4° C.
C	9	☐	11. The temperature of the incubator is maintained at 35 ± 0.5° C.
C	11	☐	12. Thermometers used in the air incubator(s) are graduated at no greater than 0.5° C increments.
K	9	☐	13 Working thermometer located on top and bottom shelves of use in the air incubator(s).

C	11	☐	14. Temperature of the waterbath is maintained at 44.5 ± 0.2° C under any loading capacity.
C	9	☐	15. The thermometers used in the waterbath are graduated in 0.1° C increments.
O	13	☐	16. The waterbath has adequate capacity for workload.
K	9	☐	17. The level of water in the waterbath covers the level of liquid in the incubating tubes.
K	8, 11	☐	18. Air incubator/waterbath temperatures are taken twice daily and recorded.
K	13	☐	19. Working thermometers are tagged with identification, date of calibration, calibrated temperature and correction factor.
K	4	☐	20. All working thermometers are appropriately immersed.
K	11	☐	21. A standards thermometer has been calibrated by NIST or one of equivalent accuracy at the points 0°, 35° and 44.5° C (45.5° C for ETCP). Calibration records maintained.
K	9	☐	22. Standards thermometer is checked annually for accuracy by ice point determination. Results recorded and maintained. Date of most recent determination_____.
K	13	☐	23. Incubator and waterbath working thermometers are checked annually against the standards thermometer at the temperatures at which they are used. Records maintained.
CODE	**REF.**	**Labware and Glassware Washing**	
O	9	☐	1. Utensils and containers are clean borosilicate glass, stainless steel or other noncorroding materials
K	9	☐	2. Culture tubes are of a suitable size to accommodate the volume for nutritive ingredients and samples
K	9	☐	3. Sample containers are made of glass or some other inert material (i.e. polypropylene).
O	9	☐	4. Dilution bottles and tubes are made of borosilicate glass or plastic and closed with rubber stoppers, caps or screw caps with nontoxic liners.
K	9	☐	5. Graduations are indelibly marked on dilution bottles and tubes or an acceptable alternative method is used to ensure appropriate volumes.
K	9	☐	6. Pipettes used to inoculate the sample deliver accurate aliquots, have unbroken tips and are appropriately graduated. Pipettes larger than 10 ml are not used to deliver 1ml; nor, are pipits larger than 1ml used to deliver 0.1ml.
K	9	☐	7. Reusable sample containers are capable of being properly washed and sterilized.
K	9	☐	8. In washing reusable pipits, a succession of at least three fresh water rinses plus a final rinse of distilled/deionized water is used to thoroughly rinse off all the detergent.

C	9	☐	9. In washing reusable sample containers, glassware and plasticware, the effectiveness of the rinsing procedure is established annually and when detergent (brand or lot) is changed by the Inhibitory Residue Test as described in the current edition of Standard Methods for the Examination of Water and Wastewater. Records are kept. Date of most recent testing_____ Average difference between Groups A and B_____ Average difference between Groups B and D_____ Detergent Brand_____Lot #_____
K	11	☐	10. Once during each day of washing several pieces of glassware (pipettes, sample bottles, etc.) from one batch are tested for residual acid or alkali w/aqueous 0.04% bromthymol blue. Records are maintained.
CODE	**REF.**	**Sterilization and Decontamination**	
O	9	☐	1. Autoclave(s) are of sufficient size to accommodate the workload.
O	8	☐	2. Routine autoclave maintenance performed (e.g. pressure relief valves, exhaust trap, chamber drain) and records maintained.
O	8	☐	3. Autoclave(s) and/or steam generators serviced annually or as needed by qualified technician and records maintained.
C	11	☐	4. Autoclave(s) provides a sterilizing temperature of 121° C (tolerance 121 ± 2° C) as determined weekly using a calibrated working maximum registering thermometer or equivalent (thermocouples, platinum resistance thermometers).
K	11	☐	5. An autoclave standards thermometer has been calibrated by the National Institute of Standards and Technology (NIST) or its equivalent at 121° C.
K	16	☐	6. The autoclave standards thermometer is checked every five years for accuracy at either 121° C or at the steam point. Date of most recent determination_____
K	1	☐	7. Working autoclave thermometers are checked against the autoclave standards thermometer at 121° C yearly. Date of last check _____ Method _____
K	11	☐	8. Spore suspensions are used monthly to evaluate the effectiveness of the autoclave sterilization process. Results recorded.
O	11	☐	9. Heat sensitive tape is used with each autoclave batch.

K	11, 13	☐	10. Autoclave sterilization records including length of sterilization, total heat exposure time and chamber temperature are maintained. Type of record: Autoclave log, computer printout or chart recorder tracings *(circle appropriate type or types)*
K	11	☐	11. For dry heat sterilized material, the hot-air sterilizing oven provides heating and sterilizing temperature in the range of 160° to 180° C.
K	9	☐	12. A thermometer capable of determining temperatures accurately in the range of 160 to 180°C is used to monitor the operation of the hot-air sterilizing oven when in use.
K	13	☐	13. Records of temperatures and exposure times are maintained for the operation of the hot-air sterilizing oven during use.
K	11	☐	14. Spore strips are used quarterly to evaluate the effectiveness of the sterilization process in the hot-air oven. Records are maintained.
K	11	☐	15. Reusable sample containers are sterilized for 60 minutes at 170° C in a hot-air oven or autoclaved for 15 minutes at 121° C.
O	1	☐	16. The sterility of reusable/disposable sample containers is determined for each batch/lot.
K	9	☐	17. Reusable pipettes are stored and sterilized in aluminum or stainless steel canisters or equivalent alternative.
K	9	☐	18. Reusable pipettes (in canisters) are sterilized in a hot-air oven at 170° C for 2 hours.
O	2	☐	19. The sterility of reusable/disposable pipettes is determined with each batch/lot. Results are recorded and maintained.
K	18	☐	20. Hardwood applicators transfer sticks are properly sterilized.
O	13	☐	21. Spent broth cultures and agar plates are decontaminated by autoclaving for at least 30 minutes before conventional disposal.
CODE	**REF.**	**Media Preparation**	
K	3, 5	☐	1. Media is commercially dehydrated except in the case of medium A-1 which is prepared from the individual components and modified MacConkey agar which may be prepared from its components.
O	11	☐	2. Dehydrated media and media components properly stored in cool, clean, dry place.
O	11	☐	3. Dehydrated media are labeled with date of receipt and date opened.
C	12	☐	4. Caked or expired media are discarded.
C	11	☐	5. Make-up water is distilled or deionized *(circle one)* and exceeds 0.5 megohm resistance or is less than 2µ Siemens/cm conductivity at 25° C to be tested and recorded monthly for resistance or conductivity *(circle the appropriate)*.
C	11	☐	6. Make-up water is analyzed for residual chlorine monthly and is at a non-detectable level (≤ 0.1 ppm). Records are maintained. Specify method of determination_____.
K	11	☐	7. Make-up water is free from trace (<0.05mg/L) dissolved metals, specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content < or equal to 1.0mg/L and records are maintained.

K	11	☐	8. Make-up water contains <1000 CFU/ml as determined monthly using the heterotrophic plate count method and records are maintained.
K	11	☐	9. Media are sterilized according to the manufacturer's instructions.
K	9	☐	10. Volume and concentration of media in the tube are suitable for the amount of sample inoculated.
C	11	☐	11. Total time of exposure of sugar broths to autoclave temperatures does not exceed 45 minutes.
C	1	☐	12. Media sterility and positive and negative controls are run with each lot of commercially prepared media or are run with each batch of media prepared from its components as a check of media productivity. Results recorded and records maintained.
O	9	☐	13. Sterile phosphate buffered dilution water is used as the sample diluent.
K	11	☐	14. pH is determined after sterilization to ensure that it is consistent with manufacturer's requirements and records are maintained.
CODE	**REF.**	**Storage of Prepared Culture Media**	
O	9	☐	1. Prepared culture media are stored in a cool, clean, dry space where excessive evaporation and the danger of contamination are minimized.
K	5,11	☐	2. Brilliant green bile 2% broth and A-1 media are stored in the dark.
K	13	☐	3. Stored media are labeled with expiration date or sterilization date.
O	9	☐	4. Storage of prepared culture media at room temperature does not exceed 7 days.
O	2	☐	5. Storage under refrigeration of prepared media with loose fitting closures shall not exceed 1 month.
O	11	☐	6. Storage under refrigeration of prepared media with screw-cap closures does not exceed 3 months.
K	17	☐	7. All prepared media stored under refrigeration are held at room temperature overnight prior to use. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.
PART II - SEAWATER SAMPLES			
CODE	**REF.**	**ITEM**	
		Collection and Transportation of Samples	
C	11	☐	1. Containers are of suitable size to contain at least 100 ml and to allow headspace for shaking. Seawater samples are collected in clean, sterile, water tight, properly labeled sample containers.
K	1	☐	2. Sample identified with collectors name, harvest area, time and date of collection.
C	9	☐	3. After collection, seawater samples shall be kept at a temperature between 0 and 10° C until examined.
K	1	☐	4. A temperature blank is used to determine the temperature of samples upon receipt at the laboratory. Results are recorded and maintained.
C	9	☐	5. Examination of the sample is initiated as soon as possible after collection. However, seawater samples are not tested if they are held beyond 30 hours of refrigeration.
CODE	**REF.**	**Bacteriological Examination of Seawater by the APHA MPN**	
C	9	☐	1. Lactose broth or lauryl tryptose broth is used as the presumptive medium. *(circle appropriate one)*

C	9	☐	2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.
C	9	☐	3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes are recommended).
C	6	☐	4. In a single dilution series not less than 12 tubes are used (for depuration at least 5 tubes are used).
K	6	☐	5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN_____ Strength of media used_____
K	9	☐	6. Inoculated media are placed in an air incubator at 35 ± 0.5° C for up to 48 ± 3 hours.
K	2	☐	7. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____
K	9	☐	8. Inoculated media are read after 24 ± 2 hours and 48 ± 3 hours of incubation and transferred at both intervals if positive for gas.
CODE	**REF.**	**Confirmed Test for Seawater by APHA MPN**	
C	9	☐	1. Brilliant green bile 2% broth (BGB) is used as the confirmatory medium for total coliforms.
C	9	☐	2. EC medium is used as the confirmatory medium for fecal coliforms.
K	9, 11	☐	3. Transfers made to BGB/EC by either sterile loop or sterile hardwood applicator stick from positive presumptives incubated for 24 and 48 hours *(Circle the method of transfer)*.
K	2	☐	4. When the inoculation of both EC and BGB broths is performed using the same loop or transfer stick, the order of inoculation is EC first, followed by BGB.
C	9	☐	5. BGB tubes are incubated at 35 ± 0.5° C.
K	9	☐	6. BGB tubes are read after 48 ± 3 hours of incubation.
C	9	☐	7. EC tubes are incubated in a circulating waterbath at 44.5 ± 0.2° C for 24 ± 2 hours.
C	9	☐	8. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.
CODE	**REF.**	**Computation of Results**	
K	9	☐	1. Results of multiple dilution tests are read from tables in *Recommended Procedures*, 4th Edition.

K	7	☐	2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	7, 9	☐	3. Results are reported as MPN/100 ml of sample.
CODE	**REF.**	**Bacteriological Examination of Seawater by the MA-1 Method**	
C	5	☐	1. Medium A-1 sterilized for 10 minutes at 121° C.
C	9	☐	2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.
C	9	☐	3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes are recommended)
C	6	☐	4. In a single dilution series at least 12 tubes are used.
K	6	☐	5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN _____ Strength of media used _____
K	2	☐	6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____
C	2,5	☐	7. Inoculated media are placed in an air incubator at 35 ± 0.5° C for 3 ± 0.5 hours of resuscitation.
C	5	☐	8. After 3 ± 0.5 hours resuscitation at 35° C, inoculated media are incubated at 44.5 ± 0.2° C in a circulating waterbath for the remainder of the 24 ± 2 hours.
C	5	☐	9. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.
CODE	**REF.**	**Computation of Results**	
K	9	☐	1. Results of multiple dilution tests are read from tables in *Recommended Procedures*, 4th Edition.
K	7	☐	2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	7, 9	☐	3. Results are reported as MPN/100 ml of sample.
CODE	**REF.**	**Bacteriological Examination of Seawater by Membrane Filtration using mTEC Agar**	
			Equipment

C	23, 24	☐	1. When used for elevated temperature incubation, the temperature of the hot air incubator is maintained at 44.5±0.5° C under any loading capacity.
C	23	☐	2. When using a waterbath for elevated temperature incubation, the level of the water completely covers the plates.
C	23	☐	3. Pre-sterilized plastic or sterile glass culture plates that are clear, flat bottomed, free of bubbles and scratches are used.
K	11	☐	4. Colonies are counted with the aid of magnification.
C	11, 23	☐	5. Membrane filters are made from cellulose ester material, white, grid marked, 47 mm in diameter with a pore size of 0.45 µm and certified by the manufacturer for fecal coliform analyses.
O	2	☐	6. Lot number, date of receipt and if provided the expiration date of the membrane filters are recorded.
K	2, 11	☐	7. New lots of membrane filters are checked by comparing recovery of fecal coliform organisms against membrane filters from previously acceptable lots.
C	2	☐	8. The sterility of each lot or autoclave batch of membrane filters are checked before use.
K	2	☐	9. Membrane filters which are beyond their expiration date are not used.
O	11	☐	10. Forceps tips are clean.
O	11	☐	11. Forceps tips are smooth without pitting or corrugations to damage the filters being manipulated.
K	11	☐	12. Forceps are dipped in alcohol and flame sterilized between sample filters.
K	11	☐	13. If indelible graduation marks are used on clear glass or plastic funnels to measure sample volumes, their accuracy is checked with a Class A graduated cylinder before use and periodically rechecked. Funnels having a tolerance greater than 2.5% are not used. Checks are recorded and records maintained
K	11	☐	14. Membrane filtration units are made of stainless steel, glass or autoclavable plastic free of scratches, corrosion and leaks.
C	11	☐	15. Membrane filter assemblies are autoclave sterilized for 15 minutes at 121°C prior to the start of a filtration series.
O	11, 23, 26	☐	16. A UV sterilization unit is used to disinfect filter assemblies between sample and filtration runs.
K	11	☐	17. If used, the effectiveness of the UV sterilization unit is determined by biological testing monthly. Results are recorded and records maintained.
CODE	**REF.**	**Media Preparation and Storage**	
K	11	☐	1. Phosphate buffered saline is used as the sample diluent.
C	11	☐	2. Phosphate buffered saline is properly sterilized.
K	23	☐	3. A sufficient amount of medium (4-5 ml) is used in each plate.
O	11	☐	4. Refrigerated prepared plates are stored for no more than 2 weeks in sealed plastic bags or containers to minimize evaporation.
CODE	**REF.**	**Sample Analyses**	
C	24	☐	1. mTEC agar is used.
C	23	☐	2. The sample is mixed vigorously (25 times in a 12” arc in 7 seconds) before filtration.
C	23	☐	3. The membrane is placed grid side up within the sterile filter apparatus.

C	23, 25	☐	4. Sample volumes tested are consistent with the sampling regime employed (i.e. half log or other appropriate dilutions are used with systematic random sampling).
C	23	☐	5. Sample volumes are filtered under vacuum
K	26	☐	6. The pressure of the vacuum pump does not exceed 15 psi..
C	23, 26	☐	7. The sides of the filter funnel are rinsed at least twice with 20-30 ml of sterile phosphate buffered saline after sample filtration.
C	23	☐	8. The membrane filter is removed from the filtering apparatus with sterile forceps and rolled onto mTEC agar so that no bubbles form between the filter and the agar.
C	11	☐	9. Blanks are run at the beginning of filtration, after every 10th aliquot and at the end of the filtration run to check the sterility of the testing system (phosphate buffered saline, filter funnel, forceps, membrane filter, media and culture plate).
K	2, 11	☐	10. Positive and negative control cultures treated like samples accompany test samples throughout the procedure. Positive control _____ Negative control _____ Results are recorded and records maintained.
C	11, 23, 24	☐	11. Inoculated plates are placed inverted either directly in an air incubator or in a watertight, tightly sealed container at 35 + 0.5°C for 2 hours of resuscitation prior to waterbath incubation or in Ethyfoam for incubation in air at 44.5 +0.5°C.
C	11, 23, 24	☐	12. After 2 hours of resuscitation at 35°C watertight sealed containers are transferred to a circulating waterbath at 44.5 + 0.2°C, submerged completely and incubated for 22-24 hours. Individual plates are transferred inverted to a watertight container, tightly sealed and submerged completely in a circulating waterbath at 44.5 + 0.2°C for 22-24 hours of incubation.
CODE	**REF.**		**Computation of Results**
C	23	☐	1. All yellow, yellow-green or yellow-brown colonies are counted.
C	23	☐	2. Only plates having 80 or fewer colonies are counted. If it is necessary to use plates having more than 80 colonies, counts are given as >80 x 100/ the volume filtered.
K	23, 11	☐	3. The number of fecal coliforms is calculated by the following equation: Number of fecal coliforms per 100 ml = [number of colonies counted/ volume of sample filtered in ml] x 100.
K	23, 11	☐	4. Results are reported as CFU/100 ml of sample.
PART III - SHELLFISH SAMPLES			
CODE	**REF.**		**ITEM**
			Collection and Transportation of Samples
C	9	☐	1. A representative sample of shellstock is collected.
K	9	☐	2. Shellstock is collected in clean, waterproof, puncture resistant containers.

K	9	☐	3. Shellstock labeled with collector's name, type of shellstock, the source, the harvest area, time, date and place (if market sample) of collection.
C	9	☐	4. Shellstock samples are maintained in dry storage between 0 and 10° C until examined.
C	1	☐	5. Examination of the sample is initiated as soon as possible after collection. However, shellfish samples are not examined if the time interval between collection and examination exceeds 24 hours.
CODE	**REF**	**Preparation of Shellstock for Examination**	
K	2,11	☐	1. Shucking knives, scrub brushes and blender jars are (autoclave) sterilized for 15 minutes prior to use.
O	2	☐	2. Blades of shucking knives are not corroded.
O	9	☐	3. Prior to scrubbing and rinsing debris off shellstock, the hands of the analyst are thoroughly washed with soap and water.
O	2	☐	4. The faucet used to provide the potable water for rinsing the shellstock does not contain an aerator.
K	9	☐	5. Shellstock are scrubbed with a stiff, sterile brush and rinsed under water of drinking water quality.
O	9	☐	6. Shellstock are allowed to drain in a clean container or on clean towels prior to opening.
K	9	☐	7. Prior to opening, the hands (or gloved hands) of the analyst are thoroughly washed with soap and water and rinsed in 70% alcohol.
K	9	☐	8. Shellstock are not shucked directly through the hinge.
C	9	☐	9. Contents of shellstock (liquor and meat) are shucked into a sterile, tared blender jar or other sterile container.
K	9	☐	10. At least 200 grams of shellfish meat is used for analysis.
K	2, 19	☐	11. The sample is weighed to the nearest 0.1 gram and an equal amount by weight of (tempered for ETCP) diluent is added.
O	9	☐	12. Sterile phosphate buffered dilution water is used as the sample diluent.
K	3	☐	13. Sterile phosphate buffered saline is used as a sample diluent for the ETCP procedure.
C	9	☐	14. Samples are blended at high speed for 60 to 120 seconds.
K	9	☐	15. For other shellstock, APHA *Recommended Procedures* are followed for the examination of freshly shucked and frozen shellfish meats.
CODE	**REF.**	**MPN Analysis for Fecal Coliform Organisms, Presumptive Test, APHA**	
C	9	☐	1. Appropriate strength lactose or lauryl tryptose broth is used as presumptive media in the analysis. *(circle appropriate choice)*
K	9	☐	2. Immediately (within 2 minutes) after blending, the ground sample is diluted and inoculated into tubes of presumptive media.
C	9	☐	3. No fewer than 5 tubes per dilution are used in a multiple dilution MPN series.
C	9	☐	4. Allowing for the initial 1:1 dilution of the sample, appropriate portions are inoculated (i.e., 2 ml of original 1:1 dilution for the 1 g portion) and diluted for subsequent inoculation (i.e., 22 ml of l:1 diluted sample to 88 ml of diluent or the equivalent for 0.1 g portion.

K	6	☐	5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN_____ Strength of media used_____
C	2	☐	6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____
K	9	☐	7. Inoculated media are incubated at 35 ± 0.5° C.
K	10	☐	8. Presumptive tubes are read at 24 ± 2 hours of incubation and transferred if positive.
CODE	**REF.**	**Confirmed Test for Fecal Coliforms - APHA**	
C	9	☐	1. EC medium is used as the confirmatory medium.
K	9, 11	☐	2. Transfers are made to EC medium by either sterile loop or hardwood sterile applicator sticks from positive presumptives incubated for 24 hours *(circle the method of transfer).*
C	9	☐	3. EC tubes are incubated in a circulating waterbath at 44.5 ± 0.2° C for 24 ± 2 hours.
K	9	☐	4. EC tubes are read for gas production after 24 ± 2 hours of incubation.
C	9	☐	5. The presence of any amount of gas or effervescence in the Durham tube constitutes a positive test.
CODE	**REF.**	**Computation of Results for MPN Analyses**	
K	9	☐	1. Results of multiple dilution tests are read from tables in *Recommended Procedures*, 4th Edition and multiplied by the appropriate dilution factor.
K	7	☐	2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	9	☐	3. Results are reported as MPN/100 grams of sample.
CODE	**REF.**	**Standard Plate Count Method**	
O	20	☐	1. A standard plate count analysis is performed in conjunction with the analysis for fecal coliform organisms.
K	9	☐	2. In the standard plant count procedure at least four plates, duplicates of two dilutions are used to provide 30 to 300 colonies per plate.
K	2	☐	3. Fifteen to 20 ml of tempered sterile plate count agar is used.
K	9	☐	4. Agar tempering bath maintains the agar at 44 to 46° C.
O	9	☐	5. Temperature control of the plate count agar is used in the tempering bath.
K	9	☐	6. Not more than 1 ml nor less than 0.1 ml of sample or sample dilution is plated.
C	**9**	☐	**7. Samples or sample dilutions to be plated are mixed vigorously (25 times in a 12" arc in 7 seconds) before plating.**
K	11	☐	8. Control plates are used to check the sterility of the air, agar and the diluent.
K	9,21	☐	9. Solidified plates are incubated at 35 ± 0.5°C for 48 ± 3 hours inverted and stacked no more than four high.

K	9	☐	10. Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility for counting plates.
K	1	☐	11. A hand tally or its equivalent is used for accuracy in counting.
CODE	**REF.**	**Computation of Results**	
K	9	☐	1 Colony counts determined in accordance with Part III, A, Sections 4.31 through 4.33 Recommended *Procedures*, 4th Edition.
O	19	☐	2 Colony counts reported as APC/g of sample.
CODE	**REF.**	**Bacteriological Examination of Shellfish Using the ETCP**	
K	9	☐	1. Sample homogenate is cultured within 2 minutes of blending.
K	3	☐	2. Double strength Modified MacConkey Agar is used.
C	3	☐	3. Hydrated double strength Modified MacConkey Agar is heated to boiling, removed from the heat, and boiled again. This agar is never autoclaved.
K	2, 3	☐	4. Twice boiled, double strength Modified MacConkey Agar and sterile phosphate buffered saline are maintained in a tempering bath at 45 to 50° C until used. Prepared Modified MacConkey Agar is used on the day it is made.
C	2, 3	☐	5. The equivalent of 6 grams of the homogenate is placed into a sterile container and the contents brought up to 60 ml with tempered, sterile phosphate buffered saline.
K	3	☐	6. Sixty (60) ml of tempered, twice boiled double strength Modified MacConkey Agar is added.
K	2, 3, 22	☐	7. The container is gently swirled or rotated to mix the contents, which are then, distributed uniformly over 6 to 8 petri plates.
C	1	☐	8. Media and diluent sterility are determined with each use. Results are recorded and records maintained.
C	1	☐	9. To determine media productivity, positive and negative control cultures are pour plated in an appropriate concentration to accompany samples throughout the procedure. Positive control_____ Negative control _____
C	3, 13	☐	10. Plates are incubated inverted within 3 hours of plating in air at 45.5 ± 0.5° C for 18 to 30 hours. Plates are stacked not more than four high.
C	3	☐	11. Incubator temperature is maintained at 45.5 ± 0.5° C.
CODE	**REF.**	**Expression of Results**	
K	11	☐	1. Quebec Colony counter or its equivalent is used to provide the necessary magnification and visibility.
O	1	☐	2. A hand tally or its equivalent is used to aid in counting.
C	3, 6	☐	3. All brick red colonies greater than 0.5mm in diameter are totaled over all the plates and multiplied by a factor of 16.7 to report results as CFU/100 grams of sample.

REFERENCES

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12. Title 21, Code of Federal Regulations, Part 58, *Good Laboratory Practice for Nonclinical Laboratory Study.* U.S. Government Printing, Washington, D.C.
13. American Public Health Association (APHA). 1992. *Standard Methods for the Examination of Dairy Products*, 16th Edition. APHA, Washington, D.C.
14. Fisher, J. 1985. Measurement of pH. *American Laboratory* 16:54-60.
15. Consult pH electrode product literature.
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20. U.S. Food and Drug Administration (FDA) and Interstate Shellfish Sanitation Conference (ISSC). 1997. *NSSP Guide to the Control of Molluscan Shellfish*. FDA/ISSC, Washington, D.C. and Columbia, S.C.

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23. United States Environmental Protection Agency, *Improved Enumeration Methods for the Recreational Water Quality Indicators: Enterococci and Escherichia coli*. EPA/821/R-97-004, EPA, Washington, DC
24. Rippey, Scott, R, Adams, Willard, N, and Watkins, William, D. Enumeration of fecal coliforms and *E. coli* in marine and estuarine waters: an alternative to the APHA-MPN approach, Journal WPCF, 59, 8 (1987).
25. FDA Manual of Interpretations, National Shellfish Sanitation Program *Guide for the Control of Molluscan Shellfish*, 2003 Revision, Interpretation Number 03-IV-@.02-102.
26. *Membrane filtration: A Users Guide and Reference Manual*, Thomas D. Brock, Science Tech Inc., Madison, WI, 1983.

SHELLFISH LABORATORY EVALUATION CHECKLIST

SUMMARY OF NONCONFORMITIES

Page	Item	Observation	Documentation Required

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	

MICROBIOLOGICAL COMPONENT: (Part I-III)

A. Results

Total # of Critical (C) Nonconformities in Parts I-III	_____
Total # of Key (K) Nonconformities in Parts I-III	_____
Total # of Critical, Key and Other (O) Nonconformities in Parts I-III	_____

B. Criteria for Determining Laboratory Status of the Microbiological Component:

1. **Does Not Conform Status**: The Microbiological component of this laboratory is not in conformity with NSSP requirements if:

a. The total # of Critical nonconformities is **≥ 4 or**

b. The total # of Key nonconformities is **≥ 13 or**

c. The total # of Critical, Key and Other is **≥ 18**

2. **Provisionally Conforms Status**: The microbiological component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is **≥ 1 but ≤ 3**

C. Laboratory Status (*circle appropriate*)

Does Not Conform Provisionally Conforms Conforms

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature:_____ Date:_____

LEO Signature:_____ Date:_____

NSSP Form LAB-100 Microbiology Rev. 2005-08-19

Laboratory Evaluation Checklist - PSP

PUBLIC HEALTH SERVICE

U.S. FOOD AND DRUG ADMINISTRATION

SHELLFISH PROGRAM IMPLEMENTATION BRANCH

SHELLFISH SAFETY TEAM

5100 PAINT BRANCH PARKWAY

COLLEGE PARK, MD 20740-3835

TEL. 301-436-2151/2147 FAX 301-436-2672

SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE: **FAX:** **EMAIL:**		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**
LABORATORY REPRESENTED BY:	**TITLE:**	
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**	
OTHER OFFICIALS PRESENT:	**TITLE:**	

Items which do not conform are noted by:

C- Critical K - Key O - Other NA - Not Applicable Conformity is noted by a "√"

PART I - QUALITY ASSURANCE		
Code		**Item Description**
		Quality Assurance (QA) Plan
K	☐	1. Written Plan adequately covers all the following: (check √ those that apply) a. Organization of the laboratory. b. Staff training requirements. c. Standard operating procedures. d. Internal quality control measures for equipment, calibration, maintenance, repair and performance. e. Laboratory safety. f. Quality assessment. g. Proper animal care.
C	☐	**2. QA plan implemented.**
		1.2 Work Area
O	☐	1. Adequate for workload and storage.
O	☐	2. Clean and well lighted.
O	☐	3. Adequate temperature control.
O	☐	4. All work surfaces are nonporous and easily cleaned.
C	☐	**5. A separate, quiet area with adequate temperature control for mice acclimation and injection is maintained.**
		1.3 Laboratory Equipment
O	☐	1. The pH meter has a standard accuracy of 0.1 unit.
K	☐	2. pH paper in the appropriate range (i.e. 1-4) is used with minimum accuracy of 0.5 pH units.
K	☐	3. pH electrodes consist of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier to prevent passage of Ag ions into the medium that may result in inaccurate pH readings).
K	☐	4. pH meter is calibrated daily or with each use. Records maintained.
K	☐	5. Effect of temperature has been compensated for by an ATC probe or by manual adjustment.
K	☐	6. A minimum of two standard buffer solutions (2 & 7) is used to calibrate the pH meter. Standard buffer solutions are used once and discarded.
K	☐	7. Electrode efficiency is determined daily or with each use following either slope or millivolt procedure.
K	☐	8. The balance provides a sensitivity of at least 0.1g at a load of 150 grams.

K	☐	9. The balance calibration is checked monthly using NIST Class S or ASTM Class 1or 2 weights or equivalent. Records maintained.
K	☐	10. Refrigerator temperature is maintained between 0 and 4•C.
O	☐	11. Refrigerator temperature is monitored at least once daily. Record maintained.
K	☐	12. Freezer temperature is maintained at -20°C or below.
O	☐	13. Freezer temperature is monitored at least once daily. Record maintained.
O	☐	14. All glassware is clean.
O	☐	15. Once during each day of washing, several pieces of glassware from each batch washed are tested for residual detergent with aqueous 0.04% bromthymol blue solution. Records are maintained.
		1.4 Reagent and Reference Solution Preparation and Storage
C	☐	**1. Opened PSP reference stand solution (100 µg/ml) is not stored.**
K	☐	2. PSP working standard solution (1 µg/ml) and all dilutions are prepared with dilute HCl, pH 3 water, using 'Class A' volumetric glassware (flasks and pipettes) or prepared gravimetrically.
K	☐	3. Refrigerated storage of PSP working standard solution (1µg/ml) does not exceed 6 months and is checked gravimetrically for evaporation loss.
K	☐	4. PSP working dilutions are discarded after use.
K	☐	5. Make up water is distilled or deionized (*circle one*) and exceeds 0.5 megohm resistance or is less than 2 µ Siemens/cm conductivity at 25°C to be tested and recorded monthly for resistance or conductivity *(circle the appropriate)*.
O	☐	6. Make up water is analyzed for residual chlorine monthly and is at a nondetectable level (≤ 0.1 ppm). Records maintained.
K	☐	7. Make up water is free from trace (< 0.5 mg/l) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content ≤1.0 mg/l. Records maintained.
O		8. Makeup water contains < 1000 CFU/ml as determined monthly using the heterotrophic plate count method. Records maintained
		1.5 Collection and Transportation of Samples
O	☐	1. Shellstock are collected in clean, waterproof, puncture resistant containers.
K	☐	2. Samples are appropriately labeled with the collector's name, harvest area and time and date of collection.
K	☐	3. Immediately after collection, shellstock samples are placed in dry storage for transport (e.g. cooler) which is maintained between 0 and 10°C. Upon receipt at the lab, samples are placed under refrigeration.

K	☐	4. The time from collection to completion of the bioassay should not exceed 24 hours. However, if there are significant transportation delays, then shellstock samples are processed immediately as follows (*circle the appropriate choice*): a. Washed, shucked, drained, frozen until extracted; b. Washed, shucked, drained, homogenized and frozen; c. Washed, shucked, drained, extracted, the supernatant decanted and refrigerated (**best choice**); or d. The laboratory has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
K	☐	5. Frozen shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed further.
PART II - EXAMINATION OF SHELLFISH FOR PSP TOXIN		
		2.1 Preparation of Sample
C	☐	**1. At least 12 animals are used per sample or the laboratory has an appropriate contingency plan for dealing with non-typical species of shellfish.**
O	☐	2. The outside of the shell is thoroughly cleaned with fresh water.
O	☐	3. Shellstock are opened by cutting adductor muscles.
O	☐	4. The inside of the shell is rinsed with fresh water to remove sand or other foreign material.
O	☐	5. Shellfish meats are removed from the shell by separating adductor muscles and tissue connecting at the hinge.
K	☐	6. Damage to the body of the mollusk is minimized in the process of opening.
O	☐	7. Shucked shellfish are drained on a #10 mesh sieve (or equivalent) without layering for 5 minutes.
K	☐	8. Pieces of shell and drainage are discarded.
C	☐	**9. Drained meats or thawed homogenates are blended at high speed until homogenous** (60 - 120 seconds).
		2.2 Extraction
K	☐	1. 100 grams of homogenized sample is weighed into a beaker.
K	☐	2. An equal amount of 0.1 N/0.18 N HCl is added to the homogenate and thoroughly mixed (*circle the appropriate normality*).
C	☐	**3. pH is checked and, if necessary adjusted to between pH 2.0 and 4.0.**
C	☐	**4. Adjustment of pH is made by the dropwise addition of either the acid (5 N HCl) or base (0.1N NaOH) while constantly stirring the mixture.**
C	☐	**5. The homogenate/acid mixture is promptly brought to a boil, 100 ± 1°C, then gently boiled for 5 minutes**.
O	☐	6. The homogenate/acid mixture is boiled under adequate ventilation (i.e. fume hood).
O	☐	7. The extract is cooled to room temperature.

C	☐	**8. The pH of the extract is determined and adjusted, if necessary to between pH 2 and 4, preferably to pH 3 with the stirred dropwise addition of 5 N HCl to lower the pH or 0.1N NaOH to raise the pH.**
K	☐	9. The extract volume (or mass) is adjusted to 200 mls (or grams) with dilute HCl, pH 3 water.
K	☐	10. The extract is returned to the beaker, stirred to homogeneity and allowed to settle to remove particulates; or, if necessary, an aliquot of the stirred supernatant is centrifuged at 3,000 RPM for 5 minutes before injection.
K	☐	11. If mice cannot be injected immediately then the supernatant should be removed from the centrifuge tubes and refrigerated for up to 24 hours.
K	☐	12. Refrigerated extracts are allowed to reach ambient temperature before being bioassayed.
		2.3 Bioassay
O	☐	1. A 26-gauge hypodermic needle is used for injection.
K	☐	2. Healthy mice in the weight range of 17 -23 grams (19 - 21 grams preferable) from a stock colony are used for routine assays. Mice are not reused for bioassay. Stock strain used _____ Source of mice_____
C	☐	**3. Mice are allowed to acclimate for at least 24 hours prior to injection. In some cases up to 48 hours may be required.**
C	☐	**4. A conversion factor (CF) has been determined as _____. Month and year when current CF determined_____.**
C	☐	**5. CF value is checked weekly if assays are done on several days during the week, or, once each day that assays are performed if they are performed less than once per week.** **Date of most recent CF check _____** **CF verified/CF not verified** *(Circle appropriate choice)*
C	☐	**6. If the CF is not verified, 5 additional mice are injected with the dilution used in the CF check to complete a group of 10 mice. Ten additional mice are also injected with this dilution to produce a second group of 10 mice. The CF is calculated for each group of 10 mice and averaged to give the CF to be used in sample toxicity calculations for the day's or week's work only. All subsequent work must make use of the original laboratory CF value unless this value continues to fail to be verified by routine CF checks.**
C	☐	**7. If the CF fails to be verified, the cause is investigated and the situation corrected. If the cause cannot be determined with reasonable certainty and fails > 3 times per year, the bioassay is restandardized.**
O	☐	8. Mice are weighed to the nearest 0.5 gram.
C	☐	**9. Mice are injected intrapertioneally with 1 ml of the acid extract.**
K	☐	10. For the CF check, at least 5 mice are used.
C	☐	**11. At least 3 mice are used per sample in routine assays.**
C	☐	**12. Elapsed time is accurately determined and recorded.**
K	☐	13. If death occurs, the time of death to the nearest second is noted by the last gasping breath.

C	☐	**14. If median death time(2 out of 3 mice injected die) is < 5 minutes, a dilution is made with dilute HCl, pH 3 water, to obtain a median death time in the range of 5 to 7 minutes.**
		2.4 Calculation of Toxicity
C	☐	**1. The death time of each mouse is converted to mouse units (MU) using Sommer's Table (Table 6 *Recommended Procedures*, 4th edition). The death time of mice surviving beyond 60 minutes is considered to be < 0.875 MU.**
K	☐	2. A weight correction in MU is made for each mouse injected using Table 7 in *Recommended Procedures*, 4th edition.
C	☐	**3. The death time of each mouse in MU is multiplied by a weight correction in MU to give the corrected mouse unit (CMU) for each mouse.**
C	☐	**4. The median value of the array of corrected mouse units (CMU) is determined to give the median corrected mouse unit (MCMU).**
C	☐	**5. The concentration of toxin is determined by the formula, MCMU x CF X Dilution Factor X 200.**
C	☐	**6. Any value greater than 80µg/l00 grams of meat is actionable.**

REFERENCES

1. Adams, W.N. and S.A. Furfari. 1984. Evaluation of laboratory performance of the AOAC method for PSP toxin in shellfish. *J. Assoc. Off. Anal. Chem.* Vol 67, 6:1147-1148.
2. American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition. APHA, Washington, D.C.
3. American Public Health Association. 1992. *Standard Method for the Examination of Dairy Products*, 16th Edition. APHA, Washington, D.C.
4. Association of Official Analytical Chemists International. 1990. *Methods of Analysis*, 15th Edition. AOAC, Arlington, VA.
5. APHA/WEF/AWWA. 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th Edition. APHA, Washington, D.C.
6. Title 21, Code of Federal Regulations, Part 58, *Good Laboratory Practice for Nonclinical Laboratory Study*. U.S. Government Printing, Washington, D.C.
7. National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.
8. Personal communication with USFDA Washington Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.

LABORATORY:			**DATE OF EVALUATION:**
SHELLFISH LABORATORY EVALUATION CHECKLIST **SUMMARY OF NONCONFORMITIES**			
Page	**Item**	**Observation**	**Documentation Required**

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	
PARALYTIC SHELLFISH POISON COMPONENT: PARTS I and II	
A. Results Total # of Critical (C) Nonconformities Total # of Key (K) Nonconformities Total # of Critical, Key and Other (O) nonconformities	 _____ _____ _____

B. Criteria for Determining Laboratory Status of the PSP Component

1. **Does Not Conform Status** The PSP component of this laboratory is not in conformity with NSSP requirements if:

A. The total # of Critical nonconformities is $\geq$ **3 or**

B. The total # of Key nonconformities is $\geq$ **6 or**

C. The total # of Critical, Key and Other is $\geq$ **10**

2. **Provisionally Conforms Status**: The PSP component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is $\geq$ 1 but < 3

C. Laboratory Status (*circle appropriate*)

Does Not Conform - Provisionally Conforms - Conforms

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature:_____ Date:_____

LEO Signature:_____ Date:_____

NSSP Form Lab-100 Rev. 2005-08-19

Laboratory Evaluation Checklist - Analysis for NSP (Mouse Bioassay)

PUBLIC HEALTH SERVICE		
SHELLFISH LABORATORY EVALUATION CHECKLIST		
LABORATORY:		
ADDRESS:		
TELEPHONE: **FAX:** **EMAIL:**		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**

LABORATORY REPRESENTED BY:	**TITLE:**
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**
OTHER OFFICIALS PRESENT:	**TITLE:**

Items which do not conform are noted by:

C- Critical K - Key O - Other NA- Not Applicable Conformity is noted by a "√"

Weighted Code		Item Description
		Quality Assurance (QA) Plan

C	☐	**1. Written Plan adequately covers the following (check those that apply):** **1. a. Organization of the laboratory.** **2. b. Staff training requirements.** **3. c. Standard operating procedures.** **4. d. Internal quality control measures for equipment, calibration, maintenance, repair and performance.** **5. e. Laboratory safety.** **6. f. Internal performance assessment.** **7. g. External performance assessment.**
C	☐	**2. QA Plan is implemented**
		Work Area
O	☐	1. Adequate for workload and storage.
O	☐	2. Clean and well lighted.
O	☐	3. All work surfaces are nonporous and easily cleaned.
C	☐	**4. A separate, quiet area with adequate temperature control is maintained for acclimation and injection of mice.**
		Laboratory Equipment
K	☐	1. The differing sensitivities in weight measurements required by various steps in the extraction procedure as well as the bioassay are met by the balances being used. 1. a. To determine sample weight, a sensitivity of at least 0.1 g at load of 100 g is required. 2. b. To determine the weight of the lipid extract and its subsequent volume adjustment, a sensitivity of at least 10 mg at loads of 1 and 10 g is required. 3. c. To determine the weight of the mice used in the bioassay, a sensitivity of 0.1 g at a load of 20 g is required.
O	☐	2. The calibrations of the balances are checked monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent. Records are maintained.
K	☐	3. The temperature maintained by the refrigerator is between 0 and 5°C.
O	☐	4. Refrigerator temperature is monitored at least once daily. Temperatures are recorded and records are maintained.
		Reagents
K	☐	1. Concentrated (12N) HCl is used to acidify the homogenate.
O	☐	2. Reagent grade NaCl is used in the extraction procedure.
C	☐	**3. Diethyl ether purified for lipid extraction is used for extracting lipids from the shellfish homogenates.**

C	☐	**4. Cottonseed oil (0.917 g/ml) or a solvent with a similar density (0.915 to 0.927 g/ml) is used as the toxin delivery system. Name of the solvent if substituted for cottonseed oil. _____** **Specify density _____**
		Collection and Transportation of Samples
O	☐	1. Shellstock are collected in clean, waterproof, puncture resistant containers.
K	☐	2. Samples are appropriately labeled with the collector's name, the harvest area and the time and date of collection.
K	☐	3. Immediately after collection, shellstock samples are placed in dry storage between 0 and 10°C until analyzed.
K	☐	4. Shellstock samples are analyzed within 24 hours of collection or refrigerated unshucked until analyzed.
K	☐	5. Refrigerated storage of shellstock does not exceed 48 hours.
K	☐	6. If shellstock is refrigerated, only live animals are used in the analysis.
K	☐	7. If shellfish are shucked in a location other than the laboratory, they must be prepared according to steps 1-9 in "Preparation of Sample" section below.
		Preparation of Sample
C	☐	**1. At least 12 animals are used per sample.**
O	☐	2. The outside of the shell is thoroughly cleaned with fresh water.
K	☐	3. Shellstock are opened by cutting the adductor muscles.
C	☐	**4. Shell liquor is discarded.**
O	☐	5. The inside of the shells is rinsed with fresh water to remove sand or other foreign material.
K	☐	6. Shellfish meats are removed from the shell by separating the adductor muscles and tissue connecting at the hinge.
K	☐	7. Damage to the body of the mollusk is minimized in the process of opening.
K	☐	8. 100 - 150 grams of meat are collected or all the available sample if there is less than 100 grams.
O	☐	9. Shucked shellfish are drained on a #10 mesh sieve or equivalent without layering for 5 minutes.
K	☐	10. Pieces of shell and drainings are discarded.
C	☐	**11. Drained meats are blended at high speed until homogenous (60-120 seconds).**
C	☐	**12. Shellfish homogenates are digested within 2 hours of blending.**
		Digestion of Sample
K	☐	1. All glassware used is clean and properly washed with a succession of at least three fresh water rinses, and a final distilled/deionized rinse to remove residual detergent.

K	☐	2. 100 grams (or entire sample amount if less than 100 grams is available) of homogenized sample is weighted into a beaker.
C	☐	**3. 1 ml of concentrated HCl and 5 g NaCl is added to the 100 gram homogenate and thoroughly mixed. (For samples <100 g, add reagents to obtain final concentrations of 0.12N HCl and 5% NaCl.)**
C	☐	**4. The homogenate is brought to a boil and once 100 ± 1° C (sea level) is reached, gently boil for 5 minutes.**
O	☐	5. The beaker is covered with a watch glass or equivalent during boiling to prevent excessive evaporation.
O	☐	6. The homogenate is boiled under adequate ventilation (fume hood).
O	☐	7. The boiled, acidified homogenate is cooled to room temperature or below in a refrigerator or in an ice bath.
		Extraction
C	☐	**1. All steps in the extraction procedure which involve any manipulation of diethyl ether are carried out under adequate ventilation.**
C	☐	**2. 100 ml of diethyl ether is added to the cooled, acidified homogenate in a stoppered centrifuge tube and shaken vigorously for 5 minutes.**
O	☐	3. Centrifuge tubes are vented frequently while being shaken and before being centrifuged to avoid accidents.
C	☐	**4. The content of the centrifuge tubes are centrifuged at 2000 rpm for 10 to 15 minutes.**
C	☐	**5. The clear upper ether phase is transferred to a large separatory funnel.**
C	☐	**6. The contents of the centrifuge tube are extracted three additional times for a total of four times, each time with 100 ml of diethyl ether. The upper phases are combined together in the separatory funnel (as in step 5).**
C	☐	**7. The ether extract is transferred to a large, clean, dry pre-weighed beaker (discard any emulsion or tissue that may have settled in the funnel.)**
C	☐	**8. Ether is evaporated to dryness.**
C	☐	**9. The final lipid residue is weighted and the weight is recorded.**
		Bioassay
C	☐	**1. The volume of the lipid residue is adjusted by weight to 10 ml (9.17 g) per 100 g shellfish extracted using cottonseed oil. If a solvent with a density similar to cottonseed oil is used, the volume is adjusted to a weight 10 times the density of the solvent. Specify the weight to which the volume is adjusted to _____.**
K	☐	2. A 25 gauge hypodermic needle is used for injection.

C	☐	**3. Healthy male mice in the weight range of 17 to 23 grams from a stock colony are used for routine assays. Stock strain used _____. Source of the mice _____**
C	☐	**4. Mice are allowed to acclimate for at least 24 hours prior to injection. In some cases up to 48 hours may be required. Typical length of the period of acclimation is _____.**
O	☐	5. Mice are weighed to the nearest 0.1 gram.
C	☐	**6. The extract is completely mixed before it is injected.**
C	☐	**7. Mice are injected intraperitoneally with 1 ml of the lipid extract.**
C	☐	**8. A total of 5 mice are injected with undiluted or diluted extract as appropriate per sample in routine assays.** **1. The extract is not diluted when all test/assay mice survive beyond 110 minutes of injection.** **2. The extract is diluted when 2 of 2 test mice or 3 of 5 assay mice survive for fewer than 110 minutes after injection** **3. When dilution is required, only dilutions which produce mean/median death times within 110 to 360 minutes of injection are used in the analysis.**
C	☐	**9. The time of completed injection is recorded.**
C	☐	**10. Mice are continuously observed for at least 6 hours (360 minutes).**
C	☐	**11. If death occurs within the period of continuous observation, the time of death to the nearest minute is noted by the last gasping breath.**
K	☐	12. If mice survive the test, the time of death is recorded as ">" the period of continuous observation.
		Calculation of Toxicity
C	☐	**1. The death time of each mouse is converted to mouse units (MU) using Table 8 in *Recommended Procedures*, 4th Edition.**
O	☐	2. Table 8 is interpolated for death times between 110 and 360 minutes that are not listed in the Table.
K	☐	3. A weight correction in MU is made for each mouse injected using Table 8 in *Recommended Procedures*, 4th Edition.
O	☐	4. Table 8 is interpolated to accommodate weights which are not listed.
C	☐	**5. The death time for each mouse in MU is multiplied by a weight correction in MU to give the corrected mouse unit (CMU) for each mouse.**

C	☐	**6. The mean corrected mouse unit of the array of corrected mouse units (CMU) is used when all the mice injected with diluted or undiluted extract die during the period of continuous observation.**
C	☐	**7. The median corrected mouse unit of the array of corrected mouse units (CMU) is used when at least one mouse either survives the test or dies.**
C	☐	**8. The concentration of toxin is determined by the formula: Mean or median CMU x Dilution Factor x 10.**
C	☐	**9. When the time of death is known for certain for all mice injected, toxicity is determinate and the toxin concentration is reported as the number of mouse units per 100 grams of sample.**

LABORATORY:			**DATE OF EVALUATION:**
SHELLFISH LABORATORY EVALUATION CHECKLIST **SUMMARY OF NONCONFORMITIES**			
Page	**Item**	**Observation**	**Documentation Required**

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	
NEUROTOXIC SHELLFISH POISON COMPONENT:	
A. Results Total # of Critical (C) Nonconformities Total # of Key (K) Nonconformities Total # of Critical, Key and Other (O) nonconformities	_____ _____ _____

B. Criteria for Determining Laboratory Status of the NSP Component

1. **Does Not Conform Status** The NSP component of this laboratory is not in conformity with NSSP requirements if:

A. The total # of Critical nonconformities is ≥ **3 or**

B. The total # of Key nonconformities is ≥ **6 or**

C. The total # of Critical, Key and Other is ≥ **10**

2. **Provisionally Conforms Status**: The NSP component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is ≥ 1 but < 3

C. Laboratory Status (*circle appropriate*)

Does Not Conform **Provisionally Conforms** **Conforms**

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature:_____ Date:_____

LEO Signature:_____ Date:_____

NSSP Form Lab -100 Analysis for NSP (Mouse Bioassay) 2005-08-19

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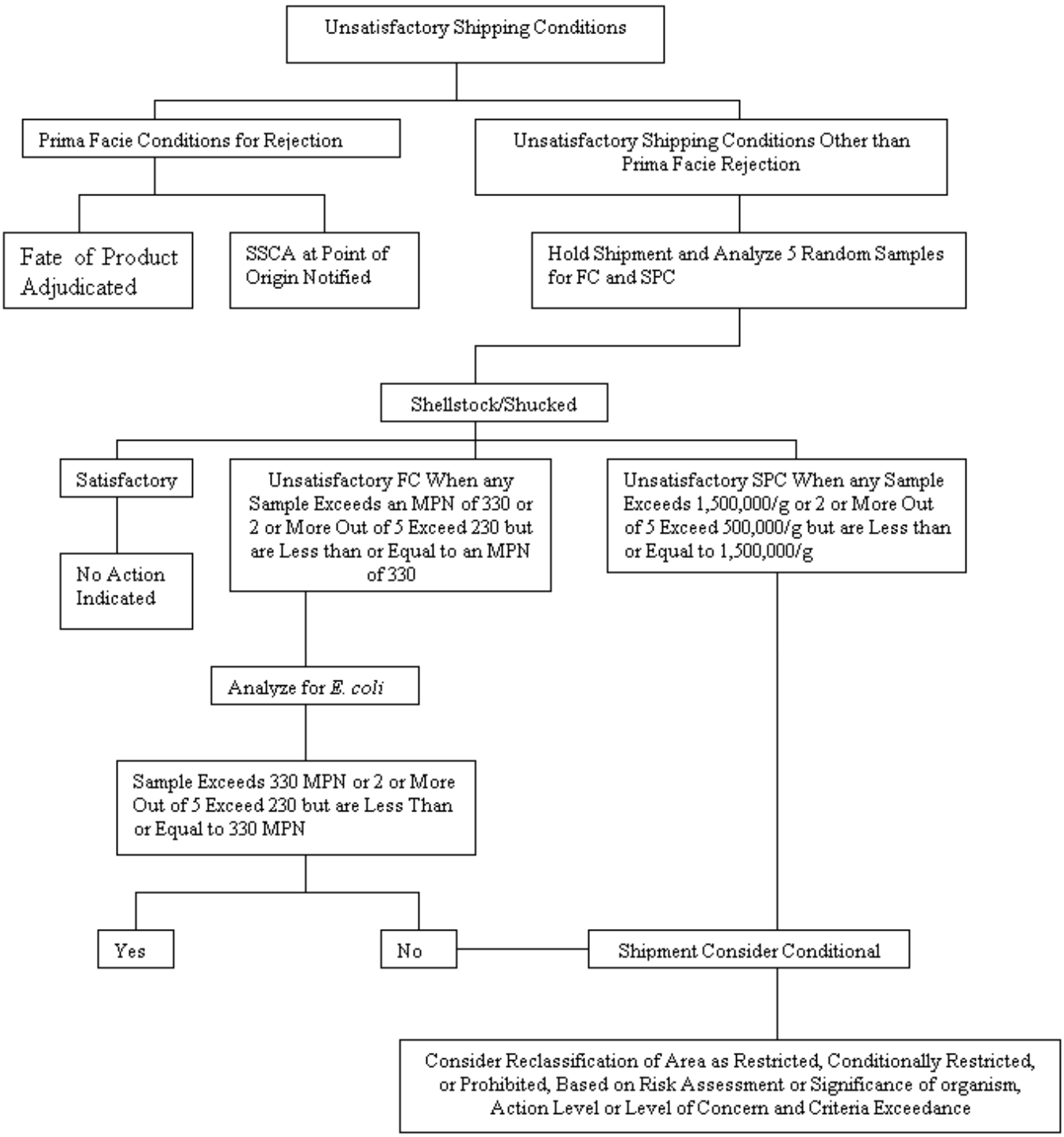
.12 Bacteriological Examination of Shellfish Shipments Decision Tree



Description: Flow chart showing the decision making process following bacteriological examination of shellstock and shucked shellfish shipments.

If the Authority determines there are unsatisfactory shipping conditions that are prima facie conditions for rejection, the fate of product is adjudicated and the State Shellfish Control Authority (SSCA) at the point of origin is notified.

If the Authority determines that unsatisfactory shipping conditions exist other than those for prima facie rejection, the Authority shall hold the shipment and analyze five random samples for fecal coliform and standard plate count.

If the sample results are satisfactory, no action is indicated.

For fecal coliform, sample results are unsatisfactory when any one sample exceeds an MPN of 330 fecal coliforms or when two or more out of five exceed an MPN of 230 but are less than or equal to an MPN of 330 fecal coliforms. If the samples are determined unsatisfactory for fecal coliform then they shall be analyzed for *E. coli.* For *E. coli.*, sample results are unsatisfactory when any one sample exceeds an MPN of 330 or when two or more out of five exceed an MPN of 230 but are less than or equal to an MPN of 330. If the sample is unsatisfactory for *E. coli.* the shipment shall be rejected. If the *E. coli*
results are satisfactory, the shipment is considered conditional and may be shipped. In such cases the Authority should consider reclassification of the area as restricted, conditionally restricted, or prohibited, based on a risk assessment or the significance of the organism, action level or level of concern and criteria exceedance.

For standard plate count, sample results are unsatisfactory when any one sample exceeds 1,500,000/g or when two or more out of five exceed 500,000/g but are less than or equal to 1,500,000/g. Shipments having unsatisfactory plate counts shall be considered conditional and may be shipped. In such cases the Authority should consider reclassification of the area as restricted, conditionally restricted, or prohibited, based on a risk assessment or significance of the organism, action level or level of concern and criteria exceedance.

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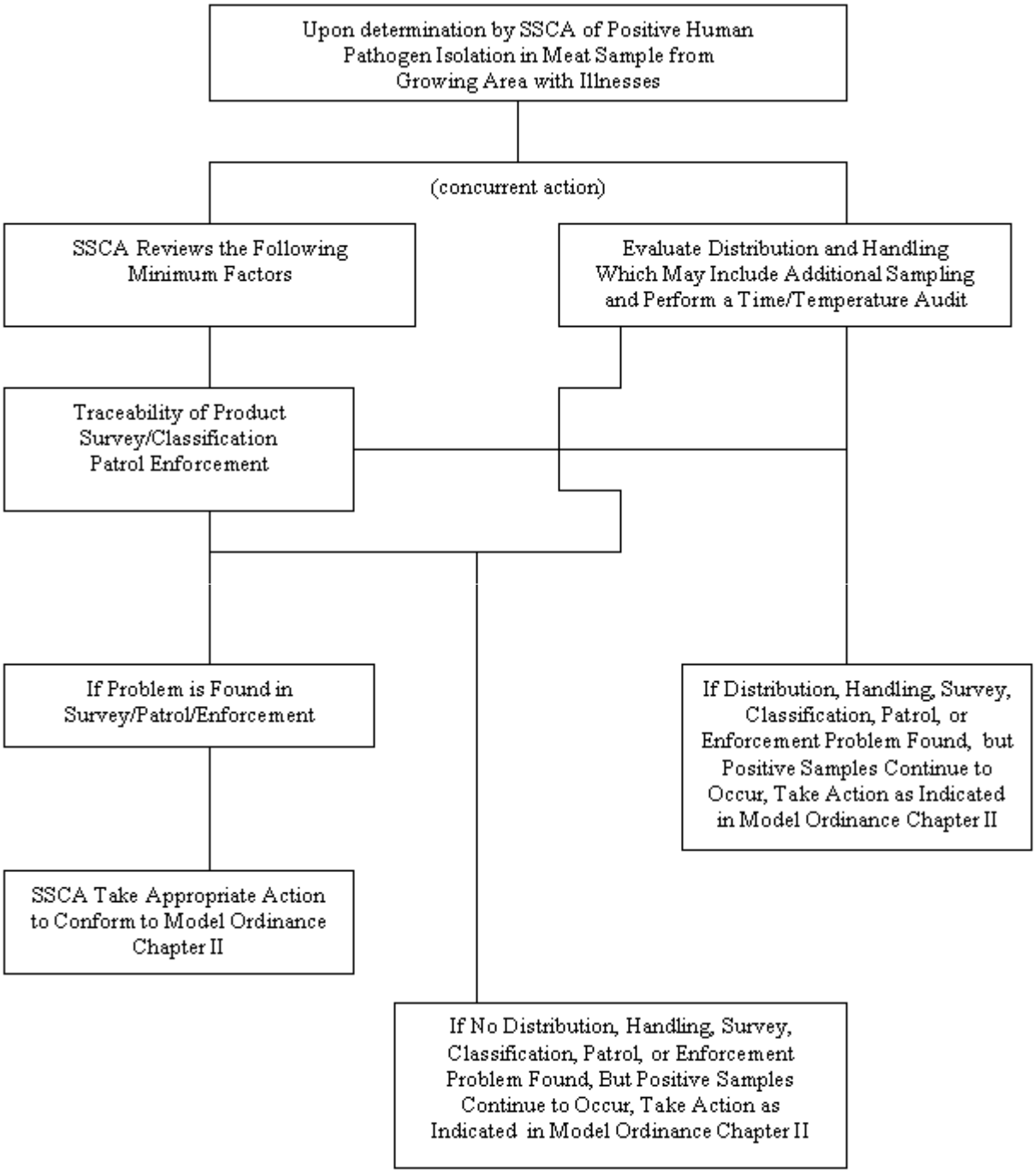
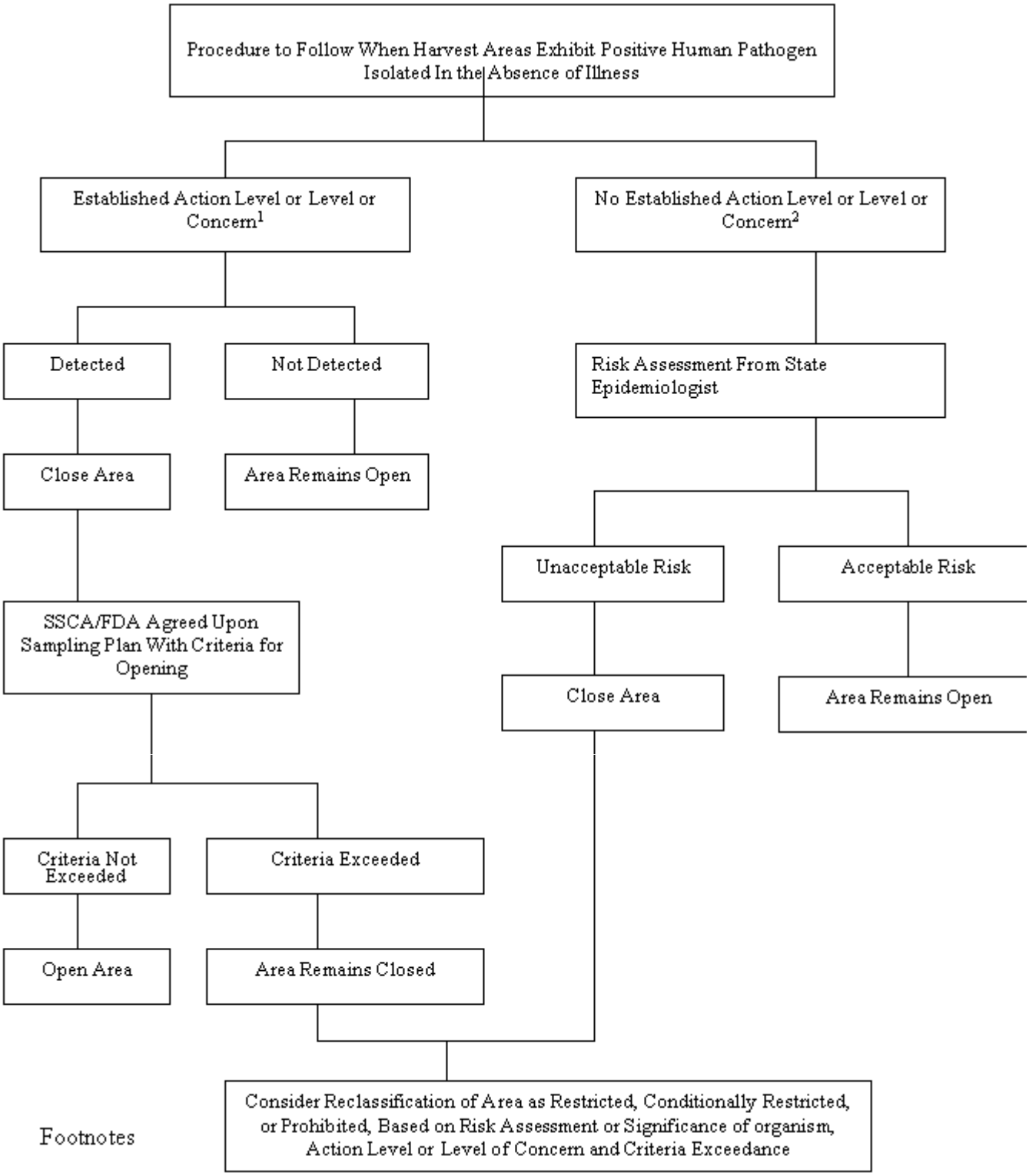
.13 Protocol for Reviewing Classification of Areas Implicated by Pathogens in Shellfish Meat Samples



PROTOCOL FOR REVIEWING CLASSIFICATION OF AREAS IMPLICATED BY PATHOGENS IN SHELLFISH MEAT SAMPLES



1

FDA has established action levels or levels of concern for certain microbial pathogens in molluscan shellfish. The

Agency will consider enforcement action against the shipment of molluscan shellfish if the following levels of pathogens are detected:

<***Salmonella*** - positive for the presence of the organism;

<Enterotoxigenic ***Escherichia coli***
(ETEC) - 1,000 per gram, heat-labile toxin (LT) or heat-stable enterotoxin (ST) positive (may be determined by MPN method);

<***Vibrio cholerae*** - presence of toxin-producing 01 or non-01 organisms;

<***Vibrio parahaemolyticus***
- levels equal to or greater than a MPN count of 10,000 per gram and Kanagawa positive or negative; and

<***Staphylococcus aureus*** - positive for staphylococcal enterotoxin or when the viable MPN count is 10,000 per gram.

[2]Other pathogens under review include: ***Listeria monocytogenes***, non-toxin producing non-01 ***Vibrio cholerae***, and ***Vibrio vulnificus***. In the absence of an established action level or level of concern for these pathogens, enforcement action is considered on a case-by-case basis taking into account all the factors associated with the specific situation.

Description: Two flow charts showing the process for reviewing the classification of growing areas implicated by pathogens in shellfish meat samples.

The first flow chart describes the procedure to follow when positive human pathogens are isolated from shellfish meat samples and there have been associated illnesses. The second chart describes the process when positive human pathogens are isolated from shellfish meat samples from a growing in the absence of illness.

Upon determination by the State Shellfish Control Authority (SSCA) of positive human pathogen isolation in meat samples from a growing area with associated illnesses, the SSCA shall review the following minimum factors: (1) Traceability of product, (2) Sanitary survey/classification of the growing area, and (3) Patrol and enforcement. If a problem is found in one of these three factors, the SSCA shall take action as indicated in Model Ordinance Chapter II.

Concurrent with review of the three factors described above the SSCA shall evaluate distribution and handling of the shellfish. This may include additional sampling and performance of a time/temperature audit of the product.

If a distribution, handling, sanitary survey, classification of the growing area, patrol or enforcement problem is found, but positive sample results continue to occur, the SSCA shall take action as indicated in Model Ordinance Chapter II.

If no distribution, handling, sanitary survey, classification or the growing area, patrol or enforcement problem is found, but positive sample results continue to occur, the SSCA shall take action as indicated in Model Ordinance Chapter II.

The second flow chart describes the procedure to follow when positive human pathogens are isolated from shellfish meat samples in the absence of illness.

If there is an established action level or level of concern for the pathogen detected and that level is exceeded then the

area shall be closed[1]. In such cases the SSCA and Food and Drug Administration (FDA) will develop an agreed upon sampling plan with criteria for opening the area that is closed. If the reopening criteria are not exceeded, the area can be reopened. If the reopening criteria are exceeded, the area shall remain closed and be considered for reclassification as restricted, conditionally restricted, or prohibited, based on a risk assessment or the significance of the organism, action level or level of concern and criteria exceedance.

If the established action level or level of concern is not exceeded, then the area can remain open.

If there is not an established action level or level of concern for the pathogen detected, the state epidemiologist shall conduct a risk assessment[2]. If the risk is determined acceptable, the area can remain open. If the risk is determined unacceptable, the area shall be closed and considered for reclassification as restricted, conditionally restricted, or prohibited, based on a risk assessment or the significance of the organism, action level or level of concern and criteria exceedance.

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.14 Calculating the 90th Percentile for End-Product Depurated Shellfish

Process verification in depuration is performed continuously to ensure that the microbial contaminant load is being effectively reduced. Two indices of performance, the geometric mean and the 90th percentile have been developed to describe the effectiveness of the depuration process. Critical limits for these parameters have been established empirically by shellfish species. For soft clams (*Mya arenaria*), a geometric mean of 50 and a 90th percentile of 130 have been set. For hard clams, oysters, manilla clams and mussels, a geometric mean of 20 and a 90th percentile of 70 have been adopted.

Geometric means and 90th percentiles are determined daily or as end-product results become available from the analysis of the most recent ten (10) consecutive harvest lots per species, per restricted harvest area used. If the critical limits for either the geometric mean and/or the 90th percentile are exceeded, the process is considered to be unverified; and, additional sampling requirements must be instituted to ensure effective process control.

End-product depurated shellfish samples are analyzed using two different methods of recovery, a pour plate procedure and a single dilution MPN test. Calculation of the 90th percentile for these samples is complicated by the fact that fecal coliforms recovered by the MPN and ETCP methods follow different statistical distributions. To accommodate these differences and maintain a high likelihood for detecting an unacceptable amount of process variability without having to change or alter the formula used requires the use of nonparametric or "distribution free statistics." Using "distribution free statistics," the 90th percentile for end-product depurated shellfish samples is calculated by arraying the fecal coliform count data in ascending order and applying the formula (n + 1)P/100.

As an example of the use of this formula, the *Model Ordinance* requires that the 90th percentile of the fecal coliform analytical data be calculated from the most recent ten (10) consecutive harvest lots for each shellfish species depurated from each restricted harvest area. Fecal coliform count data, whether from the ETCP or MPN procedure for these ten (10) lots must be arrayed from the smallest to the largest value using the arithmetic (not logarithmically transformed) count data. Applying the formula, n would equal 10 for the ten (10) most recent consecutive harvest lots required by the *Model Ordinance*. P, the percentile of interest would be 90. Multiplying the formula out gives the position of the 90th percentile in the arrayed data. Performing these calculations, 10 + 1 = 11, 11 x 90 = 990/100 = 9.9. Thus, the 90th percentile for end-product depurated shellfish data is the value of the 9.9th sample in the ten (10) sample array.

Using the ten (10) samples as required by the *Model Ordinance*, the 90th percentile for end-product depurated shellfish samples would always be the value of the 9.9th sample in the ascending array of the arithmetic count data. To calculate this value from the arrayed data, interpolation between samples 9 and 10 is necessary. This is best illustrated using several samples.

Example 1

For soft clams, the ten (10) most recent consecutive harvest lots from a particular restricted harvest area produced the following end-product fecal coliform count data which has been arrayed in ascending order for ease in calculation.

	Sample #	FC Count (MPN/100 grams)	
	1	**8.9 (<9.0)**	
	2	**9.0**	
	3	**9.0**	
	4	**9.0**	
	5	**9.0**	
	6	**18**	
	7	**18**	
	8	**18**	
	9	**29**	
	10	**248**	

a.
By convention and for the purpose of these 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. For example <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.

b. The 90^{th} percentile for a ten (10) sample array is the 9.9^{th} sample in the array. The value for the 9.9^{th} sample in the array is interpolated by subtracting the value for sample #9 from the value for sample #10 in the array. This value is subsequently multiplied by 0.9 and then added to the value of sample #9 to give the value for the 9.9^{th} sample in the array or the 90^{th} percentile.

c.
In this example, sample #9 which is 29 is subtracted from sample #10 which is 248 to give 219. 219 is subsequently multiplied by 0.9 to give 197.1. 197.1 is then added to the value of sample #9, which is 29 to give 226.1. Rounding this off to 226, the value of the 90^{th} percentile becomes 226.

Example 2

Soft clams from another restricted harvest area produced the following end-product depurated fecal coliform counts which have been arrayed in ascending order for ease in calculation.

	Sample #	FC Count (MPN/100 grams)	
	1	**16 (<17)**	
	2	**16 (<17)**	
	3	**16 (<17)**	
	4	**17**	
	5	**17**	
	6	**33**	
	7	**50**	

	8	**50**	
	9	**67**	
	10	**84**	

In this example as above, the 90th percentile equals the value of the 9.9th sample in this ten (10) sample array. The value for the 9.9th
sample in the array is interpolated by subtracting the value of sample # 9 which is 67 from the value of sample #10 which is 84 to give 17. 17 is then multiplied by 0.9 to give 15.3 which is added to the value of sample #9 which is 67 to give 82.3. Rounding this value off to 82, the value for the 90th percentile becomes 82.

Example 3

In this case, oysters from a restricted harvest area produced the following end-product depurated fecal coliform counts which have been arrayed in ascending order for ease in calculation.

	Sample #	**FC Count (MPN/100 grams)**	
	1	**8.9 (<9.0)**	
	2	**8.9 (<9.0)**	
	3	**8.9 (<9.0)**	
	4	**8.9 (<9.0)**	

	5	**9.0**	
	6	**9.0**	
	7	**9.0**	
	8	**18**	
	9	**88**	
	10	**88**	

In this example as in the other two, the 90^{th} percentile equals the value of the 9.9^{th} sample in the ten (10) sample array. Unlike the other two examples, however, the values for samples # 9 and #10 are identical making interpolation unnecessary in finding the value for the 9.9^{th}
sample in this array. This value is by convention identical to the value for samples #9 and #10. In this case, the value is 88.

Conditional Protocol

In examples 1 and 3 above, the values of the 90^{th}
percentiles calculated exceeded the critical limits set for the individual shellfish species depurated. Such high levels of variability when detected in the performance of the depuration process subsequently trigger the conditional protocol. Implementation of the conditional protocol requires the institution of a number of additional control measures designed to ensure adequate depuration. One such control measure involves the analysis of at least one (1) zero hour shellfish sample from each harvest lot. Like end-product depurated shellfish samples, the Elevated Temperature Coliform Plate Method may also be used for these analyses. However, the 12-tube, single dilution MPN test must not be used because of its limited effective count range (from 9 to 248). Instead, the 5-tube, 3-decimal dilution MPN test must be used to accommodate the expanded range in fecal coliform counts which may be encountered.

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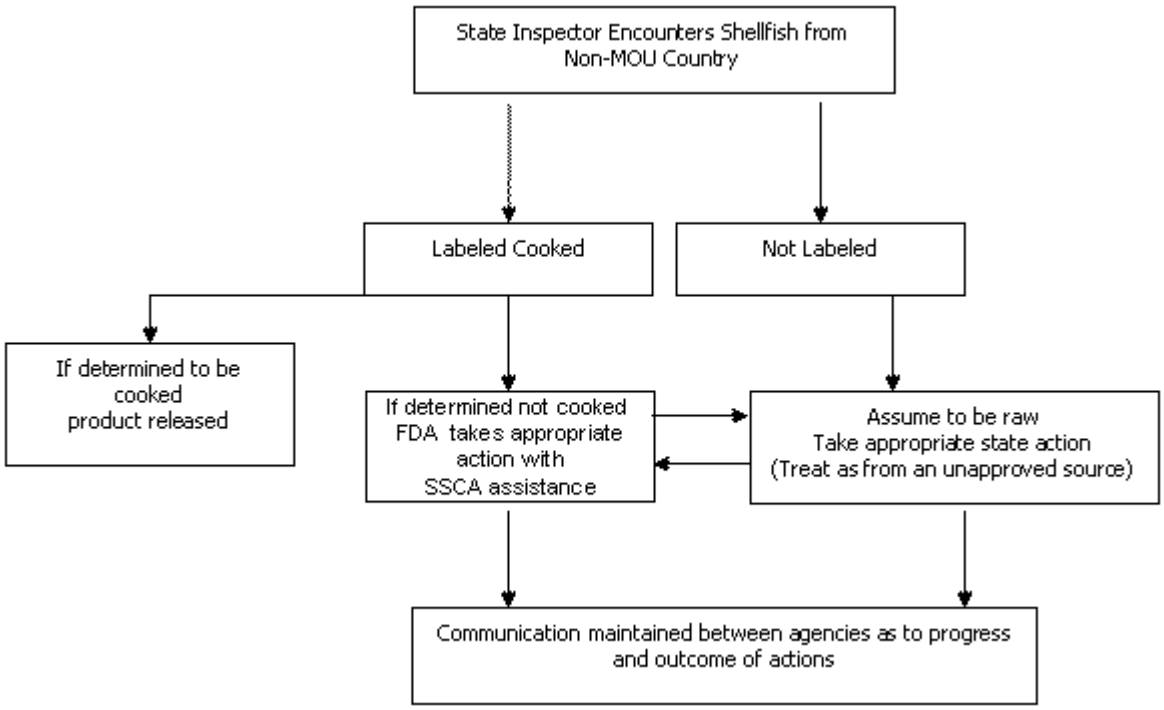
IV. Guidance Documents
Chapter II. Growing Areas

.15 Decision Tree - Shellfish From Non-MOU Countries



Description: Flow chart showing the steps that a state inspector should follow when he or she encounters shellfish from a non-MOU country.

If the product is labeled cooked and determined to be cooked, the product should be released.

If the product is labeled cooked, but is determined to be uncooked, FDA will take action with assistance from the State Shellfish Control Authority. Communication shall be maintained between agencies as to the progress and outcome of actions.

If the product is not labeled, it is assumed to be raw and shall be treated as if it is from an unapproved source. FDA will take action with assistance from the State Shellfish Control Authority (SSCA). Communication shall be maintained between FDA and the SSCA regarding the progress and outcome of actions.

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IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.01 Shellfish Industry Equipment Construction Guide

Introduction

Since 1925 the Public Health Service, the States and the shellfish industry have cooperated in a program designed to maintain a high level of sanitation in the growing, harvesting, and processing of oysters, clams and mussels to be marketed as a fresh or frozen product. The basic sanitary standards used in this program are fully described in PHS Publication No. 33, Manual of Recommended Practice for Sanitary Control of the Shellfish Industry, Parts I and II. General construction standards for equipment used by the shellfish industry are an integral part of these basic standards.

The need for more specific construction guides for equipment used by the shellfish industry was reviewed at the 1958 Shellfish Sanitation Workshop[1]
and the Public Health Service (PHS) was requested to initiate development of such guides. As result of this request, the PHS developed drafts of equipment construction guides. Agencies and organizations which received these initial drafts and thus contributed to the development of the completed construction guides included: Oyster Institute of North America, Bureau of Commercial Fisheries, Food and Drug Administration, Canadian Department of National Health and Welfare, and two equipment manufacturing companies. The completed construction guides were reviewed and adopted by the 1961 National Shellfish Sanitation Workshop. Subsequently, the 1993 annual meeting of the Interstate Shellfish Sanitation Conference asked FDA to review and update the definitions to be consistent with other documents such as Model Code, Pasteurized Milk Ordinance, National Sanitation Foundation, and Code of Federal Regulations. FDA agreed to provide an update to the committee.

It is the purpose of this guide to describe construction and fabrication procedures which will ensure that blower tanks, skimmers, returnable shipping containers, shellfish shucking buckets and pans and will meet the equipment construction standard of the Cooperative program and the functional needs of the industry. However, the development of new methods of equipment construction or fabrication with acceptable materials, construction and fabrication is also encouraged. Therefore, shellfish equipment specifications developed which differ in design, material, fabrication, or otherwise do not to conform with the following standards, but which in the fabricator's opinion are equivalent to or better may be submitted for consideration.

Scope

This guide covers the sanitary construction aspects of (1) shellfish blower tanks, including the sanitary piping for air, water, and drain lines; (2) the stand-supported skimmer, including the supporting stand; (3) returnable shipping containers; (4) shellfish shucking buckets; (5) shellfish shucking pans; (6) tables; (7) conveyors; (8) mechanical shucking devices.

This guideline will aid FDA, state regulatory officials and other interested individuals in making evaluations of the materials, construction and fabrication of equipment used to collect, convey, store, transport, process and package molluscan shellfish products.

This guideline will also provide manufacturers with knowledge of what documentation reviewers might expect them to provide in order to verify the acceptability of materials, construction and fabrication.

Definitions

(1) *Air break* - A piping arrangement in which a drain from a fixture, appliance, or device discharge indirectly into another fixture, receptacle, or interceptor at a point below the flood level rim.

(2) *Air Gap* - The unobstructed vertical distance (twice the diameter of largest inlet pipe) through the free atmosphere between the water inlet supplying a tank, plumbing fixture or other device and the effective overflow level of the receptacle.

(3) *Air Under Pressure* - The pressure of which has been increased by mechanical means to exceed atmospheric pressure, and which is used for agitation of shucked shellfish.

(4) *Alternate Materials* - Is whenever specific materials are mentioned, it is understood that the use of materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

(5) *Blower* - A tank-like device for immersion washing of shucked shellfish. Air may be introduced at the bottom of the tank to produce agitation.

(6) *Coatings* - The results of a process where a different material is deposited to create a new surface. There is appreciable build-up of new material, typically more than 1µm.

(7) *Corrosion Resistant Materials* - Those materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal, and other conditions of use.

(8) *Cleaned-in-place* - Refers specifically to the cleaning and sanitizing of food processing equipment and piping in its assembled condition by recirculation of the necessary rinse, detergent and sanitizing solutions under appropriate conditions of time, temperature, detergency and physical action.

(9) *Dead End* - Area or space wherein a product, ingredient, cleaning, or sanitizing agent, or other extraneous matter may be trapped, retained or not completely displaced during operational or cleaning procedures.

(10) *Drain gate and chute* - The opening located either in the blower or skimmer through which the washed shellfish are eliminated.

(11) *Drain valve* - The valve through which the wash water is released to the floor or waste line.

(12) *Easily Cleanable* - A surface which is readily accessible and is made of such materials, has a finish and is so fabricated that residue may be effectively removed by normal cleaning methods.

(13) *Equipment* - Blower, skimmer, tables, shucking benches, can seamer, sinks, refrigerators, and similar items other than utensils, used in the operation of a shellfish processing facility.

(14) *Filter Media* - Filters for the air intake of a blower shall consist of fiberglass with down stream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, non-woven fabric or other suitable materials which under conditions of use, are non-toxic and nonshedding and which do not release toxic volatile or other contaminants to the air, or volatile which may impart any flavor or odor to the product. Dispos

(15) *Flood Level Rim* - The edge of the receptacle from which water overflows.

(16) *Food contact surface* - Surface of equipment or a utensil which food normally comes into contact; or a surface of equipment or a utensil from which food or liquid may drain, drips, or splash into a food; or onto a surface normally in contact with food. Food contact surfaces include, but are not limited to, equipment and utensils such as; shucking knives and handles, shucking hammers and handles, shucking blocks, ice scoops and shovels, ice bins, skimmer

(17) *Metals* - Metals which are nontoxic, nonabsorbent and corrosion resistant under conditions of intended use.

(18) *Nonfood Contact Surfaces* - All exposed surfaces other than food or splash contact surfaces.

(19) *Nontoxic Materials* - Materials which are free of substances which may render shellfish injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and which meet the requirements of the Federal Food Drug and Cosmetic Act as amended.

(20) *Plastic* - A material that contains as an essential ingredient an organic substance of high molecular weight, is solid in its finished state, and at some stage in its manufacture or in its processing into finished articles, can be shaped by flow.

(21) *Rim* - An unobstructed open edge of a fixture.

(22) *Readily accessible* - Exposed or capable of being exposed for cleaning and inspection without the use of tools.

(23) *Readily Demountable or Removable* - Capable of being taken away from a unit with the bare hands or the use of simple tools such as screwdriver, pliers or an open end wrench.

(24) *Returnable Shipping Container* - Multiple use container for holding or shipping of shucked shellfish.

(25) *Safe Materials* - Articles manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(26) *Sealed* - Free of cracks or other openings that permit the entry or passage of moisture.

(27) *Molluscan Shellfish* - All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and /or shell liquor of oysters, clams, mussels or scallops will be regarded as a "processed food" and will not be included in the Cooperative Program.

(28) *Shellfish Shucking Bucket* - Containers for temporarily holding shucked shellfish during the shucking process.

(29) *Shellfish Shucking Pan* - Containers for temporarily holding shucked shellfish during the shucking process.

(30) *Shucked Shellfish* - Shellfish, or parts thereof, which have been removed from their shells.

(31) *Single Service Articles* - Any metal or plastic containers, lids and closures, wrapping materials such as burlap or hessian bags and similar materials intended for one-time use, one person use and then discarded.

(32) *Skimmers* - A perforated tray in which shucked shellfish are sprayed washed and/or drained.

(33) *Skimmers Paddle* - The utensils used as the gate on the skimmer exit chute and/or one used to scrape the product through the exit chute.

(34) *Smooth* - A surface free of pits and inclusions having a clean ability or better than the following:

(a) food contact a No. 4 (150 grit) or better finish as obtained with silicon carbide, properly applied on stainless steel surface;

(b) Non-food contact surfaces free of visible scale.

(35) *Splash Contact Surfaces* - Any surfaces other than food contact surfaces which are subject to routine splash (wet or dry), spillage and contamination during normal use.

(36) *Toxic* - Having an adverse physiological effect on man.

(37) *Utensils* - Any implement used in the preparation, transportation, and storage of molluscan bivalves such as shucking knives, skimmer paddles, strainers, shucking buckets, shucking pans, etc.

(38) *Weld* - Permanent seams or joints. When welded seams are used, the weld area and the deposited material shall be as corrosion-resistant as the parent material.

Materials

I. **Metals**

A. **Stainless Steel**

Stainless steel is a family of iron based alloys that must contain at least 10.5% Chromium (**Cr**). The presence of chromium creates an invisible surface film that resists oxidation and makes the material "passive" or corrosion resistant (i.e. "stainless"). This family can be simply and logically grouped into five (5) branches. Each of these branches has specific properties and a basic grade or "type." In addition, further alloy modifications can be made to "tailor" the chemical composition to meet the needs of different corrosion conditions, temperature ranges, strength requirements, or to improve welding, machine, work hardening and form.

Stainless is designated by three different systems: Metallurgical structure - Austenitic; Grade - 304 (most used see photos 1 and 2 for Polish No. 3 and No 4) and Unified Numbering System UNS.

Stainless steel product contact surfaces of the American Iron and Steel Institute (AISI) 303, 304, 316 Series[3] or corresponding Alloy Cast Institute (ACI) types.[4] Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M.[5]
Metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, can also be used, except that:

Equipment may also be made of stainless steel of the AISI 400 Series that is made as corrosion resistant as AISI 300 Series by surface treatment or coating(s) or made of nontoxic, nonabsorbent metal that is as corrosion resistant, under the conditions of intended use, as stainless steel of the AISI 300 Series.

B. **Optional Metal Alloys**

Metal alloy of the following types may be used but only in applications requiring disassembly and manual cleaning. (See **Table 1**; values are in percentages)

Equipment made of optional metal alloy may have product contact surfaces modified by surface treating or coating.

Photo 1 – *Stainless Steel Type 304, No.3*
Polish satisfactory for many industrial and commercial products requiring a good polished surface. Typical applications include vent hoods.

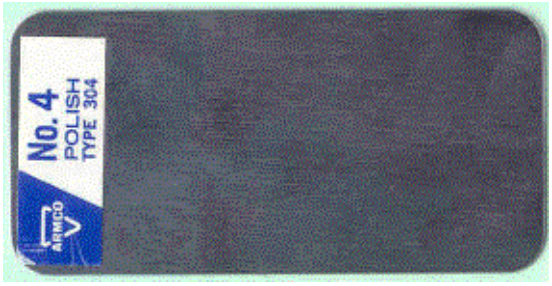


Photo 2 *- Stainless Steel Type 304, No.4*
Polish is exceptionally uniform normally used without further finishing. This is the established standard for dairy and food processing equipment because it is easy to keep clean and sanitary.

C. **Electroless Nickel Alloy Coating**

An electroless nickel alloy coating having the following composition is acceptable:

- Nickel — 90% minimum
- Phosphorous — 6% minimum and 10% maximum as supersaturated solution of nickel phosphide in nickel
- Trace amounts of carbon, oxygen, hydrogen and nitrogen
- **No other elements**

Equipment to be manually or mechanically cleaned may be covered by an engineering coating of electroless nickel alloy conforming to the applicable provisions of military specification MIL-C-26074 E, as amended. [6]

Equipment may also be made of other nontoxic structurally suitable metal(s) that have their product contact surfaces modified by surface coating(s).

D. **Solder**

Solder, when used, should be silver bearing solder and should be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and should not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

Table 1 -- Optional Metal Alloys

	UNS NO8367 ASTM A743 Grade CN-3MN	**UNS S21800 ASTM A743 Grade CF-10 SMnN**	**UNS S20161**	**UNS N26055 ASTM A494 Grade CY5SnBiM**	**UNS N26455 ASTM A494 Grade CW-2M**	**UNS S17400 ASTM A747 Grade CB7Cu-1**	**UNS S15500 ASTM A747 Grade CB7Cu-2**	**UNS S32900**	**UNS R20500 ASTM A560 Grade 50Cr-50Ni**	**UNS R50400 ASTM B67 Grade C-2**
C	0.03	0.1	0.015	0.05	0.02	0.07	0.07	0.2	0.1	0.1
Mn	2.00	7.00 -9.00	4.00 -6.00	1.5	1.00	0.70	0.70	1.00	0.30	
Si	1.00	3.50 -4.50	3.00 - 4.00	0.5	0.80	1.00	1.00	0.75	1.00	
P	0.040	0.040	0.040	0.03	0.03	0.035	0.035	0.040	0.02	
S	0.010	0.030	0.040	0.03	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00 - 18.00	15.0 - 18.0	11.0 - 14.0	15.0 - 17.5	5.50-17.7	14.0-15.5	23.0-28.0	48.0 - 52.0	
Ni	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	4.50-5.50	2.5-5.0	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.0-2.0		
Cb						0.15-0.35	0.15-0.35			
Cu	0.75					2.5-3.2	2.5-3.2			
N	0.18-0.26	0.08-0.18	0.08-0.020			0.05	0.05		0.30	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Tl									0.50	Balance
Al									0.25	
Other										H=0.015 N=0.03 O=0.25

NOTE:

Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 20 mil per year. The test parameters such as the type of chemical(s), their concentration(s) and temperature(s) should be representative of cleaning and sanitizing conditions used in dairy equipment. **Alloys containing lead, leachable copper or other toxic metals should not be used.**

E. **Aluminum**

Aluminum is satisfactory for certain dry products applications. Aluminum may be used for liquid or high moisture content product contact surfaces only when a specific functional requirement exists and the parts are not subjected to strong caustic cleaning solutions or to the corrosive action of dissimilar metals.

The aluminum type chosen for the application shall be demonstrated to be appropriate and acceptable for the intended use. (Provisions have been made in existing 3-A (dry product) Standards for Aluminum Association designations 5052, 6061, 6063, A-360, A-380, A-319, A-315G, and C-413, Danish Standards DS#3002 and #4261, and ASTM standards B179, and S12c for certain specified uses.)

F. **Nonmetals**

Non-metallic materials may be used for food contact and non-food contact equipment and service items. When utilized these materials shall be in compliance with appropriate sections of the 21 Code of Federal Regulations, Parts 170-199 (21 CFR 170-199).

These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively non-absorbent, relatively insoluble and shall not release component chemicals or impart a flavor to the product.

1. **Rubber** and **rubber-like materials** may be used where functionally appropriate.

   Rubber and rubber-like materials when used for the above specified application(s) should conform with the applicable provisions of the "3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment", Number 18- (or equivalent).

2. **Plastic materials** may be used where functionally appropriate.
   Plastic materials when used for the above specified application(s) should conform with the applicable provisions of the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment," number 20 - (or equivalent).

   When used in sight and/or light openings and as direct reading gauge tubes, plastic should be of a clear, heat resistance type.

3. **Durability of rubber and plastic**
   Rubber and rubber-like materials and plastic materials having product contact surfaces should be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

4. **Bonded Rubber**
   The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials should be nontoxic[7].

G. **Materials for Non-product Contact Surfaces**

Materials for non-product contact surfaces should be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used should adhere. All non-product contact surfaces should be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces should not be painted.

II. **Fabrication**

A. **Surface Texture**

All product contact surfaces should have a finish at least as smooth as No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, constitutes a No.4 ground finish. A maximum Ra of 32 micro-inch (0.80), when measured according to the recommendations in ANSI/ASME B46.1[8] - Surface Texture, is considered to be equivalent to a No. 4 finish.

B. **Permanent Joints**

1. **Welding**

Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%.

All permanent joints in metallic product contact surfaces should be continuously welded. Welded areas on product contact surfaces should be at least as smooth as No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices when in the final fabricated form except that:

2. **Soldering**

In such cases where welding is impractical, soldering, may be employed where necessary for essential functional reasons. Silver bearing solder may be used for producing fillets for minimum radii or other appropriate functional purposes.

3. **Press fits or shrink-fits**

Press-fits or shrink-fits may be used to produce crevice free permanent joints in metallic product contact surfaces when neither welding nor soldering is practical. Joints of these types may only be used to assemble parts having circular cross sections, free of shoulders or relieved areas. For example: they may be used to assemble round pins or round bushings into round holes. In both of these fits the outside diameter of the part being inserted is greater than the inside diameter of the hole.

In the case of the press-fit the parts are forced together by applying pressure. The pressure required is dependent upon the diameter of the parts, the amount of interference and the distance the inner member is forced in.

In shrink-fits, the diameter of the inner member is reduced by chilling it to a low temperature. Dry ice is commonly used to shrink the inner member. Heat may also be applied to the outer member of the press-fit. Less assembly force is required for this type of fit.

The design of these fits depends on a variety of factors. The designer should follow recommended practices to assure that a crevice-free joint is produced. A recognized authoritative reference is Machinery’s handbook published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157.

4. **Surface finish**

Press-fitting, shrink-fitting or soldering should produce contact surfaces which are at least as smooth as No. 4 ground finish on stainless steel sheets and which are free of imperfections such as pits, folds and crevices.

C. **Bonded Materials**

Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces should be bonded in a manner that the bond is continuous and mechanically sound so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization if applicable) the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D. **Coatings**

Coatings, if used, should be free from surface delamination, pitting, flaking, spalling (chipping), blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

E. **Cleaning and Inspection**

Equipment that is to be mechanically cleaned should be designed so that the product contact surfaces and all non-removable appurtenances thereto can be mechanically cleaned and are easily accessible and readily removable for inspection. Removable parts shall be readily demountable employing simple hand tools, which are available to operating or cleaning personnel; except that equipment that is to be CIP cleaned should have representative product contact surfaces easily accessible for inspection.

Product contact surfaces, not designed to be mechanically cleaned, should be accessible for cleaning and inspection when in an assembled position or when removed.

Appurtenances having product contact surfaces should be readily removable using simple hand tools or they should be cleanable when assembled or installed and should be easily accessible for inspection.

F. **Draining**

All product contact surfaces, when properly installed, should be self-draining except for normal clingage. However, if the product contact surfaces are not self-draining, they should have sufficient pitch to suitable drain points so they can be drained.

G. **Fittings, Valves, Instruments and Similar Appurtenances**

Sanitary fittings and connections which conform with the appropriate 3-A Sanitary Standards are acceptable. All other fittings must be reviewed using the criteria in this document.

The thermometer connections and/or openings, if provided or required, should be located so that the thermometer is not influenced by a heating or cooling jacket.

If the fittings for temperature sensing devices do not pierce the tank lining, either the temperature sensing element receptacles should be securely attached to the exterior of the lining or means to attach the temperature sensing element(s) securely to the exterior of the lining should be provided.

H. **Sanitary Tubing**

All metal tubing should conform with the applicable provisions for welded sanitary product pipelines found in the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605- or equivalent and with the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33- or equivalent.

I. **Gaskets**

Gaskets having a product contact surface should be removable or bonded.

Grooves in gaskets should be no deeper than their width unless the gasket is readily removable and reversible for cleaning, (i.e., storage tank door gaskets).

Gasket retaining grooves in product contact surfaces for removable gaskets should not exceed 1/4" (6.35 mm) in depth or be less than 1/4" (6.35 mm) wide except those for standard O-rings smaller than 1/4" (6.35

mm) and those allowed in the 3-A Standard for Sanitary Fittings, Number 63.

J. **Radii**

All internal angles 135° or less on product contact surfaces should have a minimum radii of 1/4" (6.35 mm) except that:

1. Minimum radii for fillets of welds where head(s) and the side wall(s) of tanks join should not be less than 3/4" (19.05 mm).

2. Smaller radii may be used when they are required for essential functional reasons. In no case should such radii be less than 1/32" (0.794 mm).

3. The radii in gasket retaining grooves or grooves in gaskets should be not less than 1/16” (1.59 mm) except for those standard, 1/4" (6.35 mm) and smaller O-rings, and those provided for in the “3-A Standards for Sanitary Fittings”, Number 63.

4. The radii in grooves for standard 1/4 in. (6.35 mm) and smaller O-rings should be at least:
   - 0.016 in. (0.406 mm) for 1/16 in. (1.59 mm) O-rings
   - 0.031 in. (0.787 mm) for 3/32 in. (2.38 mm) O-rings
   - 0.031 in. (0.787 mm) for 1/8 in. (3.18 mm) O-rings
   - 0.062 in. (1.575 mm) for 3/16 in. (4.76 mm) O-rings
   - 0.094 in. (2.388 mm) for 1/4 in. (6.35mm) O-rings

K. **Threads**

There should be no threads on product contact surfaces accept where necessary for non-permanent joints in piping and for making various attachments to equipment.

In such case(s) the threads should conform with the “Acceptable Sanitary Thread”. The thread angle should be not less than 60° and with not more than eight threads to the inch (25.4 mm), nor less than 5/8" (15.88 mm) major basic diameter. The length of the nut should not exceed three-quarters of the basic thread diameter. The nut should be of the open type. Equipment with exposed threads as described above should be manually cleaned. Equipment with enclosed threads, (such as “acorn” nuts used to attach impeller blades to pump shafts), should be designed for mechanical cleaning.

L. **Perforated Product Contact Surfaces**

Perforations in product contact surfaces may be round, square, or rectangular. If round the holes should be a minimum of 1/32" (0.794 mm) in diameter. If square, or rectangular, the least dimension should be no less than 0.020" (0.51 mm) with corner radii of no less than 0.0050" (0.13 mm). All perforations should be free of burrs.

M. **Shafts and Bearings**

Shafts entering equipment should have a seal of the packless type and sanitary design, and should be readily accessible for cleaning and inspection.

Where a shaft passes through a product contact surface, in a milk room or processing area, the portion of the opening surrounding the shaft should be protected to prevent the entrance of contaminants.

Bearings having a product contact surface should be of a non-lubricated type.

Lubricated bearings, including the permanent sealed type, should be located outside the product contact surface with at least 1" (25.4 mm) clearance open for inspection between the bearing and any product contact surface unless specifically provided for in a 3-A standards.

General Equipment and Service Items

I. **Blower Tank**

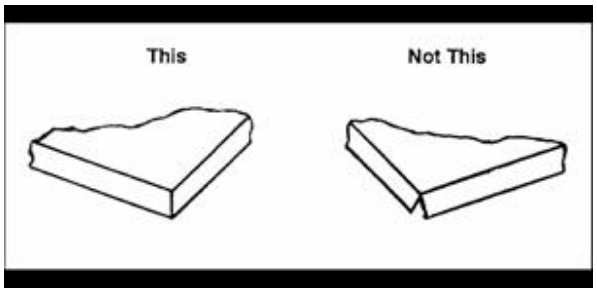
A. **Material**

1. All product-contact surfaces shall be of A.I.S.I.[2] Type No. 304 stainless steel or equally corrosion resistant metal that is non-toxic and non-absorbent except that:
   (a.) Plastic materials may be used for the blower tank drain gate and drain valve. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart a flavor to the product[3].
   (b.) Rubber and rubber-like materials may be used for blower tanks paddles or gate, drain gate, and drain valve. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively non-absorbent, relatively insoluble and shall not release component chemicals, nor impart a flavor to the product.[3]
2. All non-product contact surfaces shall be of inherently corrosion-resistant material, shall be rendered corrosion-resistant, or shall be painted. Surfaces to be painted shall be effectively prepared for painting; and the paint used shall adhere, be relatively non-absorbent, and shall provide a smooth, cleanable and durable surface. Parts having both product-contact and non-product-contact shall not be painted.

B. **Fabrication**

1. All product-contact surfaces shall be at least smooth as No. 4 ground finish on stainless steel sheets.

2. All seams in product-contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 finish. All outside seams shall be smooth and waterproof. All weld areas and deposited weld material shall be substantially as corrosion-resistant. ***(Figure 1)***



(Figure 1) – Product contact surface seams

3. All appurtenances, including drain gates and chutes having product-contact surfaces, shall be easily removable for cleaning, or shall be readily cleanable in place.

4. All product-contact surfaces shall be easily accessible, visible, and readily cleanable, either when in an assembled position or when removed.

5. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm), except that minimum radii for fillets or welds in product-contact surfaces may be smaller for essential functional reasons. In no case shall radii be less than1/8" (3.18 mm). ***(Figure 2)***

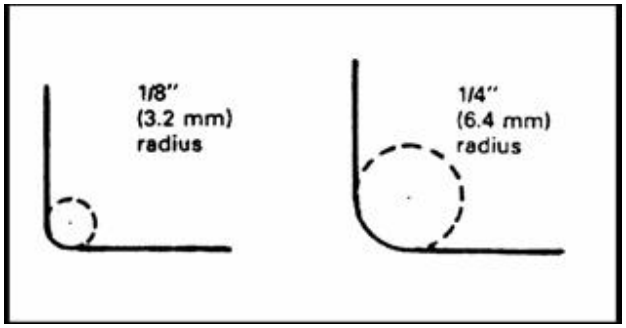


Figure 2 – Internal angles of 135° or less on product contact areas

6. All sanitary pipe fittings shall conform to "3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment," and supplements thereto.[4] (***Figure 3***)

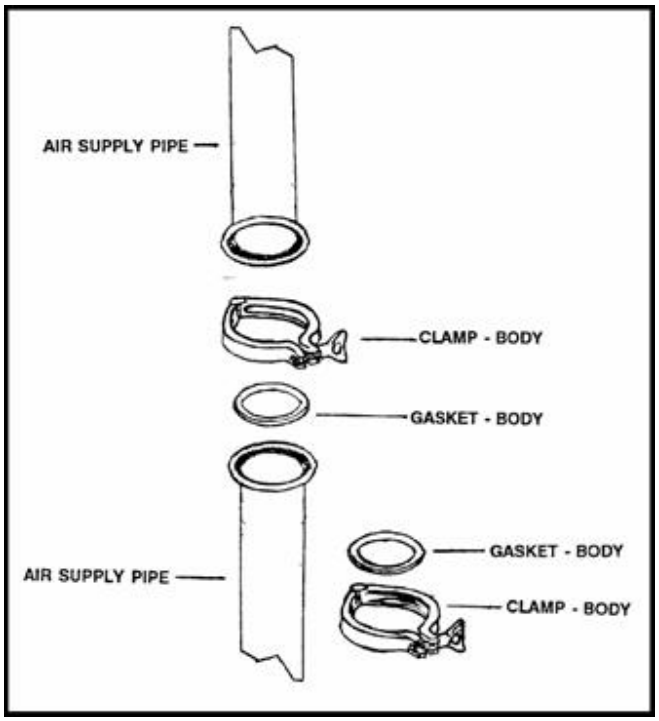


Figure 3 – Sanitary Pipe Fitting

7. Nonproduct-contact surfaces shall have a smooth finish, be free of pockets and crevices, and readily cleanable.

8. Legs shall be of sufficient length to provide at least 12" (30.5 cm) clearance between the lowest fixed point of the tank and the floor, shall be smooth with rounded ends, and shall not hollow tube stock, they shall be effectively sealed. If legs are of hollow tube stock, they shall be effectively sealed. ***(See Figures 4 and 5)***

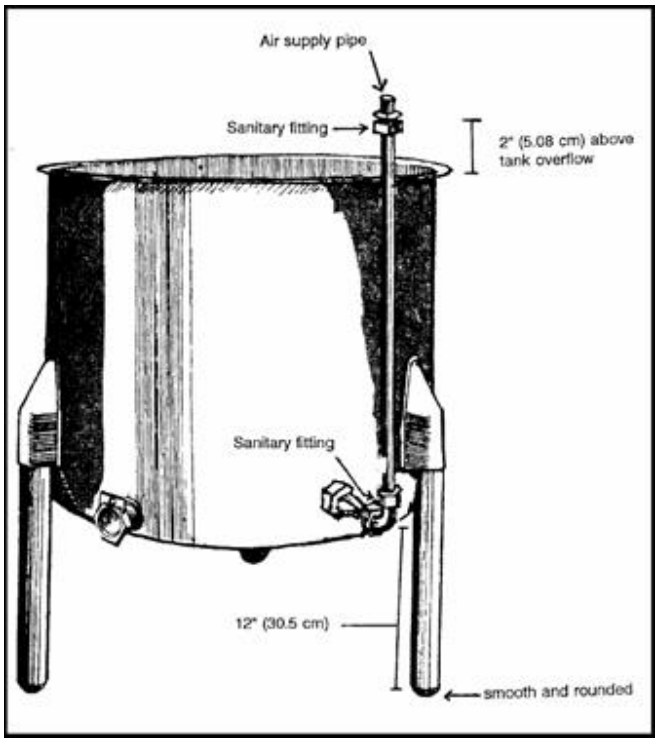


Figure 4 – Blower Tank

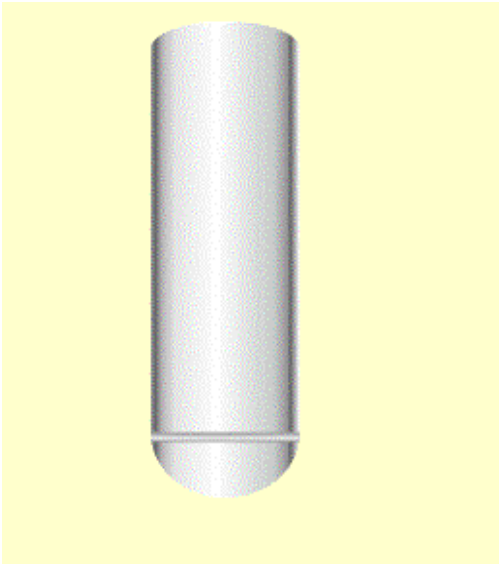


Figure 5 – Close up for a smooth and rounded leg

9. All threads on product-contact surfaces shall comply with specifications for threads contained in the 3-A Sanitary Standards for Fittings.[4]

10. External and internal sections of the air pipe shall be easily cleanable to a point at least two inches above the tank overflow level. ***(Figure 4)***

11. The false bottom shall be so constructed as to be as rigid and, in any event, of at least 16 U.S. Standard gage stainless steel, or equivalent material. ***(Figure 6)***

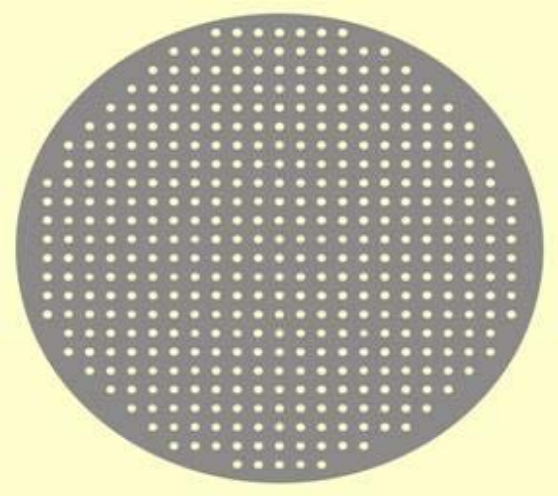


Figure 6 – Blower false bottom plate

12. Perforations or slots in the false bottom shall not be less than 3/16 inch (4.76 mm) in the minimum diameter and the end radius of the perforations shall be not less than 3/32 inch (2.38 mm). After perforation, the flat surface of the sheet from which the perforating punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. ***(Figure 6)***

13. The compressing equipment shall be of such design so as to preclude contamination of the air with lubricant vapors and fumes. The air supply shall be taken from a clean space or from relatively outer air, and shall pass through a filter upstream from the compressing equipment. This filter shall be so located and constructed that it is easily accessible for examination, and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage,

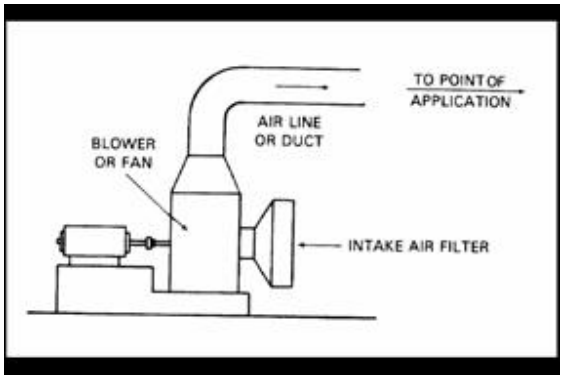


Figure 7 – Air pump

14. Air distribution piping, fittings, and gaskets between the downstream terminal filter and any product or product contact surface shall conform to sanitary 3-A design.

15. Air lines shall be easily cleanable construction to a point 2" (5.08 cm) above the tank overflow. ***(Figure 4)***

16. Filter should be located as close as possible to point of use.

17. Air distribution piping or manifold located inside the blower tank shall be designed so as to preclude contamination of the product. This manifold shall be designed to be easily removed from the tank and removable end caps to facilitate sanitary cleaning. ***(Figures 8 and 9)***

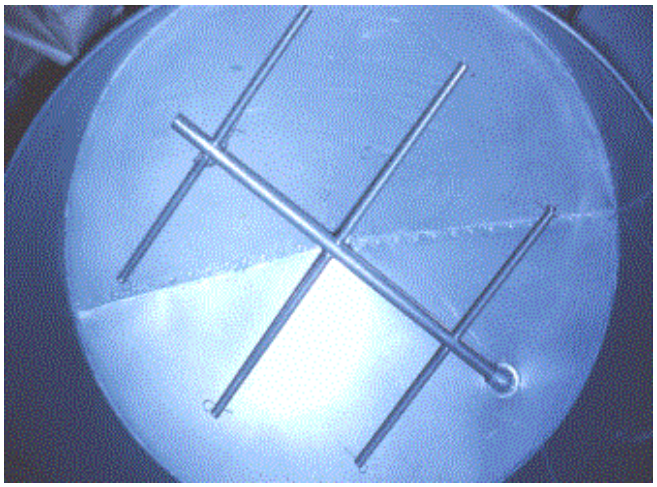


Figure 8 – Air manifold installed inside the blower tank

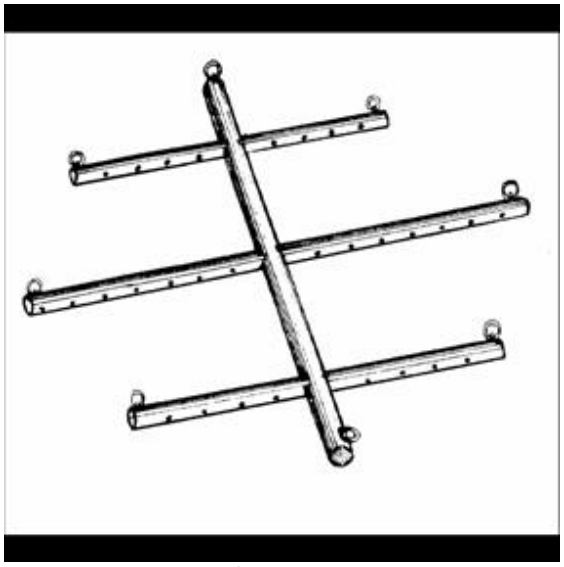


Figure 9 – Air manifold located inside tank

18. Perforations or slots in the manifold or air distribution pipe shall not be less than 1/8" (3.18 mm) in the minimum diameter. After perforation, the pipe from which the perforation punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. ***(Figure 9)***

19. Wire mesh shall not be used as a filter.

20. The blower tank shall be constructed so that it will not buckle or sag and so that it will be self-draining. Product-contact surfaces shall be constructed of not less than 16 U.S. standard gage stainless steel or equivalent material.

21. Maximum dimension of the tank from point of overflow to drain valve flange shall not exceed 40" (101.6 cm).

22. Drain valves and flange shall comply with the 3-A Sanitary Standards for Fitting used on Milk and Milk Products Equipment. The flange shall be welded to the body of the blower tank.

23. There shall be no exposed screw, bolt, or rivet heads in product-contact surfaces.

II. **Skimmers**

A. **Material**

1. All product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel, or equally

corrosion-resistant metal that is non-toxic and nonabsorbent, except that:

(a.) Suitable plastic materials or rubber and rubber-like materials may be used for the skimmer paddle or gate. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals nor impart a flavor to the product.[3]

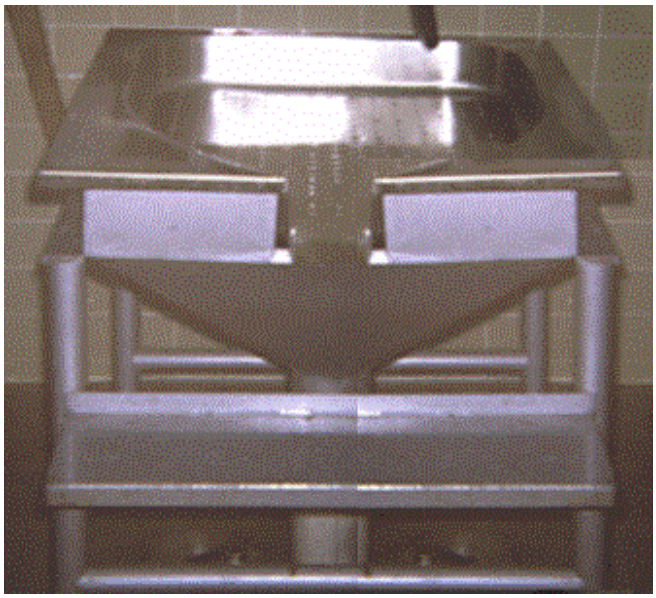


Figure 10 – Photo front view of a skimmer

2. All non product-contact surfaces shall be inherently corrosion-resistant, and except for funnel drain, shall be painted. Surfaces to be painted shall be effectively prepared for painting and the paint used shall adhere, be relatively nonabsorbent, and shall provide a smooth, cleanable, and durable surface. Parts having both product and non product-contact surfaces shall not be painted.

B. **Fabrication**

1. All product-contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets.

2. All seams in product-contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 ground finish. All outside seams shall be smooth and waterproof. All weld areas and deposited weld metal shall be substantially as corrosion resistant as the parent metal.

3. All appurtenances having product-contact surfaces shall be easily removable for cleaning, or shall be readily cleanable in place.

4. All product-contact surfaces shall be easily accessible, visible, and readily cleanable, either when in an assembled position or when removed. The skimmer shall be demountable from the supporting stand for cleaning. (***Figure 11)***

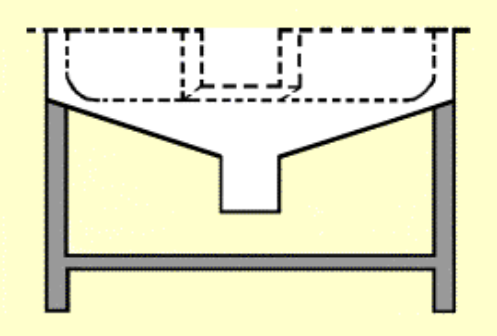


Figure 11 – Front view of skimmer frame; broken lines are the removable part of the skimmer food contact area

5. All internal angles of 135° or less on product-contact surfaces shall have minimum radii of 1/4" (6.35 mm) except that minimum radii for fillets of welds in product-contact surfaces may be smaller for essential functional reasons. (***Figure 2***)

6. The skimmer shall be constructed so that it will not buckle or sag while in use, so that both the perforated area and drainage funnel are self-draining, and so as to provide plane surfaces free of depressions, indentations, or bulges which prevent draining when the pitch is not greater than 1" (25.4 mm) in 50" (127 cm). (Corners and rims of a perforated skimmer should be adequately reinforced to prevent damage from handling during cleaning and bactericidal treatment.)

7. The product-contact surfaces shall be constructed of not less than 16 U.S. standard gage stainless steel or equivalent material. The perforations or slots in the strainer shall be at least 1/4" (6.35 mm) in diameter or width, respectfully (***Figure 12 and Dimension A, Figure 13)*** and not more than 1 1/4" (31.75 mm) apart (***Dimension B, Figure 13***)[5]. The strainer area shall have no perforations within 1/2" (12.7 mm) of the edge (***Dimension C, Figure 13***).[4] After perforations, the flat surface of the sheet from which the perforating punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. No bracing for the skimmer or the skimmer support stand shall block any perforations unless the brace is made of corrosion-resistant material and fabricated in a manner suitable for a product-contact surface, and unless it can be readily removed for cleaning. A minimum of 3 1/2" (8.89 cm) shall be provided between the strainer and the top of the skimmer (***Dimension E, Figure 13***).

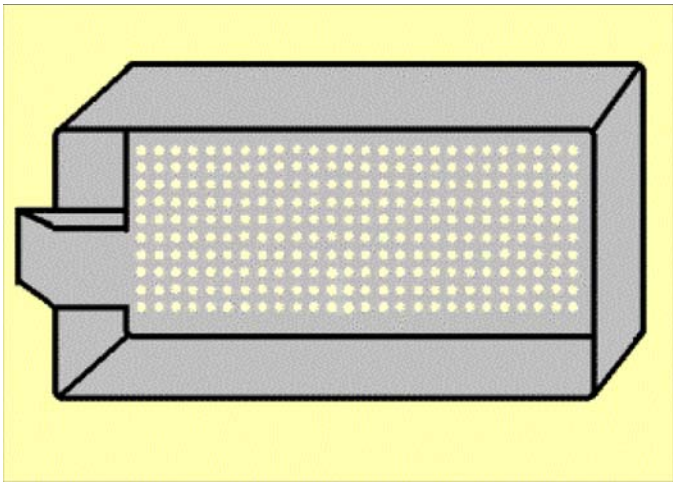


Figure 12 – Skimmer perforations or slots in the strainer shall be at least 1/4 ” in diameter

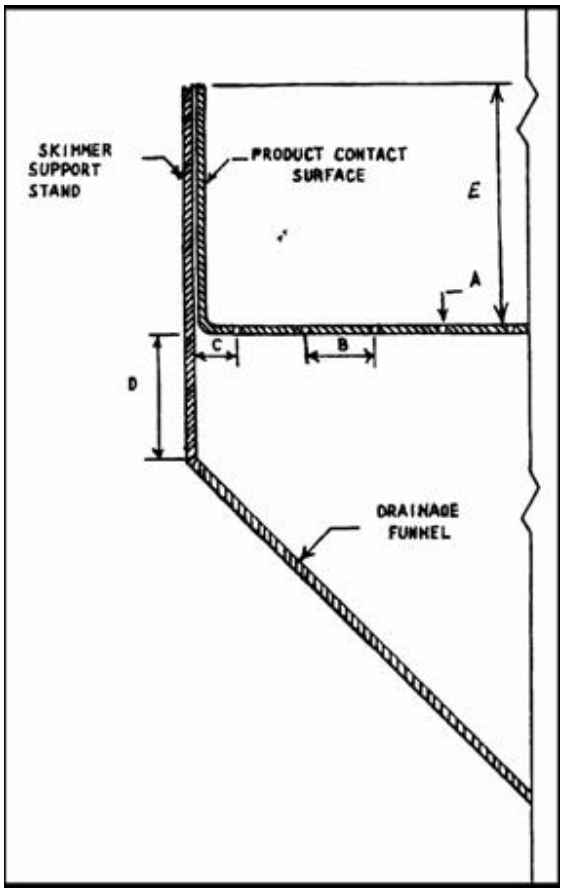


Figure 13 – Skimmer cross sectional side view

8. A minimum vertical clearance of 2" (5.08 cm) shall be provided between the perforated skimmer area and the drainage funnel. (***Dimension D, Figure 13***).

9. The funnel drain shall have a discharge opening of a size sufficient to discharge the drainage without pooling above, and be not less than equivalent to a diameter of 4" (10.16 cm). The funnel drain shall terminate in a free discharge, a distance of at least 6" (15.24 cm) above the floor or the drain connection if located at a higher elevation than the floor. (***Figure 13***)

10. There shall be no threads on product contact surfaces except as provided for in the 3-A Sanitary Standards for Fittings.

11. Legs shall be smooth with rounded ends, and have no exposed threads. If legs are of hollow tube stock, they shall be effectively sealed. (***Figure 5***)

12. Frames, frame legs, and supporting edge for the skimmer shall have:
    (a.) Structural parts not in contact with the product, and parts constructed with a smooth finish so as to be readily cleanable.
    (b.) Self-draining exterior surfaces.
    (c.) A minimum of 6" (15.24 cm) of space between the lowest part of the frame and the floor to provide ready access for cleaning legs and feet and those parts not readily removable.
13. The frame shall provide continuous support for the outside edge of the skimmer strainer. ***(Figure 14)***

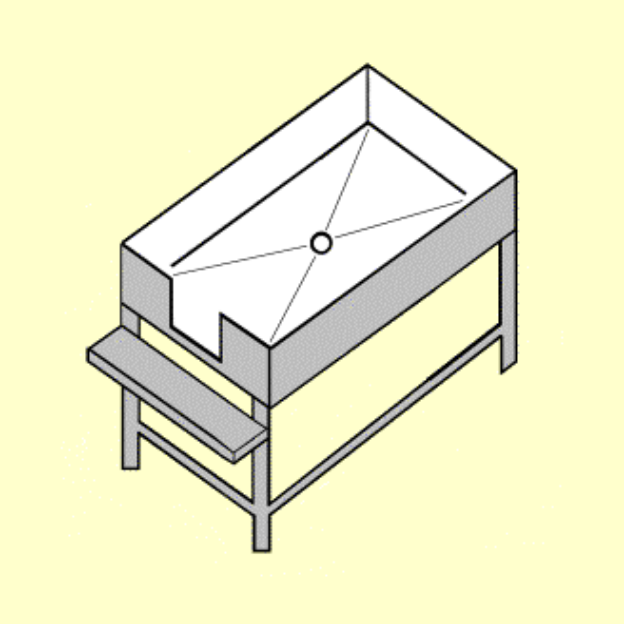


Figure 14 – Skimmer frame table

14. The receiving-container shelf under the skimmer chute, where provided as an integral part of the skimmer support frame, shall be constructed of nonabsorbent, corrosion-resistant material and located so that the receiving-container rim will be at least two feet above the floor. (***Figure 14***)

15. All seams in the funnel drain area shall be smooth and waterproof, and substantially as corrosion resistant as the parent metal.

16. There shall be no exposed bolts, screws, or rivets in the product-contact surfaces.

17. Caster, rollers can be mounted on the skimmer. These shall be of such material, design and construction as to permit its being easily moved by one person. Casters shall be so installed as to be easily cleanable.

18. Reinforcing and framing members are to be placed in such a manner as to be easy to clean. All framing and reinforcing members shall be so placed as to eliminate harborage for vermin. The ends of all hollow sections of reinforcing and framing members shall be closed.
    (a.) Horizontal angle reinforcing and gussets shall not be placed where food or debris may accumulate thereon.
    (b.) Where angles are used horizontally, they shall have one leg turned down wherever the nature of the equipment permits or shall be formed integral with the sides.
    (c.) All vertical sections shall be either completely closed or open to the floor.

III. **Returnable Shipping Containers**

A. **Material**

1. All metallic product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or Aluminum Association type No. 5052-0 alloy, or equally corrosion-resistant metal that is nontoxic.

2. Plastic materials may be used as a food-contact surface or non food-contact surface. When used, these materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart flavor to the product.[3]

3. If constructed of stainless steel, the containers shall not be constructed of less than 20 gauge material. If constructed of aluminum alloy the material shall not have a thickness less than 0.064" (1.63 mm).

4. All non product-contact surfaces shall be of corrosion-resistant material, and shall provide a smooth, cleanable, and durable surface.

B. **Fabrication**

1. All product-contact surfaces shall be at least as smooth as a number 4-ground finish on stainless steel, or equivalent surface finish on aluminum.

2. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm).

3. There shall be no seams, crevices, or other openings within the food-contact surfaces.

4. The container rim shall be rolled so as to permit easy and complete cleaning. The bead shall either be an open type with an external radii of not less than 3/16" (4.76 mm) or a sealed closed type.

5. The container lid shall be so constructed as to afford easy and complete cleaning, shall be reasonably tight fitting, and a lip shall extend at least one inch down the outside of the container. Provisions shall be made for sealing the container so that any tampering will be evident. ***(See Figure 15)***

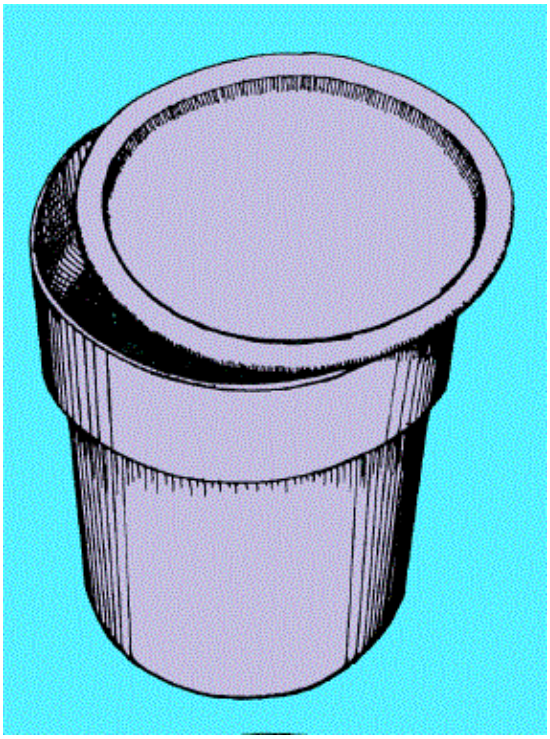


Figure 15 – Returnable container with lid

6. Handles shall be provided on 5-gallon or larger containers. The handles shall be considered as a non product-contact surface.

IV. **Shucking Buckets and Pans**

A. **Material**

1. All metallic product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or Aluminum Association type No. 5052-0 aluminum alloy, or equally corrosion-resistant metal that is nontoxic.

2. Plastic materials may be used as a food-contact surface or non food-contact surface. When used, these materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart flavor to the product.[3]

3. If constructed of stainless steel, the buckets shall not be constructed of less than 22 gauge material and the pans shall not be constructed with less than 24 gauge material or if constructed of aluminum alloy, the material shall not have a thickness less than 0.064"(1.63 mm).

4. All non product-contact surfaces shall be of corrosion-resistant material and shall provide a smooth, cleanable, and durable surface.

B. **Fabrication**

1. All product-contact surfaces shall be as smooth as a number 4 ground finish on stainless steel or equivalent surface finish on aluminum.

2. All internal angles of 135° or less on product-contact surfaces shall have minimum radii of 1/4" (6.35 mm)

3. The shellfish shucking bucket shall not exceed a nine-pint capacity, except for the soft clam (*Mya arenaria*) shucking pan which shall not exceed a four pint capacity. ***(Figures 16 and 17)***

Figure 16 – Mya arenaria shucking pan, four pint capacity

Figure 17 – Oyster shucking bucket, nine pint capacity

4. There shall be no seams, crevices or other openings within the food-contact surfaces, except that two holes 180° apart shall be permitted in the side of each bucket near the top to accommodate a removable ball-type handle. ***(See Figure 18)***

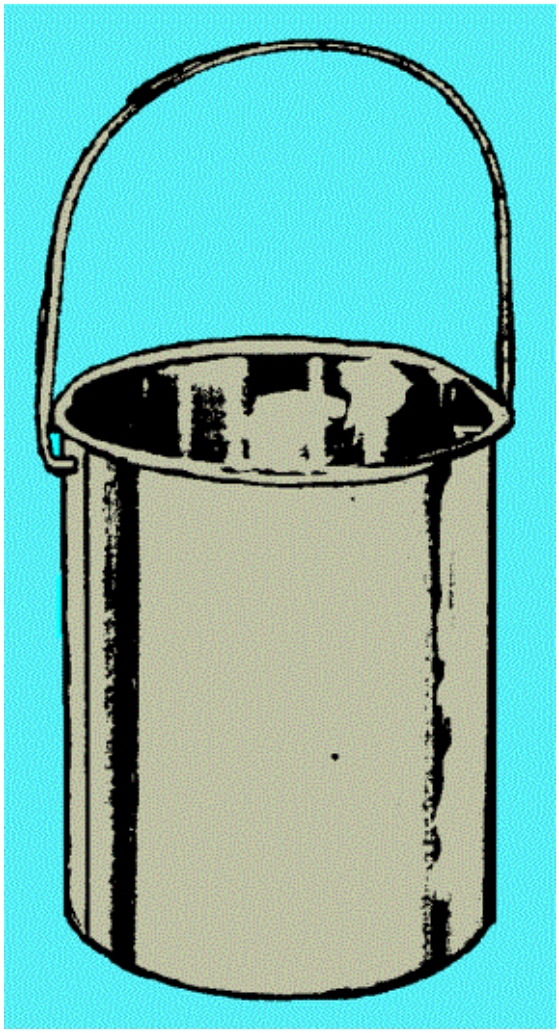


Figure 18 – Shucking bucket handle 180° apart side by side

5. The container rim shall be so constructed as to afford maximum strength and protection against damage, and shall be so rolled as to permit easy and complete cleaning. The bead shall be open type with an external radii of not less than 3/16" (4.76 mm) or a sealed closed type.

6. The bail, if provided, shall be considered as contact surface and subject to material specifications as outlined in paragraph A of this standard. The bail shall be not less than 3/16" in diameter (4.76 mm); it shall be so constructed that it will be held into place by spring tension. The bail shall be so constructed that it can be easily removed from the shucking bucket for cleaning purposes.

V. **TABLES**

A. **Materials**

1. All metallic product contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or equally corrosion resistant metal that is nontoxic and non-absorbent.

2. Only such materials shall be used in the construction of a table as will withstand wear, penetration of vermin, the corrosive action of food, cleaning compounds and such other elements as may be found in the environment. Such materials shall not impart an odor, color, taste or toxic material to the food.

3. Whenever alternate materials are used, the use of such materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

4. All non-product contact surfaces shall be inherently corrosion resistant, and shall provide a smooth, cleanable and durable surface. Parts having both product and non-product contact surfaces shall not be painted.

B. **Fabrication**

1. All product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets.

2. All seams in product contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 ground finish. All outside seams shall be smooth and waterproof. All weld areas and deposited weld metal shall be substantially as corrosion resistant as the parent metal.

3. All product contact surface shall be easily accessible, visible and readily cleanable, either when in an assembled position or when removed.

4. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm) except that minimum radii for fillets of welds in product contact surface may be smaller for essential functional reasons.

5. The table shall be constructed so that it will not buckle or sag while in use, so as to provide plane surface free of depressions, indentations, or bulges which prevents draining when the pitch is not greater than 1" (2.54 cm).

6. The product contact surfaces shall be constructed of not less than 16 U.S. standard gauge stainless steel or equivalent material.

7. The splash contact surfaces shall be of smooth, easily cleanable and corrosion resistant materials, or they shall be rendered corrosion resistant with a material which is non-cracking, non-chipping and non-spalling. Paint shall not be used.

8. Non-food contact surfaces shall be smooth and of corrosion resistant material or shall be rendered corrosion resistant or painted. Lead base paint shall not be used.

9. When welded seams are used, the weld area and the deposited weld material shall be as corrosion resistant as the parent material. The welded area surface requiring routine cleaning in surface in contact with food shall be smooth.

10. All exposed external angles or corners are to be sealed and smooth.

11. All joints and seams in the food zone shall be sealed and shall be smooth as the surfaces being joined. Wherever feasible and practical, equipment or parts in the food zone shall be stamped, extruded, formed or cast in one piece.

12. Exposed threads, screws, bolts and rivet heads, nuts shall be eliminated from the food contact surfaces.

13. Food contact surfaces which during the course of fabrication are so worked as to reduce their corrosion resistant characteristics, shall receive such additional treatment as is necessary to render, or to return them to a corrosion resistant state.

14. All exposed edges and nosings on horizontal surfaces shall be integral with tops, regardless of profiles, and where exposed to fingers and cleaning and cleaning they shall be made smooth.
    (a.) Nosings shall be open 3/4" (19.05 mm) or completely closed against the body of the unit on all sides to prevent the harborage of insects.
    (b.) The space between the top and the flange shall be not less than 3/4" (19.05 mm).
    (c.) The space between the sheared edge and the frame angle shall not be less than 3/4" (19.05 mm) to provide access for cleaning.

    (Figure 19)

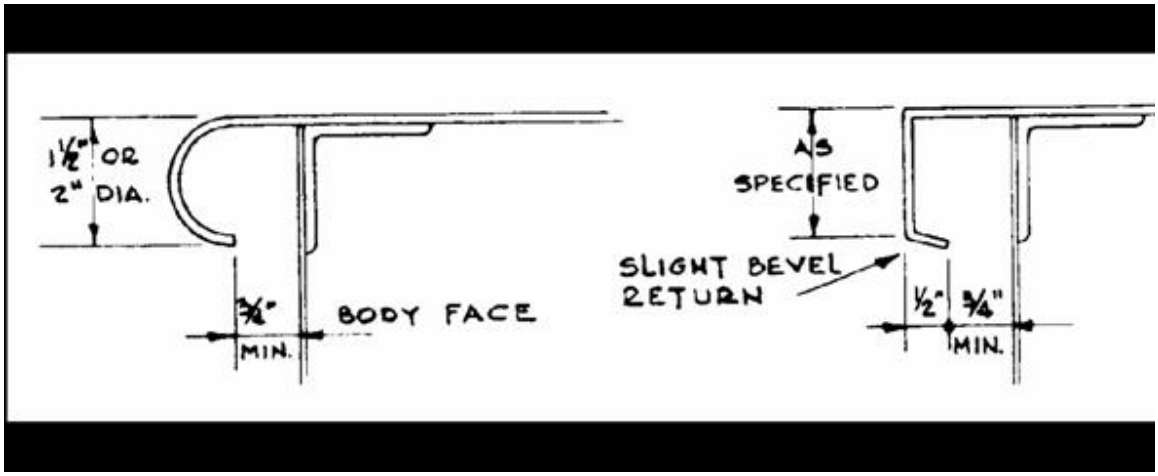


Figure 19 – Exposed edges and nosings on horizontal surfaces

15. Legs and feet shall be non-absorbent and of sufficient rigidity to provide support with a minimum cross bracing and so fastened to the body of the equipment.***(Figure 20)***

    (a.) When the outside dimension of the leg is greater that the outside dimension of the foot by 1/2 " (12.7 mm) or more in the same plane, the foot shall, at minimum adjustment extended 1" (2.54 cm) below the leg.

    (b.) All opening to hollow sections between feet and legs shall be drip proof construction with no opening greater than 1/32" (0.794 mm) All other opening to hollow sections shall be sealed.

    (c.) Gussets, when used, shall be assembled to the equipment in such a manner as to insure easy cleanability and to eliminate insect harborage. The assembly shall have no recessed areas or spaces. (***Figure 21***)

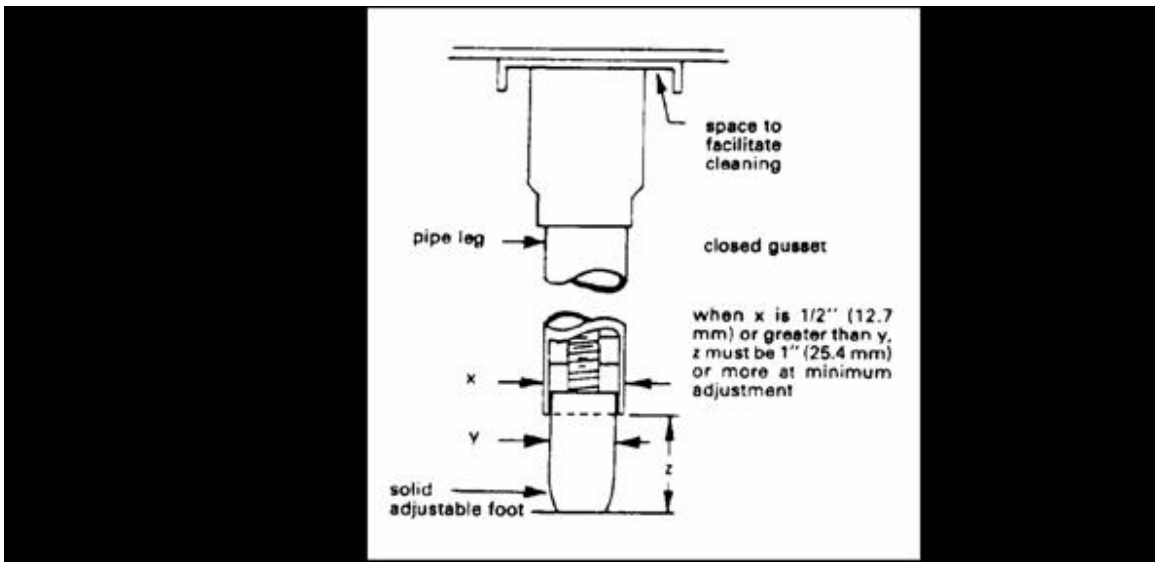


Figure 20 – Legs and gussets

16. Reinforcing and framing members not totally enclosed are to be placed in such a manner as to be easy to clean. ***(Figure 21)***

    (a.) All framing and reinforcing members shall be so placed as to eliminate harborage for vermin.

    (b.) The ends of all hollow sections of reinforcing and framing members shall be sealed.

    (c.) Horizontal angle reinforcing and gussets shall not be placed where food or garbage may accumulate thereon.

    (d.) Where angles are used horizontally, they shall have one leg turned down wherever the nature of the equipment permits, or shall be integral with the sides.

(e.) All vertical sections shall be either completely closed or open to the floor.

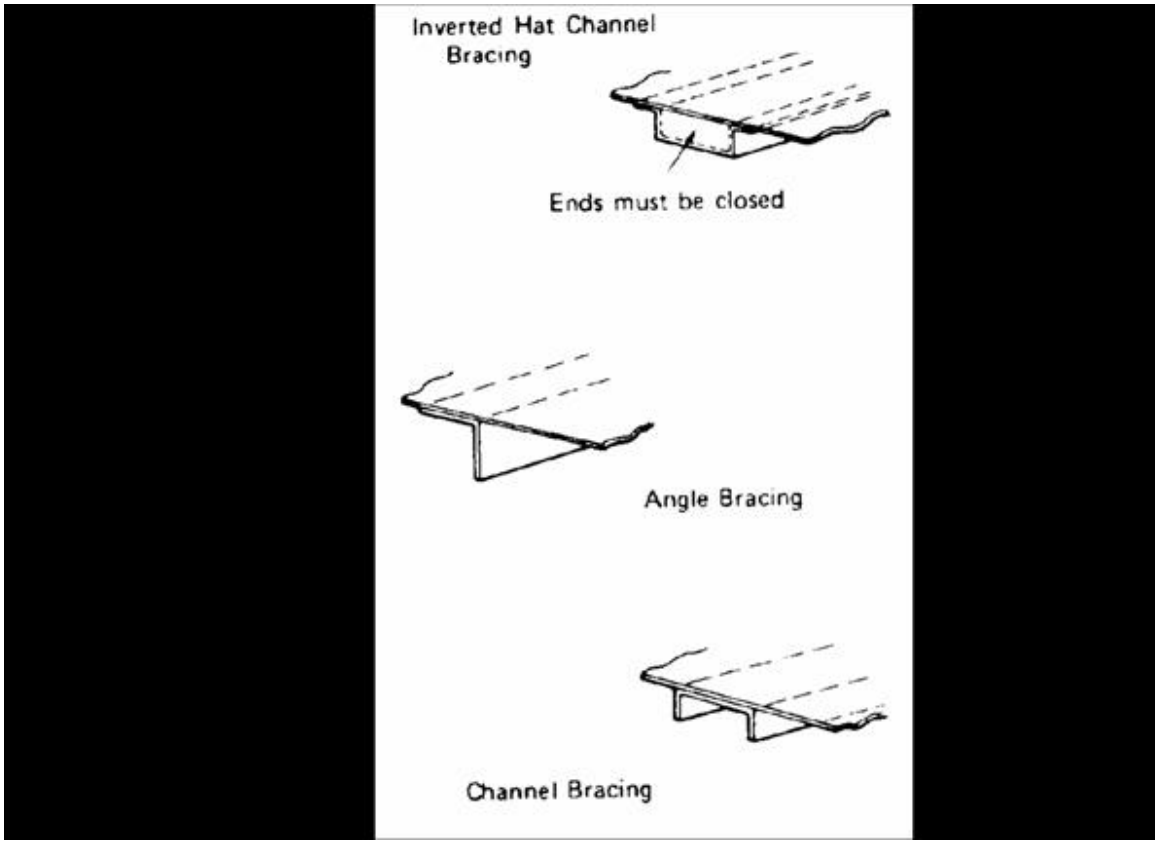


Figure 21 – Reinforcing and framing

VI. **CONVEYORS**

A. **Materials**

1. Only those corrosion resistant materials capable of maintaining original surface characteristics under the prolonged influence of the use environment, including the expected food contact and normal use of cleaning compounds and sanitizing solutions.

2. Belt materials shall be nontoxic, oil proof and of such construction that raw edges and sides will be sealed. The belt shall be relatively nonabsorbent. Belt lacings or fastenings shall meet the applicable clean ability requirements for food, splash and nonfood zones.

3. Whenever alternate materials are used, the use of such materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

B. **Fabrication**

1. Conveyor belt, belt support pan, rollers, driving mechanism and pulleys shall be readily accessible for cleaning.

2. The base of conveyor units shall have readily removable access panels to permit cleaning.

3. Readily removable catch pans of proper design and adequate capacity shall be provided wherever spillage, splash and similar debris may accumulate. Food waste collection and disposal stations shall be designed, constructed and equipped to facilitate the collection and/or disposal of shell waste in an acceptable manner and to be easily cleaned.

4. Drains, when provided in connection with conveyors shall be equipped with readily removable strainer baskets or similar device.

5. Motors shall be so located as to be protected against splash, spillage and the like, or to be otherwise protected.

6. In the non-food zone, exposed threads and projecting screws and studs should be used only when it has been demonstrated that other fastening methods are impractical and they shall be eliminated from the splash contact surfaces.
(a.) Exposed rivet, screw, or bolt in the splash zone shall be of low profile type such as brazier, or modified brazier rivets or pan and oval screw and bolt heads. ***(Figure 22)***

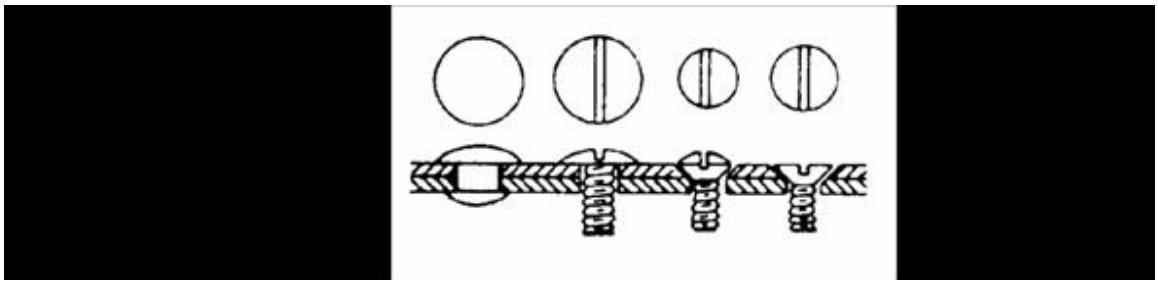


Figure 22 – Low profile fasteners for nonfood contact surfaces

VII. **Oyster Shucking Grinders**

A. **Materials**

1. Only those corrosion resistant materials capable of maintaining original surface characteristics under the prolonged influence of the use environment, including the expected food contact and normal use of cleaning compounds and sanitizing solutions. The machine is designed to operate in a wet spray environment.

2. Food contact surfaces shall be effectively washed to remove or completely loosen soils by manual or mechanical means such as the application of detergents; hot water; brushes; or high pressure sprays.

3. Parts of a shellstock grinder which are considered food contact surfaces include; the blade, the area behind the blade including the motor shaft from the blade to the motor housing, and the inside surface of the housing or cover surrounding the blade. These food contact parts shall be manufactured from high impact materials that are easily cleanable and non-corrosive. The grinder must be constructed to be easily disassembled and assembled to facilitate inspection, maintenance, cleaning, and sanitizing. ***(Figure 23)***

Figure 23 – Mechanical stainless steel oyster grinder

B. **Fabrication**

1. The motor shaft should be of corrosion resistant material.
2. Juncture point where the motor shaft enters the blade chamber must be sealed to reduce dirt and detritus deposition around the shaft.
3. The blade must be made from a single piece of high impact non-corrosive material. Blade teeth must be an integral part of the blade, or if grinding surfaces are used instead of teeth, they must be welded to the face of the blade with all welds ground smooth.

4. The housing around the blade assembly must be constructed of material that is corrosion resistant.
5. Bolts or screws must be constructed of corrosion resistant material to prevent rust and corrosion.
6. The inside surface of the blade housing must be smooth, and if welded ground smooth for easy cleaning.
7. The blade housing must be designed with an easily removable cover that will open up the entire blade assembly area to facilitate inspection, cleaning, sanitizing, and maintenance.

Notes:

1. Proceedings, 1958 Shellfish Sanitation Workshop, U.S. Public Health Service, Washington DC.

2. American Iron and Steel Institute. Copy of the AISI Steel Products Manual, Stainless & Heat Resisting Steels can be obtained from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086, Telephone 412-776-9460.

3. Plastic, rubber, and rubber-like materials used for equipment may be subject to the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The acceptability of such materials under Food Additive Amendment shall be obtained from equipment manufactures.

4. Sanitary standards describing the construction of valves, fittings, and pumps may be obtained from International Association of Milk and Environmental Sanitarians, Inc., 200 W Merle Hay Centre, Suite 404, Cedar Rapids, IA, 52402, Telephone 319-395-9151, FAX 319-393-1102.

5. Skimmer size: The Food and Drug Administration definition and standard of identity for raw oysters states in part: "The oysters are drained on a strainer or skimmer which has an area of at least 300 square inches per gallon of oysters drained, and has perforations of at least 1/4 of an inch in diameter and not more than 1 1/4 inches apart, or perforations of equivalent areas and distribution. (Definitions and Standards under the Federal Food, Drug, and Cosmetic Act, Title 21, Part 36, F

References:

3-A Sanitary Standard Committee,
3-A Sanitary Standards for Sanitary Fitting for Milk and Milk Products Number 63-00 (08-17 Amended), 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee,
3-A Sanitary Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Food Contact Surfaces Serial #60403, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee,
3-A Sanitary Standards for Mechanical Conveyors For Dry Milk and Milk Products #41-00, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee,
3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, No. 20-17, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee,
3-A Sanitary Standards for Uninsulated Tanks for Milk and Milk Products, No. 32-01, 6245 Executive Boulevard, Rockville, MD 29852.

Building Officials & Code Administrators,
The BOCA National Plumbing Code, 1987: Model plumbing regulations for the protection of public health, safety and welfare, 4051 W. Flossmoor Rd. Country Club Hills, IL 60477, 1988.

C.D.B. Company, Equipment for the Shellfish Industry, 335 Hill-N-Date Drive, York, PA 17403.

Lunsford, L.R., Shellfish Industry: Equipment Construction Guides, U.S. Department of Health, Education and Welfare, Public Health Service, Division of Environmental Engineering and Food Protection, Washington 25, D.C., Public Health Service Publication No. 943, Adopted by the 1961 National Shellfish Sanitation Workshop (April 1962).

National Sanitation Foundation, Food Service Equipment Standards, 3475 Plymouth Road, Ann Arbor, Michigan, 48106, September 1978.

Office of the Federal Register, 21 Code of Federal Regulations, Parts 170-199, U.S. Government Printing Office, Washington, DC, 1992.

Stainless Steel Information Center, Specialty Steel Industry of North America, STAINLESS STEEL:An introduction to a versatile, aesthetically pleasing and "full life cycle" material, 3050 K Street, N.W. Washington, DC 20007. Website http://www.ssina.com

U.S. Food and Drug Administration,
Milk and Milk Product Equipment: A Guide for Evaluating Sanitary Construction, Developed by the Milk Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204.

U.S. Food and Drug Administration, Grade "A" Pasteurized Milk Ordinance, Developed by the Milk Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1991 Revision.

U.S. Food and Drug Administration,
Standards for the Fabrication of Single Service Containers and Closures for Milk and Milk Products, Developed by the Milk Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1991 Revision.

U.S. Food and Drug Administration, Food Service Sanitation Manual: A Model Food Service Sanitation Ordinance, H.E.W. Publication No. (FDA) 78-2081, Developed by the Division of Retail Food Protection, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1978.

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.02 Shellfish Plant Inspection Standardization Procedures
NSSP Standardized Shellfish Processing Plant Inspection Form

Table of Contents

Chapter 1 - Introduction to Plant Standardization

PURPOSE:

In 1988, the Interstate Shellfish Sanitation Conference (ISSC) adopted, as a primary goal, an initiative to standardize FDA Regional Shellfish Specialists and State Standardization Officers. The Conference affirmed that standardization of shellfish regulators will result in uniform plant inspections and strengthen consumer confidence in shellfish products. In 1991, the Conference adopted issue 91-222 requiring the certification of the shellfish plant inspections before listing in the Interstate Certified Shellfish Shipper's List (ICSSL), effective January 1, 1994. As a result of that issue, FDA developed procedures to standardize Regional Shellfish Specialists and State Standardization Officers. The requirements and criteria described in this Standardization procedures document apply only to standardization of the Regional Shellfish Specialists and State Standardization Officers.

OBJECTIVE:

The standardization process provides regulatory personnel the opportunity to standardized their knowledge and skills related to the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) with the knowledge and skills of FDA's National Plant *Standard*(s) and/or Regional Shellfish Specialists. The process and criteria for demonstrating uniformity in the required performance areas are described in Chapter 4.

Through the application of this procedure, the *Candidate* should demonstrate uniformity with "the *Standard*" or

“State Standardization Officer” through his/her knowledge and expertise in the application and interpretation of the MO requirements for HACCP principles, sanitation, and the use of the NSSP STANDARDIZATION SHELLFISH PROCESSING PLANT INSPECTION FORM. The application of this procedure is not intended to provide basic shellfish plant sanitation training to individual *Candidates*.

DEFINITIONS:

The following definitions apply in the interpretation and application of this procedure.

(1) CANDIDATE means an individual applying for initial Standardization who has completed the prerequisite requirements or/and an applicant who is applying for re-standardization.

(2) MODEL ORDINANCE (MO), also known as "Guide for the control of molluscan shellfish," provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

(3) NATIONAL STANDARDIZATION OFFICER, also known as "FDA's National Plant *Standard*," means an FDA individual(s) at the national level responsible for interpreting NSSP MO requirements for shellfish plant operations. The *Standard* represents the FDA position on all Standardization issues. The *Standard* is also responsible for standardizing FDA Regional Shellfish Specialists.

(4) NOMINEE means the applicant designated for standardization based on the procedures contained in this document.

(5) STANDARDIZATION means the process whereby a *Candidate* demonstrates the knowledge and skills necessary to be considered uniform with the *Standard* as defined in the National Shellfish Sanitation Program's (NSSP), Plant Standardization Procedures.

(6) STANDARDIZED INSPECTOR means a state/federal shellfish plant inspector who has been authorized to certify shellfish shippers as demonstrated by successfully passing a standardized test.

(7) STATE STANDARDIZATION OFFICER means a state shellfish program employee who has met the qualification requirements in the National Shellfish Sanitation Program Plant Standardization Procedures and successfully completed field standardization inspections with a Standardized FDA Regional Shellfish Specialist.

Chapter 2 - Standardization Participants

FDA

The FDA National Plant *Standard*(s) will be responsible for standardizing all Regional Shellfish Specialists. Standardized FDA Regional Shellfish Specialists will standardize the State’s "Standardization Officer" *Candidate(s)*. The FDA National *Standard*
will conduct standardization inspections to evaluate and assure the proficiency of the FDA Regional Shellfish Specialists. The Standardization inspection process will consist of three (3) practice inspections and five (5) standardization inspections.

STATE

Each participating state will sponsor an adequate number of individuals for positions as State Standardization Officers and inspectors to guarantee that each certified shellfish dealer is routinely inspected for compliance with the MO plant processing requirements. The State should select no more than two (2) individuals as Shellfish Standardization Officers. The FDA Regional Shellfish Specialists will conduct standardization inspections to evaluate and assure the proficiency of the State Standardization Officer(s). The Standardization inspection process will consist of three (3) practice inspections and five (5) standardization inspections.

State Standardized Inspectors are standardized by State Standardization Officers. Each State shall provide the

necessary resources to support the training of state shellfish inspectors by the State Standardization Officer(s) to ensure that each shellfish firm receives uniform routine inspections. The State Standardization Officer also has the option of sanctioning the participation of local, city, and/or county shellfish plant inspectors. It is recommended that the State Standardization Officer standardize State Standardized Inspector *Candidates* utilizing the same standardization procedures identified for State Standardization Officers.

Chapter 3 - Qualifications For Standardization

This chapter defines those requirements that the *Candidate* must complete prior to standardization. In order for a *Candidate*
to engage in the process of initial field standardization, they will qualify by completing the prerequisite and experience requirements specified in this chapter. Those requirements only apply to first time applicants applying for standardization.

QUALIFICATIONS FOR STATE PERSONNEL:

When nominating a *Candidate*, the supervisor making the nomination should provide the required *Candidate* background information on the STANDARDIZATION NOMINATION FORM (Attachment 1). This information will be maintained in a file at the appropriate FDA Office.

- **NOMINATION** - To be eligible for standardization, the *Candidate* should be a senior inspector with experience and responsibility in the shellfish program.

- **JOB EXPERIENCE** - The *Candidate* should be responsible for conducting molluscan shellfish plant inspections and providing training in shellfish inspection procedures. It is a requirement that the *Candidate* has at least one (1) year of full time experience performing shellfish plant inspections within the past three (3) years.

- **CLASSROOM TRAINING** - Prior to field standardization, the *Candidate* must successfully complete the following courses:
    - 3 or 2 day Seafood Alliance HACCP (Basic Seafood HACCP)
    - 2 day Seafood Regulators Training
    - ***FD 1040*** Basic Shellfish Plant Sanitation; and
    - ***FD 2041*** Shellfish State Standardization Officer Training (**not recommended for State Standardized inspectors unless specifically offered**)

- **EDUCATION** - It is recommended that the *Candidate* have at least 20 hours of training in the application of Food Science and related studies in Microbiology and/or Epidemiology, HACCP principles/Plan Review, and State regulations.

QUALIFICATIONS FOR FDA PERSONNEL:

When nominating a *Candidate*, the supervisor making the nomination should provide the required *Candidate* background information on the STANDARDIZATION NOMINATION FORM (Attachment 1). This information will be maintained in a file at the Division of Cooperative Program Office.

- **NOMINATION** - To be eligible for standardization, the *Candidate* must be a FDA Regional Shellfish Specialist.

- **JOB EXPERIENCE**
  - Experience will be in accordance with FDA's defined position description including job responsibilities.

- **CLASSROOM TRAINING** - Prior to field standardization, the *Candidate* must successfully complete the following courses:
    - 3 or 2 day Seafood Alliance HACCP (Basic Seafood HACCP)
    - 2 day Seafood Regulators
    - ***FD 1040*** Basic Shellfish Plant Sanitation and

- ***FD 2041*** Shellfish State Standardization Officer

- **EDUCATION** - Education will be in accordance with FDA's defined position description.

Chapter 4 - Performance Criteria For Field Standardization

All Standardization *Candidates* shall meet the following performance criteria:

(a.) **HACCP:** The *Candidate* shall demonstrate the ability to verify that HACCP Plan exists and is being adequately implemented by the dealer.

(b.) **SANITATION ITEMS:** The *Candidate* shall demonstrate the ability to recognize, through records review, the "8" National Shellfish Sanitation Program (NSSP), Model Ordinance (MO), “02 Sanitation Items" are being adequately monitored and that those records are accurate and complete.

(c.) **ADDITIONAL MO REQUIREMENTS:** The *Candidate* shall demonstrate knowledge of the NSSP Model Ordinance, “03 Other Model Ordinance Requirements", and “Good Manufacturing Practice” (GMP) by correctly identifying deficiencies relating to those items during the field evaluation process.

(d.) **INSPECTION EQUIPMENT:** The *Candidate* shall be equipped and familiar with the equipment necessary to conduct a Shellfish plant inspection. The *Candidate shall* be evaluated on the proper use of inspection equipment during the standardization process.

The following is a ***MINIMUM*** list of required forms and equipment for use during shellfish plant inspections:

- Current Edition of the NSSP Standardized Shellfish Processing Plant Inspection Form)
- Administrative materials (Model Ordinance, Field Guide, etc.)
- Head cover: baseball cap, hair net, lab coat or equivalent protection, etc.
- Calibrated stem or digital thermometer with not >2°F increments.
- Chemical test kit or strips for Chlorine, Quaternary, or Iodine sanitizers.
- Flashlight; and
- A 70 % solution of Isopropyl alcohol or equivalent "wipes".
- A camera (Optional)

(e.) **COMMUNICATION:** The *Candidate* shall demonstrate the ability to effectively communicate with plant management about deficiencies noted during the evaluation. Many different types of communication skills and approaches are necessary and valuable during the inspection process. The *Candidate* shall be required to take the lead in communicating with industry personnel during all inspections and the *Standard* shall evaluate the *Candidate*’s communication skills.

INTRODUCTION:
The *Candidate* shall be required to make all introductions. A complete introduction consists of:

(a.) Introducing all persons participating in the inspection;

(b.) Describing the purpose and flow of the inspection;

(c.) Identifying and explaining to the PERSON IN CHARGE that it will be necessary to ask questions about the operation during the inspection; and

(d.) Explaining that this is not intended as a regulatory inspection and that there will be no written report left at the end of the inspection; however, significant findings will be brought to the attention of the PERSON IN CHARGE.

In addition to verbal and written communication, the *Candidate* shall also use the inspection process to

communicate and demonstrate FOOD SAFETY concepts by example. Activities such as proper hand washing, sanitizing thermometer before probing shellfish, and wearing the proper inspection apparel should be used to reinforce spoken and written communications.

INTERVIEW WITH THE PERSON IN CHARGE:
The *Candidate* shall conduct a discussion with the PERSON IN CHARGE to determine:

(a.) If a HACCP PLAN exists, and if so, whether the PERSON IN CHARGE understands the principles of the HACCP PLAN and is ensuring that the employees are effectively using the plan.

EXIT CONFERENCE:
The *Candidate*, at the exit of conference shall clearly convey and discuss in detail with the PERSON IN CHARGE the inspection findings including:

(a.) The compliance status of the firm describing each significant violative condition and, where appropriate, acceptable compliance alternatives,

(b.) The response and plans of the PERSON IN CHARGE for correcting violations, and

(c.) Corrective actions observed during the inspection. Such proactive food safety measures shall be commended.

Explain the public health significance of the deficiencies and demonstrate the ability to discuss and resolve in a courteous and professional manner, issues that the PERSON IN CHARGE might not agree with or clearly understand.

Table 1: Summary of evaluation methods for initial STANDARDIZATION.

PERFORMANCE AREA	FIELD STANDARDIZATION
HACCP (Items 1 - 7)	Evaluation of existing HACCP Plan
Sanitation (Items 8 - 16)	Evaluation/inspection
Additional MO Requirements (Items 17 - 30)	Evaluation/inspection
Inspection Equipment	Observation
Communication	Observation

Chapter 5 - Pre-standardization Field Procedure

Pre-standardization - This phase consists of three (3) joint "practice" field inspections by the *Candidate* and the *Standard*. During these “practice” inspections there will be open discussion between the *Candidate* and the *Standard*
on all matters relating to the standardization process including: the NSSP Model Ordinance interpretations, inspection form debiting requirements (where is "it" marked on the form); questions and discussions relating to the firm's HACCP plan; related Sanitation and Monitoring records and Corrective Action. The current edition of the NSSP Standardized Shellfish Processing Plant Inspection Form (Attachment 4) will be used during all aspects of the standardization procedure.

During pre-standardization inspections, the *Standard* and *Candidate* shall conduct the inspection together and discuss each noted deficiency. They shall agree on the number of times and locations where a specific deficiency was observed in the plant.

Following pre-standardization, the *Standard* may decide that the *Candidate* is unprepared to proceed to the formal field standardization process. If the *Standard* determines the *Candidate* needs additional field training, after discussion with the *Candidate*, they may decide to complete additional "practice" inspections. If the *Standard* determines that more "practice" inspections will not help in the *Candidate's* understanding of the process and/ or procedure then the *Candidate* and *Candidate's* supervisor will be informed.

Chapter 6 - Field Standardization Procedure

The Field Standardization Process consists of the *Standard* and the *Candidate* jointly conducting five (5) shellfish plant evaluations. Always select five (5) Shucker/packer (SP) plants if they are available. If a state has less than five (5) Shucker/packer's (SP), then the remaining plants will be selected according to the following priority:

1) Repackers (RP)
2) Shellstock Shippers (SS)
3) Reshippers (RS)

During all joint field inspections, the *Candidate* will be the lead person. He or she will be responsible for the following: Introduction (determining who is the "most responsible" person), requesting the firm's HACCP Plan and its related documents, and sanitation monitoring records. The minimum number of records required for review will be at least three months. The *Candidate*
shall also conduct the "exit" interview and discuss all significant deficiencies with management.

Chapter 7 - Standardization Scoring

COMPARISON OF FINDINGS:
Following each inspection, the *Standard* shall compare his/her findings with the *Candidate*. At the conclusion of the field standardization, the *Standard* shall tabulate and compare the *Candidate's* inspection findings to determine if the *Candidate* has successfully completed the requirements for Standardization. The *Standard* shall discuss any differences, results and other observations with the *Candidate*.

The *Standard* will evaluate each inspection report to determine the number of disagreements ***(using Standardization Requirements below)*** between the *Standard* and the *Candidate*. Disagreements shall be recorded on the Comparative Results form provided as Attachment 2.

CANDIDATE SCORING: The *Standard*
shall grade each inspection report by circling each incorrectly marked item. The *Standard* shall determine the number of disagreements on items and record that number in the form provided in ATTACHMENT 3. For inspectional equipment and communication scoring is not used but impacts the outcome of the *Candidate*'s performance.

The *Candidate*s shall meet the following level of agreement to achieve Standardization after completing five (5) formal field evaluations.

(a.) HACCP: (item 1-7)
The *Candidate*s **SHALL NOT DISAGREE** with the *Standard* more than an average of three (3) times in five (5) evaluations.**

(b.) Sanitation Items: (item 8- 16)
The *Candidate*s **SHALL NOT DISAGREE** with the *Standard* more than an average of three (3) times in five (5) evaluations. **

(c.) Other Model Ordinance Requirements: (item 17 –30)
The *Candidate*s **SHALL NOT DISAGREE** with the *Standard* more than an average of four (4) times in five (5) evaluations. **

(d.) Inspection Equipment: The *Candidates* **SHALL** have all essential equipment, listed in Chapter 4 "Performance Criteria for Field Standardization" available for use during each inspection. This section shall rate as **SATISFACTORY or NEEDS IMPROVEMENT.**

(e.) Communications: The *Candidates* **SHALL** communicate per the requirements in Chapter 4 "Performance Criteria for Field Standardization". This section shall rate as **SATISFACTORY**

or NEEDS IMPROVEMENT.

****NOTE: With the exception of *Candidate*s deficiencies that were not observed by the *Standard***

CRITERIA FOR SUCCESS STANDARDIZATION:

To achieve standardization, the *Candidates*
shall meet requirements for the Performance criteria (a-c) described in Chapter 4. The *Candidates* may receive "Needs Improvement" classification in the section inspectional equipment and communications and still be standardized.

When either inspection equipment or communication performance area are classified as needing improvement, the *Candidates* and the *Candidate's*
supervisor shall be notified that the "Needs Improvement" area(s) must be satisfactorily addressed before restandardization is granted. Prior to restandardization, the *Candidate's* supervisor must notify the *Standard* that the area(s) or concern has been addressed.

Chapter 8 - Standardization Results

REPORTING

The *Standard* and *Candidate*
shall describe on the narrative section on the NSSP SHELLFISH PROCESSING PLANT FORM each specific deficiency and location within the firm where the deficiency was observed. The *Candidate* shall not fail to recognize any critical items. After each inspection has been completed, the *Standard* shall compare the number and description of the deficiencies found in the plant for each item on the narrative section of the NSSP Standardized Shellfish Processing Plant Inspection Form. The *Standard* shall determine if both observed the same specific deficiencies throughout the plant.

The *Standard*
will use the Comparative Results Form (Attachment 2) to determine the level of agreement between the *Standard* and *Candidate*. At the conclusion of the formal Field Standardization exercise, the *Standard* will complete a Composite Results Report (Attachment 3).

After successfully completing the Field Standardization Exercise, the *Candidate* will be granted the TITLE of *STANDARDIZATION OFFICER OR STANDARDIZED INSPECTOR.* A certificate recognizing that accomplishment will be forwarded to the *Candidate*, along with formal notification to the *Candidate's* supervisor, within thirty (30) days.

Chapter 9 - Re-standardization

STANDARDIZATION EXPIRATION:

The *Candidate's*
STANDARDIZATION is valid for a period of 5 years. Expiration dates will appear on the certificate issued by the *Standard*.

STANDARDIZATION MAINTENANCE:

The maintenance process consists of joint inspections conducted during evaluation activities. Maintenance will also be provided in the form of updated FD 2041 Shellfish State Standardization Officer courses, ORA University web based course, updated field standardization guides, and other guidance/technical assistance activities on an as needed basis.

Chapter 10 - Termination, Suspension, or Revocation of Standardization

TERMINATION OF FIELD STANDARDIZATION:

(a.) The *Standard* has the option to terminate the field exercise at any time during the procedure if the *Candidate*, in the opinion of the *Standard*, is not achieving the required level of agreement for standardization.

(b.) The *Standard* shall notify the *Candidate* and the *Candidate's* supervisor in writing of the reasons for failure.

(c.) The *Standard* will document the reason(s) for termination of the field. This information shall be forwarded to the *Candidate's* supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the *Standard* and shall be kept for 3 years in accordance with the Freedom of Information Act.

SUSPENSION/REVOCATION OF STANDARDIZATION CERTIFICATION

(a.) Fails to utilize and/or properly complete the current NSSP Standardized Shellfish Processing Plant Inspection Form.

(b.) Fails to properly code (critically code) deficiencies (critical, key, and other) on the NSSP STANDARDIZATION SHELLFISH PROCESSING PLANT INSPECTION FORM.

(c.) Fails to fulfill the required maintenance activities described in *CHAPTER 9*.

(d.) Before suspension or revocation, the *Standard* will consult with appropriate personnel in the FDA and/or the *State's* agency to reach a decision on whether:

i. The standardization shall be suspended temporarily with notice regarding conditions required for reinstatement; or

ii. The standardization shall be revoked.

(e.) When a STANDARDIZATION certificate is revoked or suspended, the *Standard shall* notify the supervisor in writing, of his/her decision.

(f.) The *Standard* will document the reason(s) for suspension or revocation of the standardization certification. This information shall be forwarded to the *Candidate's* supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the *Standard* and shall be kept for 3 years in accordance with the Freedom of Information Act.

RE-STANDARDIZATION AFTER SUSPENSION OR REVOCATION.

The *Candidate*
may apply for re-standardization, within thirty (30) days, after suspension or revocation. He or she must contact and work with the appropriate FDA or *State Standardization Officer to correct all prior deficiencies before the re-standardization process begins.

NOTE: State Standardization Officers can only standardize their inspectors. Only FDA National *Standards* or standardized FDA Regional Specialists can standardize state standardization officers.

Chapter 11 - Appeals

FILING AN APPEAL.

Candidate
after being notified of a failure to successfully achieve Standardization or re-standardization may appeal the decision. Should the *Candidate*
elect to appeal, this action must be initiated within thirty days (30) of the date of the written notification of the failure, suspension or revocation. The appeal's request shall be addressed to the FDA Standard Officer at FDA, Division of Cooperative Programs, 5100 Paint Branch Parkway, College Park, MD 20740.

APPEAL BOARD MEMBERS.

The FDA National Plant *Standard*
and representatives from the ISSC and FDA Regional Shellfish Specialist will comprise the STANDARDIZATION Appeals Board. The ISSC will select states representatives to participate in the appeals process.

HEARINGS.

If the Appeal Board finds the appeal unjustified, the decision of the FDA *Standard* will stand.

If the Appeal Board determines that the State Standardization Officer's appeal is justified, the *State Standardization Officer* and the FDA *Standard* will be notified in writing that a hearing will be scheduled.

HEARING PROCEDURE.

At the hearing, the following procedure will be followed:

(1) The *State Standardization Officer* will present his/her argument for reversing the FDA *Standard's* decision;

(2) The Appeal Board will have the opportunity to question the action or conduct of the State Standardization Officer and the FDA *Standard*; and

(3) The Appeal Board will render a decision.

ATTACHMENT I

STANDARDIZATION NOMINATION FORM

TO:
FROM:
SUBJECT: REQUEST FOR STANDARDIZATION
DATE:
Name: Title:
Agency Name:
Address:
City/State/Zip:
Telephone:
Fax:

Education: (list degree or include a transcript)	
	Length of Service:
	Describe shellfish experience:
CHECK (**X**) BELOW COURSES ATTENDED: Basic Shellfish Plant Sanitation ( ) Basic Seafood HACCP Alliance Course ( ) Regulator's HACCP Course ( ) List Other Courses	*How many routine shellfish plant evaluations per year?* 1 - 5 ( ) 6 - 10 ( ) >20 ( )

ATTACHMENT 2

COMPOSITE PERFORMANCE REPORT

FIRM NAME:	**Candidate(O)**	**Standard(X)**	**Disagreements**
#1 HACCP Plan			
#2 Plan Elements (a) Hazards			
#2 Plan Elements (b) Records			
#2 Plan Elements (c) Critical Limits			
#2 Plan Elements (d) Signed and Dated			
#2 Plan Elements (e) Critical Control Points			
#2 Plan Elements (f) Monitoring			
#2 Plan Elements (g) Verification Procedures			
#2 Plan Elements (h) Corrective Action if identified			
#3 HACCP Training			
#4 Plan Implementation (a) Receiving			
#4 Plan Implementation (b) Shellstock Storage			
#4 Plan Implementation (c) Processing			
#4 Plan Implementation (d) Shucked Meat Storage			
#4 Plan Implementation (e) Other Critical Limits			
#5 Approved Source Control Failure			
#6 Time/Temperature Control Failure			
#7 Other Critical Control Failure			
TOTAL NUMBER OF DISAGREEMENTS			

SANITATION ITEMS

#8 Safety of water for processing and ice production			
#9 Condition and cleanliness of food contact surfaces			
#10 Prevention of cross-contamination			
#11 Maintenance of hand-washing, hand sanitizing, toilet facilities			
#12 Protection from adulterants			
#13 Proper labeling, storage, and use of toxic compounds			
#14 Control of employees with adverse health conditions			
#15 Exclusion of pests			

#16 Sanitation Monitoring and Records			
TOTAL NUMBER OF DISAGREEMENTS			

ADDITIONAL MODEL ORDINANCE REQUIREMENTS

#17 Plants and Grounds			
#18 Plumbing and related facilities			
#19 Utilities			
#20 Insects and vermin control			
#21 Disposal of other waste			
#22 Equipment construction (non-food contact surfaces)			
#23 Cleaning non-food contact surfaces			
#24 Shellfish storage and handling			
#25 Heat shock			
#26 Personnel			
#27 Supervision			
#28 Transportation (To include only the person shipping)			
#29 Labeling and Tagging (Other than receiving)			
#30 Shipping Documents and Records			
TOTAL NUMBER OF DISAGREEMENTS			

FIELD REQUIREMENT FOR THE SUCCESSFUL COMPLETION OF STANDARDIZATION

In order for the *Candidate*
to successfully complete standardization he/she must meet the following field standardization criteria after five (5) evaluations:

- HACCP inspection form items 1 - 7.
  Disagreements with the *standard* ***cannot exceed an average of three (3).***
- Sanitation inspection form items 8 - 16.
  Disagreements with the *standard* ***cannot exceed an average of three (3).***
- Additional Model Ordinance inspection form items 17 - 30.
  Disagreements with the *standard* ***cannot exceed an average of four (4).***

ATTACHMENT 3

INDIVIDUAL FIRM COMPARISON FORM

"Candidate vs Standard: Composite performance chart"

NUMBER OF DISAGREEMENTS

FIRM NAME	HACCP	SANITATION ITEMS	ADDITIONAL MO REQUIREMENTS
TOTAL			
***Average Score**			
Acceptable Avg. Score	3	3	4
INSPECTIONAL EQUIPMENT	**SATISFACTORY**	**NEEDS IMPROVEMENT**	

COMMUNICATION	**SATISFACTORY**	**NEEDS IMPROVEMENT**

*The *Candidate*'s average composite score through five (5) formal standardization inspections meets (OR DOESN'T MEET) the acceptable average score required to achieve standardization.

STANDARDIZATION LOCATION:

DATE(S):

CANDIDATE:

STANDARD:

NSSP Standardized Shellfish Processing Plant Inspection Form

Agency Name:								Date:	
Type of Inspection	O Certification O Pre-operational O Routine O Follow-up O Standardization								
Dealer Name:							Certification Number:		
Dealer Address:									
	Hazard Analysis Critical Control Point (HACCP)								
1.	HACCP Plan OYes ONo Required for Certification								
2.	Plan Elements **Identified and Adequate**	**✓/x NA**	**Code**				**✓/x NA**	**Code**	**Overall Code**
	(a) Hazards		O	(e) Critical Control Points				K	
	(b) Records		O	(f) Monitoring				K	
	(c) Critical Limits		K	(g)Verification Procedures				O	
	(d) Name, Address, Signed and Dated		O	(h) Corrective Action if identified				K	
3.	HACCP Training O Yes O No			Code	O				
4.	**Plan Implementation**	**Corrective Actions (C)**		**Verification Procedures (K)**		**Monitoring Procedures (K)**		**Records Accurate/ Maintained (K) Records Format Signed/Dated Firm's Name (O)**	**Overall Code**
		✓/x	**Code**	**✓/x**	**Code**	**✓/x**	**Code**	**✓/x**	**Code**
	(a) Receiving								
	(b) Shellstock Storage								
	(c) Processing								
	(d) Shucked Meat Storage								
	(e) Other Critical Limits								
5.	Approved Source Control Failure								C

	Additional Model Ordinance Requirements	Citation	✓/x	Code
17.	Plants and Grounds	.03A		
18.	Plumbing and related facilities	.03B		
19.	Utilities	.03C		
20.	Insects and vermin control	.03D		
21.	Disposal of other waste	.03E		
22.	Equipment construction (non-food contact surfaces)	.03F		
23.	Cleaning non-food contact surfaces	.03G		
24.	Shellfish storage and handling	.03H		
25.	Heat shock	.03I		
26.	Personnel	03J		
27.	Supervision	.03K		
28.	Transportation (To include only the person shipping)	IX.05		K
29.	Labeling and Tagging (Other than receiving)	X.05, .06		S (K/O)
30.	Shipping Documents and Records	X.07		K

Dealer's Signature	Inspector's Signature

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.03 Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)

A principal objective of the ICSSL is to provide a mechanism for statehealth officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable sanitation criteria. This is achieved through criteria and procedures to allow a producing or receiving state to "certify" that the product from a specific dealer has been grown, harvested, transported, processed, or shipped in compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). Dealer certification depends on maintaining acceptable operational and sanitary conditions. This determination is based on nationally uniform inspections by standardized inspectors.

State health officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable NSSP MO sanitation requirements pertaining to the type of operation involved.

The NSSP MO requires that dealers obtain certification from the Authority prior to shipping shellfish in interstate commerce. Only those shellfish dealers who meet the NSSP MO requirements are eligible to be listed in FDA's monthly publication of the ICSSL. A unique certification number that is used to mark his product identifies each dealer.

Use of the Interstate Shellfish Dealer's Certificate (FDA Form 3038)

The Interstate Shellfish Dealer's certificate, FDA Form 3038, is used by the Authority to place a dealer on the ICSSL, to report changes to a certificate, and to remove a dealer from the ICSSL. The certificate allows FDA to collect the necessary information to list certified dealers in the ICSSL. Dealers should be informed by the state officer of the probable date their names will appear on the ICSSL. Dealers should be advised against making interstate shipments prior to that date. If shipments need to be made before the appearance of the shipper's name on the ICSSL, the Authority in the dealer's state must notify the appropriate agency in each of the receiving states and the FDA regional and headquarters offices.

When the Authority cancels a dealer certification, the appropriate FDA Region or District Office must be notified and a completed Form FDA 3038 must be mailed to FDA. When a certificate is renewed, the certificate must be sent to FDA. A certificate will be withdrawn automatically from the ICSSL on the date of expiration unless FDA has received the new certificate.

Instructions For Completing the Interstate Shellfish Dealer's Certificate (FDA Form 3038)

The original copy, or Part 1, of the Shellfish Dealer's Certificate is mailed to FDA, Division of Cooperative Programs, Shellfish Safety Team, HFS-628, 5100 Paint Branch Parkway, College Park, Maryland 20740; Part 2 is mailed to FDA Regional Shellfish Specialist; and, Part 3 is retained by the state shellfish control Authority. The original certificate with the appropriate signatures shall be mailed not later than the first of the month for publication in the ICSSL.

To input information check the applicable box.

Section I - Completed by State Shellfish Certification Agency

1. **Shellfish Dealer/Shipper:** Name, Address (including Street, Number, City or Town) ZIP, Telephone
2. **Certification:**

   a) **Certificate Number** - Unique number assigned to each certified shellfish dealer.
   b) **Date Certified** - Date the dealer was certified as meeting the NSSP criteria.
   c) **State** - Two letter State code.
   d) **Expiration Date** - Date the certificate expires.
   e) **Category Symbol** - Two letter code designating dealer process (*i.e. DP, SP, RP, SS, RS*).

3. **Date of On-Site Inspection:** Date the plant was inspected for certification.
4. **Standardized State Shellfish Plant Inspector:** Print the name of the inspector who conducted the on-site inspection.
5. **Expiration Date of Inspector's Certificate of Standardization:** Print the expiration date that appears on the Inspector's certificate.
6. **Cancellation Date:** Date the firm has been either decertified or recommended for de-listing.
7. **Reason for Cancellation:** Check applicable box; Other denotes voluntary or seasonal suspension of activities.
8.

   a) **State Shellfish Certification Officer:** Printed name of official to authenticate information.

b) **Signature:** Official's signature.
In the case that a state has only one Standardized State Shellfish Plant Inspector, sign this block.

c) **Date Certificate sent to FDA:** Self-explanatory.

Section II - Completed by Division of Cooperative Programs - FDA

9. **Date Certificate Received:** Date the signed original Form FDA 3038 is received by FDA.
10. **Date Certificate Published:** Date when the certified dealer's name is scheduled for publication on the ICSSL.

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.04 Shellstock Tagging

Shellstock tagging has a very direct role in public health protection. In the event of a shellfish related illness, tags are a tool, which, used in concert with records, should provide for trace ability of live shellstock from the final consumer back through every middle man, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and ultimately, if possible, the individual person who harvested the shellstock.

When an outbreak of disease attributable to shellfish occurs, health departments and other appropriate state and federal agencies must be able to determine the source of shellfish contamination to prevent any further outbreaks from this source. This can be done most effectively by using the records kept by the shellfish harvesters and dealers to trace a shellfish shipment, through all the various dealers who have handled it, back to its point of origin. Shellstock tags are the first important records concerning the origin of shellfish.

Harvesters must provide information necessary to create a record of the origin, quantity, and date of harvest, which can be used to trace a lot of questionable shellstock back to its source or sources. Investigation of disease outbreaks can be severely hindered if the source of the shellfish cannot be readily identified. Inability to identify the source can result in shellstock from the unacceptable source continuing to be used and continuing to cause illness. Health authorities may be forced to close a safe growing area, to ban a safe shellstock shipment or to seize a safe lot of shellstock as a public health precaution if the source of contaminated shellfish cannot be accurately and rapidly determined.

Maintaining adequate records is considered by some industry members to be a burden. This has resulted in various unacceptable practices being encountered by health officials, including no written records of purchase, undated shellstock shippers tags maintained in an unordered manner, new shipping tags being placed on a lot of shellstock without records to correlate the original identity of the lot with the new identity, and shellfish on the premises with no tags. Although these dealers often have "records" in the most general sense, these records are not in the form that meets the intent of the NSSP certification requirement to provide trace ability on a lot-by-lot basis. As a result, follow-up investigations of disease outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. For more information concerning dealer certification, see the NSSP Guidance Document: *Chapter III. 03: Dealer Certification and the Interstate Certified Shellfish Shippers List.*

An example where the failure to maintain adequate records was identified as one of the principal contributing factors to a series of continuing shellfish associated disease outbreaks occurred in 1981 and 1982. The outbreaks continued for several months and affected thousands of people. An investigation by the states involved and FDA revealed that some states were unable to enforce the record keeping and tagging requirements of the NSSP. FDA found in one state that approximately one-third of the certified dealers inspected failed to maintain adequate records. State officials realized that an improved tagging, labeling or manifest system was needed to track shellfish in the marketplace back to the distributor and to the harvester.

When a lot of shellstock is sold in bulk (e.g. by the truckload without being placed in containers), the harvester or dealer must provide a transaction record prior to shipment. If the transaction record is generated by the harvester, the record must contain information identical to that required on the harvester’s tags and must also include the name of the consignee. If the transaction record is generated by the dealer, the record must contain information identical to that required on dealer’s tags and must include the name of the consignee.

The NSSP recognizes two types of shellstock tags: harvester tags and dealer tags. Many of the requirements are the same for both tag types. There are some additional requirements for dealer tags when the product has been wet stored or depurated. Transaction records which provide the same information as the harvester’s or dealer’s tag may be used in lieu of tags for lot of shellstock sale and lot of shellstock shipment.

Shellstock harvest location needs to be consistently defined on all tags. The tags should provide the most precise

identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellstock were harvested in the designated growing area within the state as assigned by the Authority of the producer state. If harvest 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).

Each harvester or aquaculturist and each dealer must affix an approved, durable, waterproof tag, containing all the information required by the NSSP Model Ordinance, to each container of shellstock. Minimal required tag size is 2 5/8 by 5 1/4 inches (6.7 by 13.3 cm). Example tags are provided in Attachment 1. The harvester's tags must be in place while the shellstock is being transported to the dealer unless the harvest has occurred at more than one harvest location or aquaculture site; then each container must be tagged at the harvest location or aquaculture site. In certain situations, the truck may be considered the container for transport of bulk loads of shellstock from the growing area to the dealer. For dealers, tagging must be done prior to shipment. When the dealer is also the harvester, the dealer's tag may also be used as the harvester's tag.

HARVESTER TAG REQUIREMENTS

Information on the harvester's tags must be legible, indelible and arranged in the following specific order:

- A place may be provided where the dealer's name, address and certification number as assigned by the Authority may be added;
- The harvester's identification number as assigned by the Authority;
- The date of harvesting;
- The most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellfish were harvested and the designated growing area with that state as assigned by the Authority of the producer state. 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);
- Type and quantity of shellfish;
- The following statement, in bold capitalized type on each bag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS." and
- All shellstock intended for raw consumption shall include a consumer advisory and follow the Time-Temperature Matrix Control. The following statement, from section 3-603.11 of the 2001 Food Code, or an equivalent statement shall be included on all shellstock: “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions”

DEALER TAG REQUIREMENTS

Dealer tagging is required upon harvest or receipt from a harvester, processing and packaging of shellstock by the dealer, or sale and shipment of shellstock by the dealer to other dealers for subsequent sale, processing or additional packaging. The information on the dealer’s tags must be legible, indelible and arranged in the following specific order:

- The dealer's name, address, and certification number as assigned by the Authority;
- The original shellstock shipper's certification number;
- The date of harvesting;
- The most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellfish were harvested and the designated growing area with that state as assigned by the Authority of the producer state. 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);
- Type and quantity of shellstock;
- The following statement, in bold capitalized type, that “THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS." and
- All shellstock intended for raw consumption shall include a consumer advisory and follow the Time-Temperature Matrix Control. The following statement, from section 3-603.11 of the 2001 Food Code, or an equivalent statement shall be included on all shellstock: “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions.”

When both the dealer and harvester tags appear on the container, the dealer tag is not required to list the date of harvesting, and the harvest location or the aquaculture site. A harvester's tag must be in place while the shellstock is being transported to a dealer. The dealer must keep the harvester's tag in place until the container of shellstock is shipped or until it is broken open for washing, grading and packing. Once the container is broken open, the dealer must:

- keep the harvester tag for 90 days;
- keep track of the growing area and date of harvest of all shellstock; and
- maintain the lot identity of all shellstock in an intermediate stage.

Except for shellstock that originated from a depuration-processor, shellstock transported across state lines and placed in wet storage must include the following information on its shipping tag after removal from wet storage:

- All information required on a dealer's tag as specified above; and
- The statement that "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)"

Lot of shellstock tagging in the washing, packing and staging of shellstock is permissible only when the lot container (i.e., the pallet) is tagged as required in a protocol approved by the Authority. The protocol shall provide for lots of shellstock to be separated and identified to prevent commingling or misidentification. The tag on each lot of shellstock shall contain the following minimum information:

ALL SHELLFISH CONTAINERS IN THIS LOT HAVE THE SAME DATE AND AREA OF HARVEST.

Harvest Date_____

Harvest Area_____

Original Dealer/Shipper #_____

# of units in this lot container_____

The dealer's tag must be put on all containers of shellstock before they are shipped to another dealer or retailer. Prior to shipment, all containers of shellstock must remain easily identified and continue to be separated to prevent commingling or misidentification. The protocol approved by the Authority shall provide for lots of shellstock to be separated and identified so as to prevent commingling or misidentification. The allowable means of identification are:

- A harvester's tag containing the information required above on harvester's tags;
- A dealer's tag containing the information required above on dealers tags; and
- A lot of shellstock tag designed in the manner required above for lot tags.

TAG REQUIREMENTS FOR RELAYING

In relay operations, the method of shellstock identification (tagging, bulk load records, etc.) is left to the discretion of the Authority. When the relay process is conducted using containers, a need exists to develop a container identification system to locate and avoid removal of containers before the natural cleansing process is complete. Once the relay operation is complete, the shellstock is subject to the tagging requirements for harvesters and dealers.

DEPURATION TAG REQUIREMENTS

Shellstock that has been subjected to depuration requires an increased level of control because of the increased potential for contamination. These controls must include packaging and tagging that will serve to help identify the depuration cycle of each harvest lot and to deter illegal commingling of shellstock which has not been depurated with depurated shellstock. The Authority may require the harvester to use special tags or to provide additional information on the tags. At a minimum, the harvester's tags (or transaction records used for bulk shipments) must identify the growing area, provide the harvester's special license number, and specify the harvest date and the quantity of shellstock.

The dealer's (i.e. the depuration processor) tags must, at a minimum, include the following information in a legible and

indelible form:

- The dealer's name and address;
- The dealer's certification number as assigned by the Authority;
- The date of depuration processing;
- The depuration cycle number or lot number;
- 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 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);
- The type and quantity of shellstock;
- The statement, in bold capitalized type, that "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**" and
- All shellstock intended for raw consumption shall include a consumer advisory and follow the Time-Temperature Matrix Control. The following statement, from section 3-603.11 of the 2001 Food Code, or an equivalent statement shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS" "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions."

Attachment 1

In the event of a shellfish related illness, tags are a tool, which, used in concert with records, should provide for trace ability of live shellstock from the final consumer back through every middle man, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and ultimately, if possible, the individual person who harvested the shellstock.

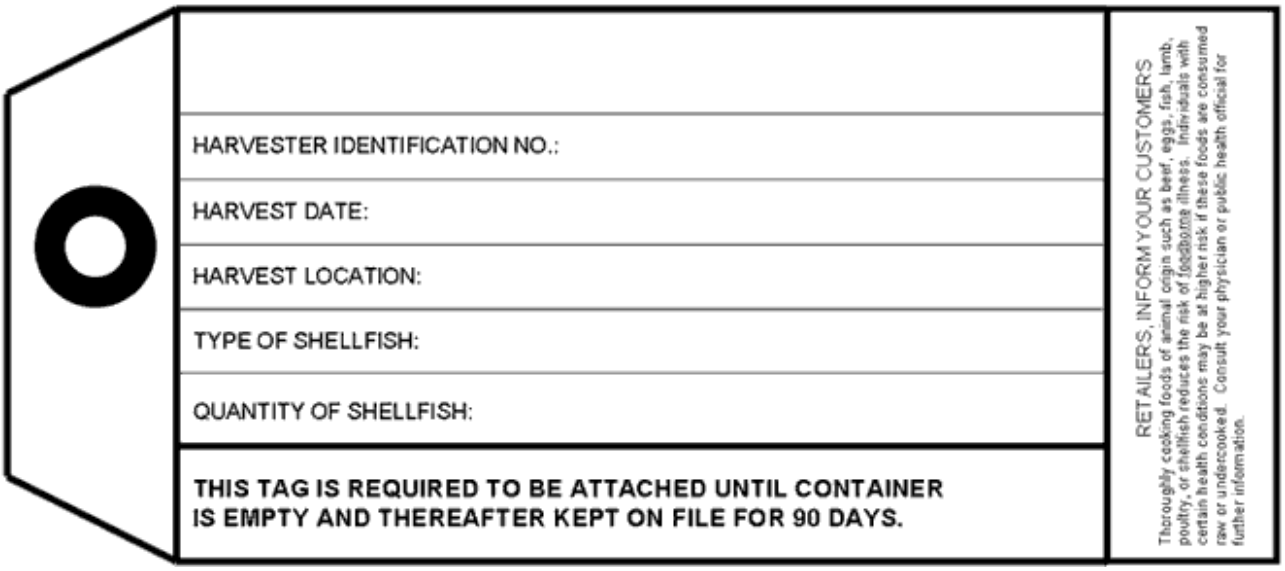
The following options are recommended for inclusion on tags to improve the effectiveness of the NSSP tagging program.

- Include the statement "**Perishable; keep refrigerated**" on the tag in bold print.
- Include the "Date Shipped" on the tag.
- Maintain flexibility in the tagging program to take advantage of evolving materials and technology (e.g. UPC coding)

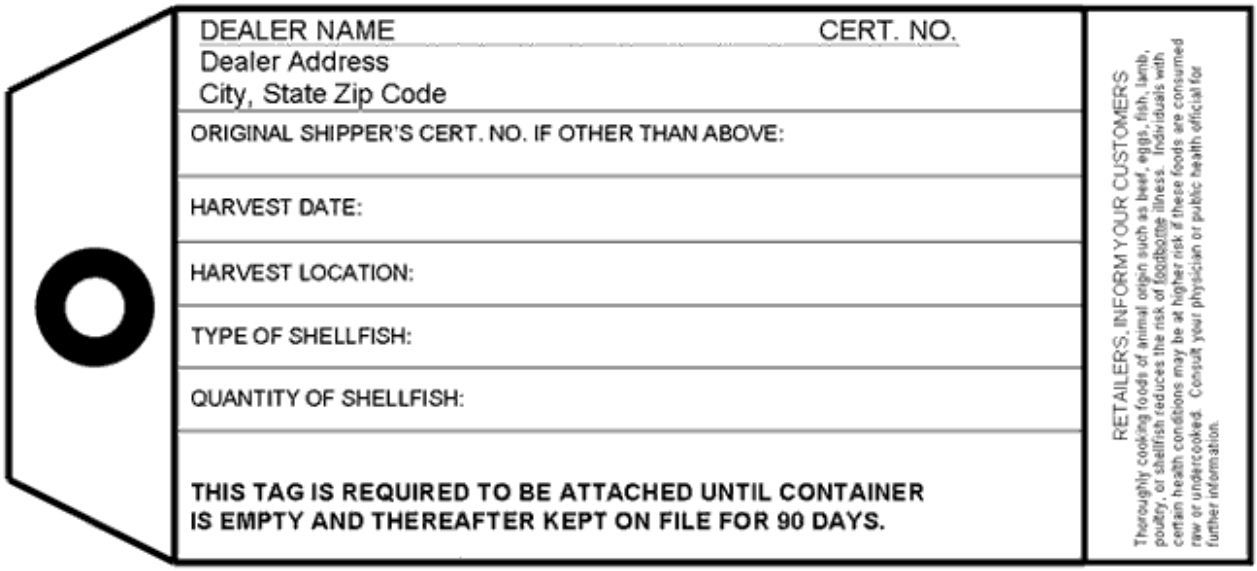
Tag Construction: Durable, waterproof and a minimum size of 2 5/8 inches by 5 1 / 4 inches (6.7 cm by 13.3 cm)

Examples of Shellstock Tags

This tag is an example of a harvester's tag with the minimum NSSP required information in the required order.

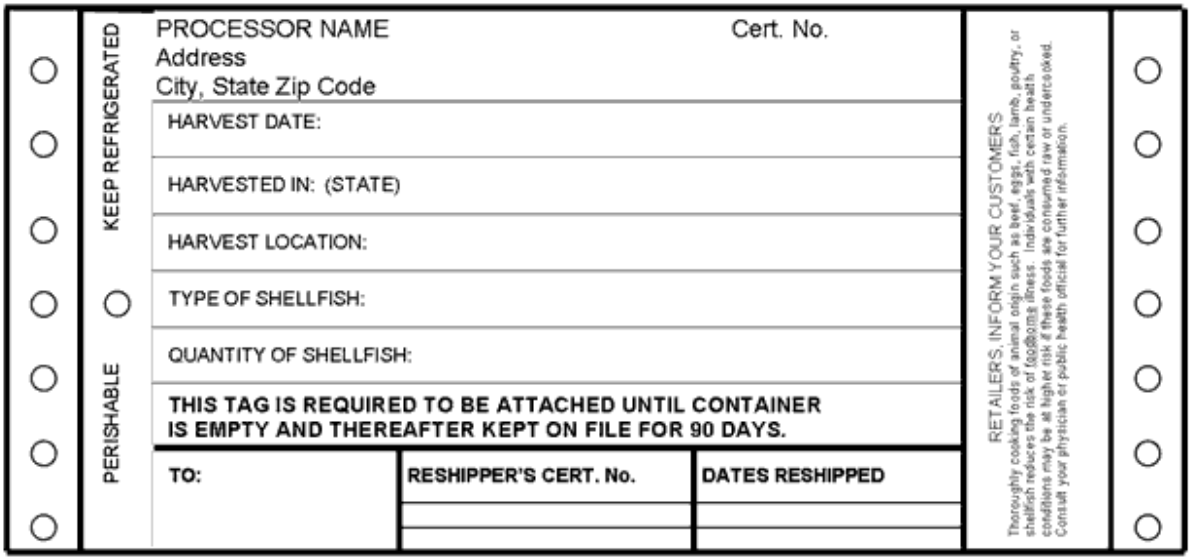


This tag is an example of a dealer's tag with the minimum NSSP required information in the required order.

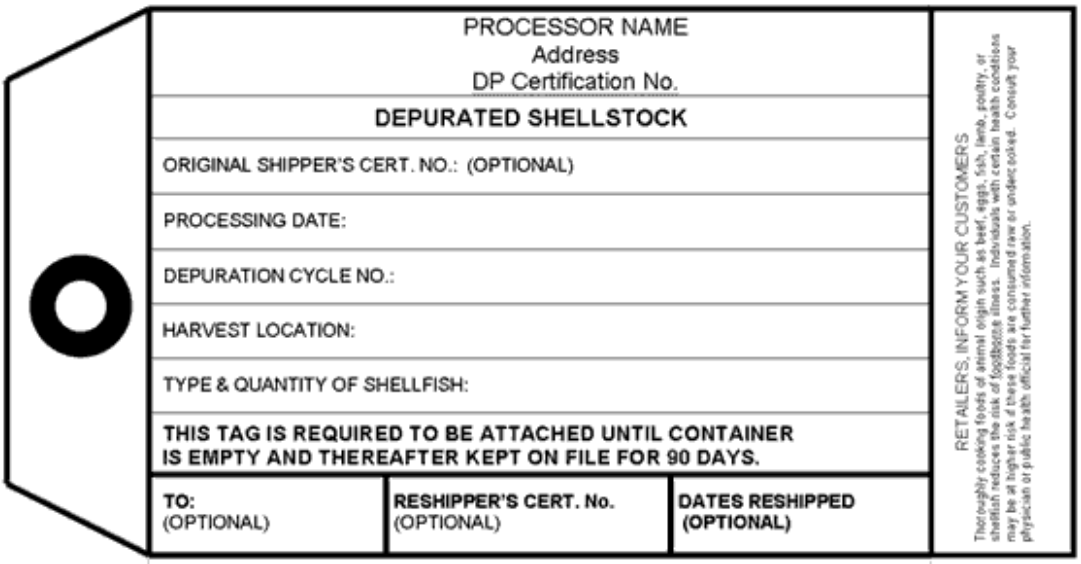


While both of the previous examples contain the minimum required information in the required order, many firms also customize the tags with additional information. Such information might include space for the consignee's address, date shipped, reshipper certification number, date reshipped, and a "Perishable- Keep Refrigerated" statement. Some firms also opt to preprint the types of shellfish with a check-off space. When customizing the tag, the order of the minimum required information cannot be changed.

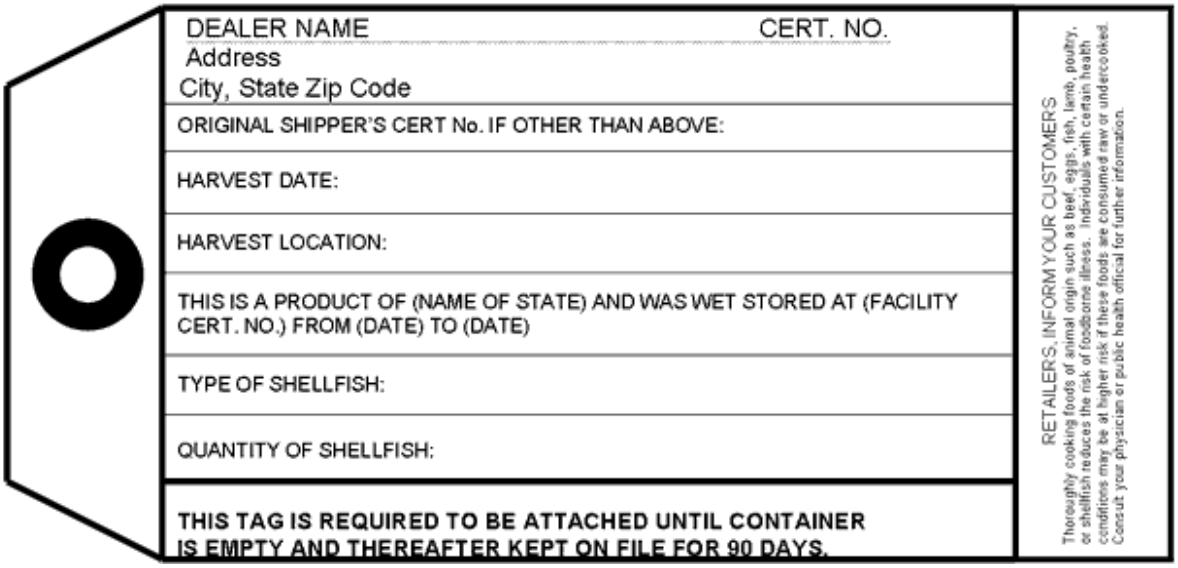
This tag is an example of a dealer tag which meets the NSSP requirements and has been modified to include additional information. It also has the pin feed feature to allow printing on the dot matrix printer.



This tag is an example of a tag for depurated shellstock with the minimum NSSP required information in the required order.



When shellstock is transported interstate and placed in wet storage, special tagging requirements must be met. See the NSSP Model Ordinance for details. This tag is an example of a dealer tag modified for labeling product transported across State lines and subsequently wet stored.



Tags are available through various sources. In some states, the Authority sells the tags which are sequentially numbered for accountability. There are also grower's associations which bulk purchase tags for their members at considerable savings. Individual dealers can also have tags printed at local print shops.

Tyvek is one example of a durable waterproof material commonly used for shellstock tags.

Some states require additional information on tags which exceeds the NSSP requirements. A dealer should verify the receiving state's requirements prior to shipment to that state.

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IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.05 Guidance For a Time-Temperature Evaluation of a Shellfish Implicated Outbreak

Because shellfish are filter feeders, they can concentrate microorganisms, marine biotoxins and poisonous or deleterious substances from the water column when these substances are present in the growing area. In addition, shellfish, like any other food product, can become unfit for human consumption through the introduction of contaminants during handling, storage, transport, distribution and processing. Furthermore, improper handling and storage can contribute to the increase of naturally occurring pathogens to hazardous levels in shellfish meats. The intrinsic risk from illness induced by microorganisms associated with consumption of raw or partially cooked shellfish products compels the shellfish control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. When illness has occurred, the Authority needs to immediately begin an investigation before critical evidence is inadvertently lost or destroyed.

Currently, the NSSP Model Ordinance does not call for any action if illness is limited to only one person. This is appropriate for molluscan shellfish borne illness caused by microorganisms associated with pollution events. However, when naturally occurring marine bacteria such as *Vibrio vulnificus* or *Vibrio parahaemolyticus* are suspected to cause the illness an evaluation of the possibility of time-temperature abuse of the product is critical to understanding how the illness may have been prevented. A time-temperature audit provides information regarding the time-temperature experience of the product implicated as well as the health conditions of any ill persons which may have contributed to their susceptibility to the disease. Although the gathering of this data has been a public health focus for several years, there has been no effort to standardize how or what data are gathered during an illness investigation. When naturally occurring marine bacteria are believed to be the source of the shellfish implicated illness or outbreak, the time-temperature history of the product and the health of the persons may be more relevant than the traditional investigatory focus on tracing the origin of the product back to the shellfish growing area.

For additional information concerning the *Vibrio* organisms, see Watkins and McCarthy (1994) and the NSSP Guidance Documents contained within Chapter IV- Naturally Occurring Pathogens..

Time-Temperature Evaluation of a Shellfish Implicated Outbreak

The Authority should promptly conduct an audit of the time-temperature history of the implicated product in a shellfish disease outbreak to the extent practicable. The Authority should use all records from any measuring devices in conveyances or coolers used to transport the product, or any records of conditions associated with the implicated product as it moved from harvest to consumption. Where necessary, the Authority in the state of shellfish product origin should be contacted to provide assistance in gathering information. The audit must include the retail market or restaurant where the victim bought the shellfish product, the facility of the person who sold the product that the retail market or restaurant, the facilities of all dealers and common carriers who handled the product following its harvest, and the practices and facilities of the person who harvested the shellfish. The audit should include, but should not be limited to, the following points.

In the retail market or restaurant implicated in the shellfish illness outbreak, the Authority should, at a minimum,

Record the ambient temperature in the establishment; observe the time-temperature control in the establishment, i.e. how the product was handled:

Examine the establishment's records for the temperature of the storage device or facility used for the implicated product while at the establishment, or observe and record the temperature of the storage device or facility during the investigation; observe and record the temperature and age of the remaining product at the establishment. The age of the product must be cross checked with transaction records;

Observe the controls to prevent cross contamination of the implicated product; and provide for the immediate sampling and testing for the suspect organism(s) of any remaining product from the retail or food service location implicated in the outbreak.

The Authority should determine if the dealer or person who sold the product to the retail market or the restaurant is on the ICSSL. If the person is not on the ICSSL, the Authority should gather any pertinent information regarding the status of time-temperature controls practiced by this person such as:

- Inspection reports for the person's facility;
- Observed temperature of the person's conveyance used to transport shellfish product; and
- Presence or absence of adequate refrigeration capability in the person's conveyance.

If the dealer is on the ICSSL, the Authority should conduct an inspection of the dealer's facility and records for purposes of gathering data from time-temperature control procedures and practices at that facility including:

- The presence or absence of adequate refrigeration capability of the dealer's conveyance;
- The presence or absence of temperature records for the delivery conveyance;
- The observed temperature and time-temperature control practices on the dealer's loading dock;

The transaction records demonstrating the product's age from the date of harvest of the implicated product; and

- The dealer's observed product rotation practice (i.e., the existence of product of widely differing ages).

For additional information concerning the ICSSL, see the NSSP Guidance Document, Chapter III .03: *Dealer Certification and the Interstate Certified Shellfish Shippers List*.
The Authority should gather data similar to that above from all dealers or common carriers (certified or uncertified) between the point of first receipt from the harvester and the retail market or restaurant.

The Authority should inspect the original dealer's facility (i.e. the point of first receipt from the harvester). If the original dealer's facility is in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum,:

- Determine if there are adequate provisions for product refrigeration;
- Observe temperature and/or records of temperature for the dealer's refrigeration facility;
- Observe general time-temperature control procedures and practices; and
- Observe the temperature and age of shellfish product on-site under receipt from harvesters or under storage.

To the extent practicable, the Authority should gather information concerning the time-temperature control capability of the harvester of record for the implicated product. If the product was harvested in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum, determine:

- If adequate shading was provided for harvested shellfish product;
- The existence of mechanical refrigeration for storage of harvested product; and
- If records of prior enforcement actions against the harvester exist.

In cases where *Vibrio*
species are the suspected organisms causing the illness or outbreak, the Authority should investigate the health status of the victim(s) to determine:

- If there were underlying health problems which may have contributed to the occurrence of the illness(es);
- If the victim(s) was aware of his underlying condition;
- If the victim(s) was aware of his high-risk status;
- If the victim(s) had been advised not to consume raw shellfish; and
- If the establishment had posted point-of-sale information for high-risk consumers.

References

Watkins, W. and S. McCarthy. 1994. *Proceedings of the 1994 Vibrio vulnificus Workshop*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-400), Shellfish Sanitation Branch, 200 C Street, SW, Washington, D.C. 175 pages.

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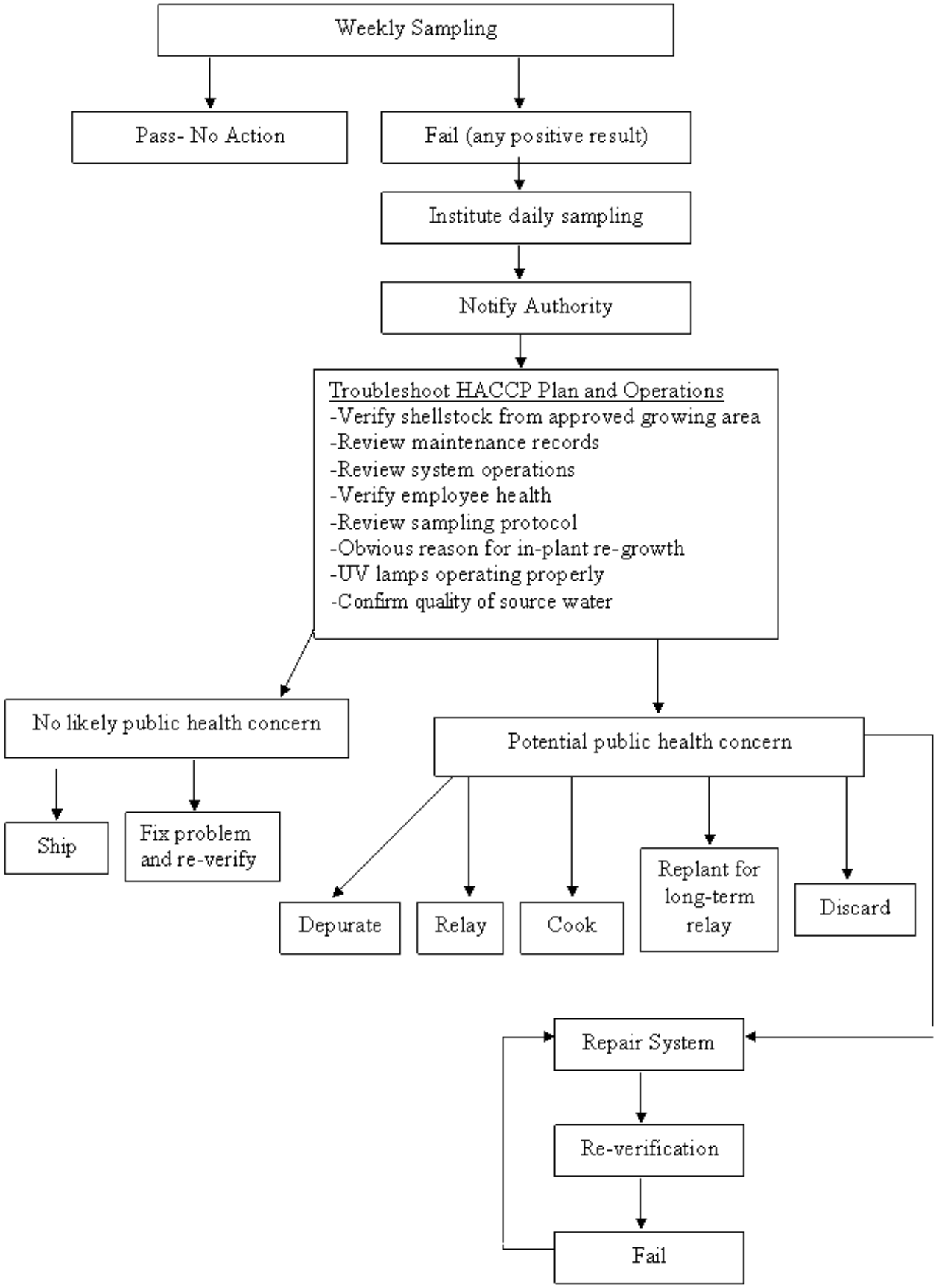
IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, Distribution

.06 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body



Description: Flow chart showing the protocol for addressing positive coliform results in artificial wet storage water bodies.

Collect weekly water samples.

If the water sample is negative for coliforms, no action is required.

If the water sample is positive for coliforms, institute daily sampling, notify the authority, and troubleshoot the HACCP Plan and operations by (1) Verifying that shellstock is from an approved growing area, (2) Reviewing maintenance records, (3) Reviewing system operations, (4) Verifying employee health, (5) Reviewing the sampling protocol, (6) Looking for an obvious reason for in-plant re-growth, (7) Determining that UV lamps are operating properly, and (8) Confirming the quality of the source water.

If no likely public health concern is found after troubleshooting, the product may be shipped and the problem causing the positive coliform result shall be fixed. Once fixed, re-verify through sampling that the system's water quality is acceptable.

If a potential public health concern is found after troubleshooting, the product may be depurated, relayed, cooked, replanted for long-term relay, or discarded and the problem causing the positive coliform result shall be repaired. Once repaired, re-verify through sampling that the system's water quality is acceptable. If the system fails after re-verification, attempts to repair the system must be made until the re-verification demonstrates acceptable water quality.

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IV. Guidance Documents
Chapter IV. Naturally Occurring Pathogens

(.01 Vibrio Risk Management for Oysters | .02 Vibrio vulnificus Management Plan | .03 Vibrio parahaemolyticus Interim Control Plan | .04 Validation/Verification Interim Guidance)

.01 *Vibrio* Risk Management for Oysters

Background

Current information concerning *Vibrio vulnificus*, which is responsible for several shellfish associated illnesses and deaths each year can be found in Watkins and McCarthy (1994).

A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio* (Bonner, 1983; Blake *et al.*,1979; Morris, 1985; Joseph *et al.*,1982; Roderick, 1982). The *Vibrios* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters (Joseph *et al*, 1982: Spira, 1984; Colwell 1984; Bachman, 1983). Among the marine *Vibrios* classified as pathogenic are strains of non-01 *Vibrio cholerae, V. parahaemolyticus,* and *V. vulnificus* (Bachman, 1983; Desmarchelier, 1984; Blake, 1980). All three species have been recovered from coastal waters in the United States and other parts of the world (Joseph, 1982; Colwell, 1984; Blake, 1980; DePoala, 1981; Madden, 1982; Davey, 1982; Oliver, 1983; Tamplin, 1982; NIH, 1984). These and other *Vibrios* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform (Bonner, 1983; Joseph, 1982; Spira, 1984).

In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (Bonner, 1983; Morris, 1985; Joseph, 1982). *V. parahaemolyticus* and non-01 *V. cholerae*
are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (Bonner, 1983; Blake, 1979; Morris, 1985; Joseph, 1982; Baross and Liston, 1970; Morris, 1981). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteria, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (Bonner *et al.*, 1983; Tacket, 1984). Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafood, especially raw oysters (Bonner *et al.*, 1983; Blake, 1979; Morris, 1985; Rodrick, 1982; Bachman, 1983; Blake, 1980; Oliver, 1983; NIH, 1984; Tacket, 1984; Oliver 1982; FDA, 1985). Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (Blake, 1983 and 1984).

.02 *Vibrio vulnificus* Management Plan

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus*
subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces reviewed the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus*
septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in California, Florida, Louisiana and Texas due to 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 0.306/million. The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and

epidemiologists from California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2002 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas), the following will apply:

(a) Illness cases counted are those reported by California, Florida, Louisiana and Texas;

(b) Each illness case is recorded under the state that reports it;

(c) Each case is not counted more than once; and

(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{number of cases}}{\text{population}}$$

The V.v. subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus*
Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (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. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the Committee, leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

- increased educational efforts,
- limited harvest restriction,
- reduction in time from harvest to refrigeration,
- phased-in post-harvest treatment requirements, or
- other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the Year 2003 or 2004 survey results to determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from *Vv*; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.

(i) The Consumer Education Program will focus educational efforts in California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 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 assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 25 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of a list of issues relating to public health, various technologies including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.

(h) Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 - 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.

.03 *Vibrio parahaemolyticus* Interim Control Plan

A. Contingency Plan.

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus*
illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.

(2) The plan should define the administrative procedures and resources necessary to accomplish the following:

(a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;

(b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;

(c) Close affected oyster growing areas;

(d) Prevent harvesting of affected oysters;

(e) Provide for oyster recall if an oyster growing area is closed as a result of illness;

(f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that oysters not be consumed raw during periods historically affected by *V. parahaemolyticus*.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

(a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,

(b) Shucking and labeling "for cooking only"; or,

(c) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b); or,

(d) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.* *

(2) In all areas where a confirmed *V .parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for V. parahaemolyticus growth and/or periods historically associated with illness as determined by the Authority Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.*

(3) In order to determine the number of samples that would be appropriate for *V. parahaemolyticus* monitoring, the following factors should be considered:

(a) The size of the growing area;

(b) The amount of oyster shellstock typically harvested from the area;

(c) The sensitivity of the methodology.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+ strains, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing *V. parahaemolyticus* illnesses.

C. Closed Status of Growing Area Based On Monitoring Results.

(1) The growing area as defined in accordance with A.(2)(a) should be placed in the closed status for oyster harvest, except as allowed under A.(3), if a total of 5 or more pathogenic (*tdh*+) *V. parahaemolyticus* colony-forming units (CFU) per 0.1 gram, confirmed by at least one pathogenic (*tdh*+) *V. parahaemolyticus* CFU per 0.1 gram by replicate analysis, are found for any oyster sample from the harvest area. If any sample shows total (*tlh*+) *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic *V. parahaemolyticus*. Should any of these additional samples show 5 or more pathogenic *V. parahaemolyticus* CFU per 0.1 gram, confirmed by at least one pathogenic *V. parahaemolyticus* by replicate analysis, the area will be placed in the closed status for oyster harvest, except as allowed under A.(3).

(2) The closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis. If any sample shows total *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic (*tdh*+) and total (*tlh*+) *V. parahaemolyticus*. Should those samples show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis, the growing area should be opened.

(3) The analysis leading to a decision to return a growing area to the open status should be adequately documented.

D. Illness Outbreak.

(1) When a growing area is implicated in a *V. parahaemolyticus* illness outbreak, the Authority shall follow the procedures prescribed in Chapter II Section@.01A through E. If a growing area is closed due to an illness outbreak, the closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no pathogenic (*tdh*+) *V. parahaemolyticus* CFU in replicate 0.1 gram portions of oyster meat and less than 5,000 total (*tlh*+) *V. parahaemolyticus* CFU per gram.

(2) If additional confirmed *V. parahaemolyticus*
illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area should immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of *V. parahaemolyticus*, or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority should maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of *V. parahaemolyticus* in the oyster 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.

F. Risk Communication

If the waters of a state have been confirmed as the original source of oysters associated with two or more *Vibrio parahaemolyticus*

illnesses, the Authority should educate all licensed harvesters and shellstock dealers concerning the public health and other advantages of effective cooling of harvested shellstock and encourage that shellstock intended for raw consumption that will be post-harvest processed in accordance with Chapter XVI. A. (1) (b) be handled in a manner that restricts the growth of *Vibrio parahaemolyticus*. The education package used by the Authority should include an illustration of how effective controls will reduce the risk of *Vibrio parahaemolyticus* illness and should be targeted to the harvest practices of the region.

* Direct plating procedure by Cook, D.W. et al, 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA, and the ISSC; gene probe methods for total (*tlh*+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. TRS. Appl. Microbiol.28:66-70) and virulent (tdh+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512).

[References for the direct plating, digoxygenin DNA probe method and the enrichment PCR procedure adapted to the VpICP can be provided.]

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.04 Post Harvest Processing (PHP) Validation/Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 10,000 per gram or greater as described below for initial load testing.
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- Microbiological testing for initial levels will be by a 3-tube MPN using appropriate dilutions (10^{-1} to 10^{-6}).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish per tube based upon the table below.
- The numerical value of the endpoint criteria should be less than 30 per gram and achieves a minimum 3.52 log reduction.
- For the process to be validated, no more than three samples out of 30 may fail. Depending upon the initial load, failure of a single sample is determined according to the table below.

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

For example, if the AGM equals 50,000, then use the second row because 37,174 ≤50,000 < 59,994. The second row tells to inoculate with .01 grams of the original oyster homogenate in each tube and the test fails if more than one of the five tubes is positive.

Equipment Validation

Used to ensure that each unit of equipment will deliver the validated process. May be accomplished using either of two methods:

- The process described under "Revalidation," below;
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.

Revalidation

Used when verification sampling indicates a failure in the process.

Option 1:

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, revalidation will fail.

Option 2:

Repeat full validation when initial levels of 100,000 per gram can't be achieved.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis.

Verification

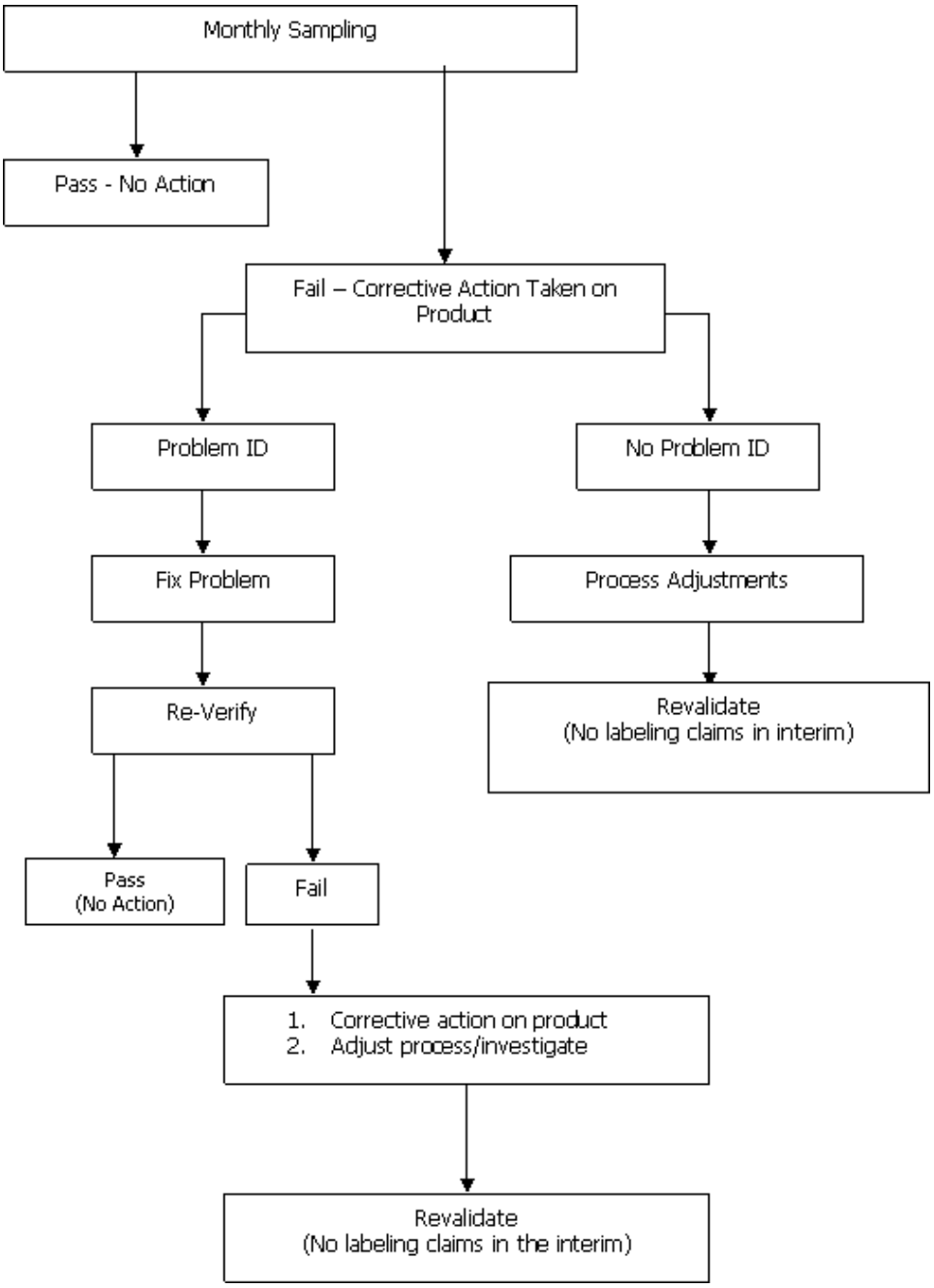
Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob

Blodgett.

- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

Verification Sampling Protocol Decision Tree



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Description: Flow chart showing the post harvest processing verification sampling protocol and decision making process.

Collect monthly shellfish meat samples for process verification.

If the monthly samples pass, no action is required.

If the monthly samples fail, take the following measures; (1) Identify the problem, (2) Fix the problem, (3) re-verify the process by sampling. If the re-verification samples pass, no further action is required. If the re-verification samples fail, then; (1) Corrective action must be taken on the product, (2) The process must be investigated, (3) Any problems identified must be adjusted, and (4) The process shall be revalidated. No labeling claims can be made during the interim revalidation process.

If the monthly samples fail and no problem can be identified then; (1) Adjustments shall be made to the process, and (2) The process shall be revalidated. No labeling claims can be made during the interim revalidation process.

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

V. Suggested Forms

(Shellfish Harvest Record | Shellfish Harvest / Purchase Record | Shellfish Sales Record | Export Health Certificate)

Shellfish Harvest Record

Certificate No: _____

Harvest Area	Harvest Date	Species	Quantity

Page _____

SHELLFISH HARVEST / PURCHASE RECORD

Cert. No.	Quantity	Species	Harvest Area	Harvest Date	Purchase Date	Harvester Cert. #

Page_____

SHELLFISH SALES RECORD

Date Sold	Sold To	Quantity	Species	Harvest Date	Harvest Area	Harvester Cert. #

Page _____

EXPORT HEALTH CERTIFICATE

STATE OF _____

ADDRESS _____

STATEMENT OF LICENSURE AND CERTIFICATION

Exported By: Certificate # _____ Consigned To:

License (*Check one*):
Shellstock Shipper ☐ Shucker-Packer ☐

Shipped Via:	Port of Embarkation:	Port of Debarkation:		
Identifying Marks:	Total # of Containers:	Total Marked Weight:		
Product:	Class, Type, Style:	Count:	Lot Weight:	Labels/Brand:

The above-named exporter hereby certifies through its authorized agent that this product was harvested from the following harvest area or areas:

Agent's Signature: _____ Date: _____ ___

The _____ State Department of Health routinely inspects shellfish operations and shellfish harvest areas to determine their compliance with state shellfish sanitation laws and the requirements of the National Shellfish Sanitation Program. The above named exporter is currently licensed and certified by the Department as indicated above. The above named harvest area is currently certified by the Department of Health as approved for harvest.

By:_____ Date:_____

(Appropriate state official/title)

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

VI. NSSP Policy Setting Documents

(Department of Health and Human Services FDA Policy Statement Consumption of Raw Molluscan Shellfish | ISSC Policy Statement Consumption of Raw Molluscan Shellfish | Interstate Shellfish Sanitation Conference Resolution 97 - 01)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Washington DC 20204

POLICY STATEMENT

CONSUMPTION OF RAW MOLLUSCAN SHELLFISH

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. However, molluscan shellfish are often consumer raw or partially cooked. Therefore, some cases of illness are inevitable from consuming them in this way.

The majority of illnesses that occur from the consumption of raw molluscan shellfish are the result of pollution. They are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

Certain medically compromised individuals are at increased risk from common marine vibrio bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, the best advice for medically compromised individuals is not to eat raw molluscan shellfish. At most risk are those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer; diabetes; and kidney disease. Those uncertain of their health should seek the advice of their physician.

To reduce the risk of illnesses associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. FDA is committed to the NSSP partnership as providing the best means of making molluscan shellfish as safe as possible. States annually spend millions of dollars to monitor waters to assure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. FDA has also increased its cooperative efforts with State and Federal law enforcement officers to prevent illegal harvesting from closed waters, a practice that probably leads to most shellfish illnesses. Adhering to NSSP controls will help to keep risks to a minimum.

ISSC POLICY STATEMENT

CONSUMPTION OF RAW MOLLUSCAN SHELLFISH

Introduction

The Interstate Shellfish Sanitation Conference (ISSC) was organized in 1982 to address the safety and sanitation of molluscan shellfish (oysters, mussels, clams, and whole and roe-on scallops. The ISSC has a formal Memorandum of Understand with the U.S. Food and Drug Administration (FDA) to promote shellfish sanitation through the National Shellfish Sanitation Program (NSSP), a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. The ISSC recognizes the success of this Program, which is founded on the premise that through appropriate controls, molluscan shellfish can be consumed raw by most people with reasonable risk. The ISSC remains committed to that premise.

Policy Statement

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. Consumption of raw shellfish, as with consumption of other types of raw animal-derived protein foods, increases the risk of illness. The majority of illnesses related to the consumption of raw molluscan shellfish are a result of pollution. These illnesses are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

To reduce the potential risk associated with consumption of raw molluscan shellfish, the FDA in cooperation with the States administers the National Shellfish Sanitation Program. States monitor shellfish growing waters to determine that they are safe before harvesting is permitted. The FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. The FDA has also increased its cooperative efforts with State and Federal law enforcement officers to prevent illegal harvesting from closed waters and ensures that all shellfish in interstate commerce are properly labeled or has a tag identifying the harvest area and shipper. The tagging and labeling requirement of the NSSP is designed to ensure that only shellfish from approved growing waters reach interstate commerce. Adherence to NSSP controls minimizes risks. Recognizing the NSSP partnership provides the best possible means of ensuring that molluscan shellfish are safe, the FDA, the States, and the ISSC are committed to continued support of the Program.

Certain medically compromised individuals are at increased risk from common marine bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, total abstinence from raw molluscan shellfish is the best advice for medically compromised individuals. Those at greatest risk include, but are not restricted to those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer, diabetes and kidney disease. Those uncertain of their health status should seek the advice of their physician.

INTERSTATE SHELLFISH SANITATION CONFERENCE

RESOLUTION 97 - 01

SUBJECT: Post-Harvest Treatment Processing

TEXT OF RESOLUTION:

WHEREAS, the effect of naturally occurring *Vibrio vulnificus* in raw shellstock oysters has been a problem that has caused considerable concern for the Interstate Shellfish Sanitation Conference (ISSC), the FDA, State public health regulators, the molluscan shellfish industry and the general public; and

WHEREAS,
the ISSC had previously adopted a position (stated in a resolution by the 1991 conference) that "in absence of definitive information regarding *Vibrio vulnificus*, the only realistic approach is education of the high risk groups"; and

WHEREAS,
the ISSC also had recommended that "states and industry take immediate steps to institute harvesting, processing and handling procedures which will eliminate illnesses attributable to *Vibrio vulnificus*"; and

WHEREAS,
the State public health regulators and shellfish control agencies are awaiting guidance from the ISSC and FDA regarding Post-Harvest Treatment (PHT) processes; therefore

BE IT RESOLVED,
that the ISSC encourages the development and SSCA approval of PHT processes which are able to consistently and reliably reduce *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish.

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

VII. Shellfish Federal Regulations

Part 7 - Enforcement Policy

Subpart A - General Provisions

Subpart B - [Reserved]

Subpart C- Recalls
(Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities

Subpart D - [Reserved]

Subpart E - Criminal Violations

Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); secs. 301, 351, 354-360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b-263n, 264).

Source: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite*
means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent*
means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product*
means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall*
means a firm§s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.

(h) *Correction*
means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm*
means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal*
means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery*
means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) *Recall strategy*
means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification*
means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale. (Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the

applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:
(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertak-ing under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B - [Reserved]

Subpart C - Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well being from products that present a risk of injury or gross deception or are otherwise defective. This section and § 7.41 through 7.59 recognize the voluntary nature of recall by providing guidelines so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

§ 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) *General*.

(1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product§s deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy*. A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall*. Depending on the product§s degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning*. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling

firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks*. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-30-5), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A-100 percent of the total number of consignees to be contacted;

(ii) Level B-Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C-10 percent of the total number of consignees to be contacted;

(iv) Level D-2 percent of the total number of consignees to be contacted; or

(v) Level E-No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981]

§ 7.45 Food and Drug Administration requested recall.

(a) The Commissioner of Food and Drugs or his designee under § 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency§s determination of the need for the recall or how the recall should be conducted.

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is

subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the time span of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm§s recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm§s strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm§s action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General*. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) *Implementation*. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents*.

(1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient*. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm§s product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were affected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administra-tion).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

PART 101 - FOOD LABELING

Subpart A - General Provisions

§ 101.1 Principal display panel of package form food.
§ 101.2 Information panel of package form food.
§ 101.3 Identity labeling of food in packaged form.
§ 101.4 Food; designation of ingredients.
§ 101.5 Food; name and place of business of manufacturer, packer, or distributor.
§ 101.8 Labeling of food with number of servings.
§ 101.9 Nutrition labeling of food.
§ 101.10 Nutrition labeling of restaurant foods.
§ 101.11 Saccharin and its salts; retail establishment notice.
§ 101.12 Reference amounts customarily consumed per eating occasion.
§ 101.13 Nutrient content claims-general principles.
§ 101.14 Health claims: general requirements.
§ 101.15 Food; prominence of required statements.
§ 101.17 Food labeling warning and notice statements.
§ 101.18 Misbranding of food.

Subpart B - Specific Food Labeling Requirements

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.
§ 101.25 [Removed]
§ 101.29 Labeling of kosher and kosher-style foods.
§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.
§ 101.33 Label declaration of D-erythro-ascorbic acid when it is an ingredient of a fabricated food.
§ 101.36 Nutrition labeling of dietary supplements of vitamins and minerals.

Subpart C - Specific Nutrition Labeling Requirements and Guidelines

§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.
§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.
§ 101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.
§ 101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993]

Subpart D - Specific Requirements for Nutrient Content Claims

§ 101.54 Nutrient content claims for "good source," "high," and "more."
§ 101.56 Nutrient content claims for "light" or "lite."
§ 101.60 Nutrient content claims for the calorie content of foods.
§ 101.61 Nutrient content claims for the sodium content of foods.
§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.
§ 101.65 Implied nutrient content claims and related label statements.
§ 101.69 Petitions for nutrient content claims.

Subpart E - Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.
§ 101.71 Health claims: claims not authorized.
§ 101.72 Health claims: calcium and osteoporosis.
§ 101.73 Health claims: dietary lipids and cancer.
§ 101.74 Health claims: sodium and hypertension.
§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.
§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.
§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.
§ 101.78 Health claims: fruits and vegetables and cancer.

Subpart F - Specific Requirements for Descriptive Claims that are neither Nutrient Content Claims nor Health Claims

§ 101.95 "Fresh," "freshly frozen," "fresh frozen," "frozen fresh."
§ 101.100 Food; exemptions from labeling.
§ 101.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
§ 101.105 Declaration of net quantity of contents when exempt.
§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

Subpart A - General Provisions

§ 101.1 Principal display panel of package form food.

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: Provided, however, that where such container presents an obvious "principal display panel"such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 101.2 Information panel of package form food.

(a) The term "information panel"as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.17, 101.25 and Part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 101.105(h) (1) and (2) and 101.15.

(1) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 10 square inches.

(iii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than three sixty-fourths inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a single "obvious principal display panel"as this term is defined in § 101.1 and has no other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(4)(i) Soft drinks packaged in bottles manufactured before October 31, 1975 shall be exempt from the requirements prescribed by this section to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the size and placement requirements of this section.

(ii) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by this section if all of the following conditions are met:

(a) If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket, or foil label, or is packaged in a non-reusable bottle bearing a label lithographed onto the surface of the bottle or is packaged in metal cans, the product shall not be exempt from any requirement of this section other than the exemptions created by § 1.24(a)(5) (ii) and (v) of this chapter and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by § 101.5 if this information appears on the bottle closure or on the lid of the can in a type size not less than one-sixteenth inch in height, or if embossed on the lid of the can in a type size not less than one-eighth inch in height.

(b) If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a reusable bottle bearing a label lithographed onto the surface of the bottle:

(1) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained shall bear nutrition labeling if required by § 101.9; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

(2) All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than one thirty-second inch in height, except that if the information required by § 101.5 is placed on the side of the closure in accordance with § 1.24(a)(5)(ii) of this chapter, such information shall appear in letters and/or numbers no less than one-sixteenth inch in height.

(3) Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Commissioner may by regulation establish an alternative

method of disseminating such information. Information appearing on the closure shall appear in the following priority:

(i) The warning required by § 100.130 of this chapter.

(ii) The statement of ingredients.

(iii) The name and address of the manufacturer, packer, or distributor.

(iv) The statement of identity.

(5) Individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from type-size requirements of this paragraph, provided:

(i) The package has a total area of 3 square inches or less available to bear labeling;

(ii) There is insufficient area on the package available to print all required information in a type size of 1/16 inch in height;

(iii) The label information includes a full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6 of this chapter; and

(iv) The information required by paragraph (b) of this section appears on the label in accordance with the provisions of this paragraph, except that the type size is not less than 1/32 inch in height.

(d)(1) All information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other non-mandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(2) Any food, not otherwise exempted in this section, if packaged in a container consisting of a separate lid and body, and bearing nutrition labeling pursuant to § 101.9, and if the lid qualifies for and is designed to serve as a principal display panel, shall be exempt from the placement requirements of this section in the following respects:

(i) The name and place of business information required by § 101.5 shall not be required on the body of the container if this information appears on the lid in accordance with this section.

(ii) The nutrition information required by § 101.9 shall not be required on the lid if this information appears on the container body in accordance with this section.

(iii) The statement of ingredients required by § 101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by § 101.4, 101.5, 101.8, 101.9, 101.17, and 101.25, and Part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 10 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 42 FR 45905, Sept. 13, 1977; 42 FR 47191, Sept. 20, 1977; 44 FR 16006, Mar. 16, 1979; 49 FR 13339, Apr. 4, 1984; 53 FR 16068, May 5, 1988]

§ 101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation"and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under § 101.9(c)(7)(iv) of this chapter per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose

appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 48 FR 10811, Mar. 15, 1983]

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this Part 101, except those exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains ___ percent or less of ___,"or "Less than ___ percent of ___."The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this Subchapter B, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk"or "nonfat milk".

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

(5) Bacterial cultures may be declared by the word "cultured"followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweet cream buttermilk, concentrated sweet cream buttermilk, reconstituted sweet cream buttermilk, and dried sweet cream buttermilk may be declared as "buttermilk".

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butter oil and anhydrous butterfat may be declared as "butterfat".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the foods as "-shortening"or "blend of - oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat"or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., "vegetable oil shortening (soybean and cotton-seed oil)". For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term "hydrogenated", or if partially hydrogenated, the name shall include the term "partially hydrogenated". If each fat and/or oil in a blend or the blend is completely hydrogenated, the term "hydrogenated"may precede the term(s) describing the blend, e.g., "hydrogenated vegetable oil (soybean, cottonseed, and palm oils)", rather than preceding the name of each individual fat and/or oil; if the blend of fats and/or oils is partially hydrogenated, the term "partially hydrogenated"may be used in the same manner. Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:", e.g., "vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)". No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105, 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

(16) Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name "leavening", e.g., "leavening (baking soda, monocalcium phosphate, and calcium carbonate)". The listing of the common or usual name of each individual leavening agent in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of leavening agents in the product, the listing of individual leavening agents need not be in descending order of predomi-nance. Leavening agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:".

(17) Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name "yeast nutrients", e.g., "yeast nutrients (calcium sulfate and ammonium phosphate)". The listing of the common or usual name of each individual yeast nutrient in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of yeast nutrients in the product, the listing of the common or usual names of individual yeast nutrients need not be in descending order of predominance. Yeast nutrients not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as

"or", "and/or", or "contains one or more of the following:".

(18) Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name "dough conditioner", e.g., "dough conditioners (L-cysteine, ammonium sulfate)". The listing of the common or usual name of each dough conditioner in parentheses shall be in descending order of predominance: *Except*, That if the manufacturer is unable to adhere to a constant pattern of dough conditioners in the product, the listing of the common or usual names of individual dough conditioners need not be in descending order of predominance. Dough conditioners not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:".

(19) Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name "firming agents". If the manufacturer is unable to adhere to a constant pattern of firming agents in the food, the listing of the individual firming agents need not be in descending order of predominance. Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:"

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water"in the ingredient statement.

[42 FR 14308, Mar. 15, 1977, as amended at 43 FR 12858, Mar. 28, 1978; 43 FR 24519, June 6, 1978; 48 FR 8054, Feb. 25, 1983; 55 FR 17433, Apr. 25, 1990]

§ 101.5 Food; name and place of business of manufacturer, packer, or distributor.

(a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as "Manufactured for -------", "Distributed by -------", or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of non-consumer packages, the ZIP code shall appear either on the label or the labeling (including invoice).

(e) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

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[Title 21, Volume 2, Parts 100 to 169]
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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTINUED

PART 109 - UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 109.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of Sec. 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of Sec. 109.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of Sec. 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTINUED

PART 109 - UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

(e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

PART 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTUR-ING, PACKING, OR HOLDING HUMAN FOOD

Subpart A - General Provisions

Subpart B - Buildings and Facilities

Subpart C - Equipment

Subpart D - [Reserved]

Subpart E - Production and Process Controls

Subpart F - [Reserved]

Subpart G - Defect Action Levels

Authority: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A - General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "*Acid foods* or *acidified foods*"means foods that have an equilibrium pH of 4.6 or below.

(b) "*Adequate*" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) "*Batter*" means a semi fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) "*Blanching,*" except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) "*Critical control point*" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) "*Food*" means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) "*Food-contact surfaces*" are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations.

"Food-contact surfaces"includes utensils and food-contact surfaces of equipment.

(h) "*Lot*" means the food produced during a period of time indicated by a specific code.

(i) "*Microorganisms*" means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial"instead of using an adjectival phrase containing the word microorganism.

(j) "*Pest*" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) "*Plant*" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) "*Quality control operation*" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) "*Rework*" means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) "*Safe-moisture level*" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An $a_w$will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given $a_w$will not support the growth of undesirable microorganisms.

(o) "*Sanitize*" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "*Shall*" is used to state mandatory requirements.

(q) "*Should*" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "*Water activity*"(a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control*. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness*. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities,"as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B - Buildings and Facilities

§ 110.20 Plant and grounds.

(a) *Grounds*. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator§s control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design*. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations.

(a) *General maintenance*. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a

sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials*.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier§s guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant§s operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control*. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces*. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply*. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing*. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal*. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities*. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) *Hand-washing facilities*. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal*. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C - Equipment

§ 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual open-ration.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D - [Reserved]

Subpart E - Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the

contamination.

(a) *Raw materials and other ingredients*.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier§s guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier§s guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier§s guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations*.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning

of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 °F (60 °C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reonditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F - [Reserved]

Subpart G - Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[Code of Federal Regulations]
[Title 21, Volume 2, Parts 100 to 169]
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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTINUEPART 123 - FISH AND FISHERY PRODUCTS

Subpart A - General Provisions

Sec.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241,

242l, 264).

Subpart B - Smoked and Smoke-Flavored Fishery Products

Subpart C - Raw Molluscan Shellfish

Source: 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

Effective Date Note: At 60 FR 65197, Dec. 18, 1995, part 123 was added, effective December 18, 1997.

Subpart A - General Provisions

Sec. 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) Critical control point 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.

(c) 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.

(d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food safety hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g) Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) Processing means, with respect to fish or fishery products:

Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) Shall is used to state mandatory requirements.

(o) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) Shellstock means raw, in-shell molluscan shellfish.

(q) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s) Smoked or smoke-flavored fishery products means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Sec. 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor 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 processor 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 fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The 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 paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) 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;

(3) List the critical limits that must be met at each of the critical control points;

(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 Sec. 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);

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

(d) Signing and dating the HACCP plan.

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

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

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).

(e) Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum*toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor§s actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

Sec. 123.7 Corrective actions.

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

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

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(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:

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

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) 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 Sec. 123.10;

(3) 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;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, 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.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the record keeping requirements of Sec. 123.9.

Sec. 123.8 Verification.

(a) Overall verification. 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:

(1) Reassessment of the HACCP plan. 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. Such changes may include changes in the following: 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 Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).

(2) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor 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 processor, the performing of periodic end product or in-process testing.

(3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, 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 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 Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in process testing that is part of the processor§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.

(b) Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: 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 Sec. 123.10.

(d) Record keeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the record keeping requirements of Sec. 123.9.

Sec. 123.9 Records.

(a) General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) 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.

(b) Record retention.

(1) All records required by this part shall be retained at the processing facility or importer§s place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) 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 or the importer§s place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, 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 pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) Public disclosure.

(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

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

Sec. 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. 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.

(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 Sec. 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and

(c) Performing the record review required by Sec. 123.8(a)(3); The trained individual need not be an employee of the processor.

Sec. 123.11 Sanitation control procedures.

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) 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;

(6) 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; and

(8) Exclusion of pests from the food plant. The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

Sec. 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a) Importer verification. Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or have been

processed under unsanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor§s facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor§s HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer§s verification procedures on the importer§s behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.

(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B - Smoked and Smoke-Flavored Fishery Products

Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C - Raw Molluscan Shellfish

Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan

shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

Sec. 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensor requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by State and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester§s vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

PART 161 - FISH AND SHELLFISH

Subpart A - General Provisions

161.170 Canned Pacific salmon.
161.173 Canned wet packed shrimp in transparent or nontransparent containers.
161.175 Frozen raw breaded shrimp.
161.176 Frozen raw lightly breaded shrimp.
161.190 Canned tuna.
161.130 Oysters.
161.30 Declaration of quantity of contents on labels for canned oysters.
161.136 Olympia oysters.
161.145 Canned oysters

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

Source: 42 FR 14464, Mar. 15, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 161.30 Declaration of quantity of contents on labels for canned oysters.

(a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act and the regulations there under require food in package form to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 161.145(c), establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill

Subpart B - Requirements for Specific Standardized Fish and Shellfish

§ 161.130 Oysters.

(a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity prescribed in § 161.131 to 161.140, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) "Shell oysters" means live oysters of any of the species, *Ostrea virginica*, *Ostrea gigas*, *Ostrea lurida*, in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) "Thoroughly drained" means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least 1/4 of an inch in diameter and not more than 1 1/4 inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by paragraph (c)(2)(i) of this section whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in paragraph (c)(2)(i) of this section for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 161.136 Olympia oysters.

Olympia oysters, raw Olympia oysters, shucked Olympia oysters, are of the species *Ostrea lurida* and conform to the definition and standard of identity prescribed for oysters in § 161.130.

§ 161.145 Canned oysters.

(a) *Identity*.

(1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.

(2) The forms of oysters referred to in paragraph (a)(1) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal there from, and are as follows:

(i) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.

(ii) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.

(iii) Cut oysters obtained by cutting whole oysters.

(3)(i) When the form of oysters specified in paragraph (a)(2)(i) of this section is used, the name of the food is "Oysters"or "Cove oysters", if of the species *Ostrea virginica*; "Oysters"or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters"or "Olympia oysters", if of the species *Ostrea lurida*.

(ii) When the form of oysters specified in paragraph (a)(2)(ii) of this section is used, the name of the food is "Pieces of ----", the blank being filled in with the name "Oysters"or "Cove oysters", if of the species *Ostrea virginica*; "Oysters"or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters"or "Olympia oysters", if of the species *Ostrea lurida*.

(iii) When the form of oysters specified in paragraph (a)(2)(iii) of this section is used, the name of the food is "Cut --", the blank being filled in with the name "Oysters"or "Cove oysters", if of the species *Ostrea virginica*; "Oysters"or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters"or "Olympia oysters", if of the species *Ostrea lurida*.

(iv) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph (a)(3) of the forms of oysters used, arranged in order of their predominance by weight.

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container*.

(1) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.

(2) Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter.

(3) Drained weight is determined by the following method: Keep the un-opened canned oyster container at a temperature of not less than 68° or more than 95° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under "2.38 mm (No. 8)"in "Official Methods of Analysis of the Association of Official Analytical Chemists,"13th Ed. (1980), Table 1, "Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),"under the heading "Definitions of Terms and Explanatory Notes,"which is incorporated by reference. Copies may be obtained

from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or may be examined at the Office of the Federal Register, 1100 L St. NW. Washington, DC 20408. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

(4) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter in the manner and form therein specified, followed by the statement, "A can of this size should contain --- oz. of oysters. This can contains only --- oz.", the blanks being filled in with the applicable figures.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11832, Mar. 19, 1982; 49 FR 101-02, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2884, Jan 6, 1993]

[Code of Federal Regulations]
[Title 21, Volume 6, Parts 500 to 599]
[Revised as of April 1, 1997]

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[CITE: 21CFR509.3]
[Page 33]

TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - (Continued)

PART 509 - UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 509.3 Definitions and interpretations.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) Food includes pet food, animal feed, and substances migrating to food from food-contact articles.

[Code of Federal Regulations]
[Title 21, Volume 6, Parts 500 to 599]
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[Page 33-34]

TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - (Continued)

PART 509 - UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 509.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of Sec. 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of Sec. 509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of Sec. 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

FDA MANUAL OF INTERPRETATIONS
Codification System

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Manual of Interpretations

Date: December 8, 2002

The Manual of Interpretation Codification System consists of nine subject areas. The nine areas are **Interpretation Number, Date,** and **National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish**, reference hereon known as **"Model Ordinance Reference," Key Words, Question, Interpretation Rationale, Other References,** and **Contact.**

Interpretation Number: The interpretation number consists of four fields:

(1) primary
(2) secondary
(3) tertiary and
(4) quaternary.

Each identified field is related to a particular section of the Model Ordinance and a chronological number is assigned for the interpretation. The following is an example:

For example: **Interpretation Number: 05-III-@.02-100**
05 - The primary field corresponds to the last published Guide for the Control of Molluscan Shellfish revision date; in this case it is "2005."
III- The secondary field corresponds to a chapter in the Guide; in this case it is "Chapter III - Laboratory."
@.02- The tertiary field corresponds to the chronological numerical sequence for a subparagraph under a particular section in a chapter.
100 - The quaternary field is a chronological number for each interpretation issued under a particular section. **Note**: All interpretations issued for the first time for each Guide section will start with the number 100.

Date:	This is the actual date when the interpretation was issued.
Model Ordinance Reference	This refers to the particular chapters, paragraphs and subparagraphs in the guide. For example "**Chapter III, Section @.02A**"
Keywords:	These are words that serve to provide significant or memorable statements for systematic index entry.
Question:	This is the particular question of concern that needs to be interpreted.
Interpretation:	The FDA written response to clarify the particular area of concern in a specific chapter or section of the **NSSP Guide for the Control of Molluscan Shellfish**.
Rationale:	This explains the reason for the interpretation. This area will cover existing policy, regulations, laws, and public health reasons.
Other References:	This includes other documents used to issue the interpretation such as laws, regulations, model codes, scientific literature, etc.

Contact: This is the office responsible for issuing the interpretation. Any questions or comments should be in writing and addressed to:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway (HFS-628)
College Park, MD 20740

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

FDA MANUAL OF INTERPRETATIONS
Interpretation Number: 05-I-@.02-100

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: July 15, 1994
Revised: December 8, 2002

Model Ordinance
Reference: Chapter I @.02 A. (1)
NSSP Guidance Document -
Shellfish Plant Inspection Standardization Procedures

Key Words: Standardization, Limited, Officers

Question:
What procedures are to be used to standardize a State Shellfish Standardization Officer in jurisdictions which have less than five (5) dealers to certify for the ICSSL?

Interpretation:

OPTIONS FOR STANDARDIZING STATE SHELLFISH STANDARDIZATION OFFICERS WITHIN JURISDICTIONS WITH FEWER THAN 5 CERTIFIED DEALERS

1. Determine the number of intrastate shellfish dealers not listed on the ICSSL and include as many as necessary to obtain the minimum 5 inspections. All certified dealers must be included in the sample.

2. Arrange to conduct standardization inspections in another jurisdiction, using as many certified dealers as necessary to complete the exercise. All certified dealers within the candidate's home state must be included in the sample. This exercise must be conducted with an FDA Standardization Officer.

3. If options 1 or 2 are possible, they must be selected before pursuing option 3. When the Regional Shellfish Specialist agrees that option 1 or 2 cannot be utilized, the FDA Standardization Officer and the State Candidate will inspect all interstate and intrastate dealers within the state. If this number of dealers equals less than 5, the standardization exercise will be based upon the inspection of the number of available plants. However, the Candidate must achieve 80% agreement on EACH inspection. The FDA Standardization Officer shall review annually the number of dealers available within the jurisdiction and standardize the State Shellfish Officer using 5 dealers whenever they become available. The State Shellfish Officer shall make every effort to achieve standardization using 5 dealers. If a State Shellfish Standardization Officer standardized under this option relocates to another state with five (5) or more dealers, that Officer must be restandardized by the Regional FDA Shellfish Specialist through field standardization using 5 dealers.

IN ALL OF THE ABOVE OPTION CASES, THE STATE SHELLFISH STANDARDIZATION OFFICER CANDIDATE MUST SUCCESSFULLY COMPLETE THE FDA CLASSROOM TRAINING PORTION OF THE STANDARDIZATION PROCESS.

4. A state may choose to contract with another state which has a recognized State Standardization Officer to conduct routine and pre-certification inspections.

Rationale:

NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures, in the Guide for the Control of Molluscan Shellfish, establishes the procedures for measuring the training and performance of an applicant to become a standardized State Shellfish Officer or Plant Inspector. NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures requires that, during the plant inspection phase of standardization, a minimum of 8 plants be jointly inspected by the FDA Standardization Officer and the candidate for State Shellfish Officer. Three of the 8 plant inspections are considered to be a review or warm-up inspections, and 5 inspections are counted as the official number of inspections for the standardization process.

However, several states and foreign countries that participate in the ISSC and want to list firms on the ICSSL have fewer than 5 plants within their jurisdiction. Therefore, they are unable to follow the procedures set forth in NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures to standardize a State official. NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures addresses this issue vaguely, stating that, "For states that do not have 8 plants, all of the available plants must be inspected with the Standard determining the appropriate review number."

To clarify this issue, FDA offers the above options. Election of any option will:

- Meet the intent of the standardization procedures;
- Maintain uniform requirements for Standardized State Officers; and
- Uphold the criteria for listing dealers on the ICSSL.

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Distribution:

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Regional Federal State Program Managers
Division of Federal State Relations
Shellfish Sanitation Branch
Interstate Shellfish Sanitation Conference

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

FDA MANUAL OF INTERPRETATIONS
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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: November 5,2004
Final: March 25 , 2005

Interpretation Number: 05-I-@.02-101

Model Ordinance Reference: Chapter I@02.F (1)

Key Words: Inspections, unannounced, announced

Question:

The USFDA did not concur with ISSC adoption of Proposal 03-200. The FDA indicated that states presently have the discretion to schedule inspections when unannounced visits are not successful. The ISSC Executive Board and FDA agreed that resolution of the issue of unannounced inspections could be accomplished by the development of an NSSP interpretation acknowledging state discretion.

Interpretation:

The Authority shall make unannounced inspections of the dealer's facilities unless extenuating circumstances exist that would preclude this. Such extenuating circumstances are to be determined by the Authority, at their discretion, as long as documentation detailing the extenuating circumstances is maintained and the minimum inspection frequencies stipulated in §(1)(b) are met.

Rationale:

Unannounced inspections for HACCP and/or sanitation based food processing inspection programs always offer the best evaluation of a firm's compliance with the rules and regulations that apply to a process. For dealers regulated by the NSSP, the same reason for unannounced inspections applies to shellfish facilities. The Authority should make every effort to conduct unannounced inspections at shellfish facilities. It is recognized, however, that there are times when unannounced inspections may not be feasible, or may create undo hardship on the Authority's shellfish inspection program. In all cases, professional judgment should be used in determining when it is appropriate to announce an inspection, and announced inspections should only be conducted when other options have been exhausted.

Examples of instances where announced inspections should be considered include:
(A) When inspection staff members repeatedly have been unable to make contact with a facility operator in order to conduct an inspection during operating hours (such as may occur with small staffed operations that open intermittently, operations that open only seasonally, or facilities that are open only during certain occasions);
(B) A dealer's facility is located a considerable distance from the inspector's office, such that coordination is needed to ensure that the facility will be open and operating during an inspection visit, thereby ensuring that the inspector can manage his/her workload and travel funds without wasting the Authority's personnel time or budget.

Other References: None

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Shellfish MOU Authorities in Canada, Chile, Mexico, New Zealand, Korea

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National Shellfish Sanitation Program
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Model Ordinance Reference: Chapter III @.02
NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Document - Approved NSSP Laboratory Tests
NSSP *Guide for the Control of Molluscan Shellfish* Guidance Document - Shellfish Laboratory Evaluation Checklist - Microbiology

Key Words: Single Dilution, MPN, Adverse Pollution Condition Sampling, Seawater

Question:
What are the options for use of a 12-tube single dilution most probable number (MPN) test for growing area water samples?

Interpretation:

The 12-tube, single dilution MPN test may be used to survey shellfish growing waters in the Approved classification in accordance with the conditions specified in this Interpretation. Table 1 is a summary of the applicable criteria.

Table 1 – Applicable Criteria for use of the 12-Tube, Single Dilution MPN Test

12-tube, single dilution MPN Test, Approved Areas		
Use	**Total Coliforms** **For routine monitoring and survey**	**Fecal Coliforms** **For routine monitoring and survey**
Sample inocula	1 ml per tube	5 ml per tube
Count range	9 to 248 MPN	2 to 50 MPN
Standard	70 MPN/100 ml	14 MPN/100 ml
90^{th} percentile/upper 10%	140 MPN	28 MPN

Background:

The use of a single dilution MPN test for sampling shellfish growing waters emerged from the 8^{th} National Shellfish Sanitation Workshop in 1974. At that Workshop, it was recognized that the single dilution MPN test is a simpler approach than either the 5 or 3-tube, multiple dilution MPN test because it requires fewer tubes than the 5-tube, multiple dilution MPN test, media of one strength, no diluent, quicker inoculation, less incubator and/or waterbath space, fewer pipets; and, generally yields better data. The conventional MPN procedure simply uses multiple dilutions to expand the range of

determinate counts that can be obtained by the single dilution test procedure.

In their deliberations, Workshop conferees agreed:

1. That the number of tubes in each dilution for the multiple tube test may vary from standard published tables to suit the purpose of a particular sampling program provided the confidence limits of the test shall not exceed the upper confidence limits of a 3-tube, decimal dilution MPN test.
2. That a 12-tube, single dilution series can be used to routinely monitor closure lines.
3. That the volume inoculated in the 12-tube, single dilution test should be such that when half the tubes are positive, the MPN value would correspond to the value of the microbiological standard.

Requirements for sample volumes inoculated and numbers of tubes

Although there is no limit to the number of tubes that could be used in a single dilution MPN test, Workshop conferees agreed to the use of the 12-tube, single dilution test as an alternative to the 3 and 5-tube, decimal dilution tests. Specific criteria for determining sample inoculum were developed to meet the requirement to maintain the value for the microbiological standard at 70 MPN/100 ml for total coliform organisms and 14 MPN/100 ml for fecal coliform organisms when 6 of the 12 tubes in the single dilution series are positive. The inoculum volumes required for the 12-tube, single dilution test have been calculated as 1 ml per tube and 5 ml per tube for total and fecal coliform organisms respectively. The range of determinate values for each sample volume is shown in Table 2.

Table 2 – MPN Table 12-tube, single dilution

1 ml sample inoculum		5 ml sample inoculum	
Number of Positive Tubes	**MPN/100 ml**	**Number of Positive Tubes**	**MPN /100 ml**
0	<9	0	<2
1	9	1	2
2	18	2	4
3	29	3	6
4	41	4	8
5	54	5	11
6	70	6	14
7	88	7	18
8	110	8	22
9	139	9	28
10	179	10	36
11	248	11	50
12	>248	12	>50
Range 9 to 248		Range 2 to 50	

Similar calculations for the use of the 12-tube, single dilution MPN test to meet the Restricted area classification result in sample inocula of 0.1 ml per tube for the total coliforms and 0.8 ml per tube for fecal coliforms. The range of determinate values for each sample volume is shown in Table 3.

Table 3 – MPN Table 12-tube, single dilution

0.1 ml sample inoculum		0.8 ml sample inoculum	
Number of Positive Tubes	**MPN/100 ml**	**Number of Positive Tubes**	**MPN/100 ml**
0	<87	0	<11
1	87	1	11
2	182	2	23
3	288	3	36
4	406	4	51
5	539	5	67
6	700	6	88
7	875	7	109
8	1099	8	137
9	1386	9	173
10	1792	10	224
11	2485	11	311
12	>2485	12	>311
Range 87 to 2485		Range 11 to 311	

Potential classification impact – NSSP variability criteria

The water quality criteria of the National Shellfish Sanitation Program (NSSP) consist of two parts: the measure of central tendency (geometric mean) and a measure of variability (the 90th percentile or upper 10%). In using a single dilution, the geometric mean value for the classification standard was required to remain at the level of both the 3 and 5-tube tests (70 MPN/100 ml for total coliforms and 14 MPN/100 ml for fecal coliform organisms in the Approved classification). The variability of the water quality data, however, depends on the sampling variability of the test itself and other factors related to changing conditions in the water being sampled. The NSSP has addressed this by using the upper two-sided 95% confidence limit for the value of the microbiological standard and designating it as the 90th percentile/upper 10%.

For a 3-tube, decimal dilution MPN test, the upper two-sided 95% confidence limit for a value of 70 MPN/100ml is 330 MPN/100 ml; for a 5-tube, decimal dilution MPN test, the upper two-sided 95% confidence limit for a value of 70 is 230 MPN/100 ml. For a 12-tube, single dilution test, the upper two-sided 95% confidence limit for a value of 70 MPN/100 ml is 140 MPN/100 ml. For a value of 14 MPN/100 ml, the upper two-sided 95% confidence limits for 3 and 5-tube, decimal dilution tests are 49 MPN/100 ml and 43 MPN/100 ml respectively. For the 12-tube, single dilution test, the upper two-sided 95% confidence limit for a value of 14 MPN/100 ml is 28 MPN/100 ml. Hence, the water quality criteria for the 12-tube, single dilution MPN test for total coliforms in the Approved classification is a geometric mean value of 70 MPN/100 ml and a 90th percentile/upper 10% of 140 MPN/100 ml; for fecal coliforms, the NSSP water quality criteria for the Approved classification is a geometric mean value of 14 MPN/100 ml and a 90th percentile/upper 10% of 28 MPN/100 ml.

The 5-tube, decimal dilution MPN test is more precise than the 3-tube, decimal dilution test and the greater precision is reflected in the reduced value of the 90th percentile/upper 10%. Notwithstanding the difference in numerical values, each of these water quality criteria represent an equal probability that the waters being sampled are of the same sanitary quality. Since the 12-tube, single dilution MPN test has been found to be more precise than the 5-tube, decimal dilution test over two-thirds of its range (from 3 to 11 tubes positive), the difference in the magnitude of the 90th percentile/upper 10% values (28 versus 43) between the 12-tube and 5-tube tests is merely a function of the relative precision of the two tests and represents an equal probability that the waters being sampled are of the same sanitary quality. Thus, the impact on the water sampling program from the use of the 12-tube, single dilution test should be negligible if properly applied.

Restricted Areas

By extending the guidelines developed by Workshop conferees, the 12-tube, single dilution test MPN table (Table 3) could be used with geometric means of 700 MPN/100 ml for total coliforms and 88 MPN/100 ml for fecal coliforms. For these 12-tube, single dilution tests, the 90th percentile/upper 10% would be an MPN of 1386/100 ml for total coliforms and an MPN of 173/100 ml for fecal coliforms.

Statistical Considerations

This method limits the range of determinate values obtainable and indeterminate values must be treated mathematically to ensure that they receive proper consideration. Thus, by convention, a total coliform MPN of <9 would be rendered as 8.9 MPN/100 ml; a fecal coliform MPN of <2 would be given as 1.9 MPN/100 ml. For the restricted classification, a total coliform MPN of <87 would become an MPN of 86 per 100 ml and the fecal coliform MPN of <11 would assume a value of 10 MPN/100 ml. High indeterminates would be treated in the same manner. A total coliform MPN of >248 would be rendered as 250 MPN/100 ml; the fecal coliform MPN of 50 would assume a value of 51 MPN/100 ml. In the restricted classification, the total coliform MPN of >2485 would become an MPN of 2500/100 ml; and, the fecal coliform MPN of >311 would assume a value of 320 MPN/100 ml.

Because of the limited count range of the single dilution MPN, the 12-tube, single dilution MPN test has been found to be inappropriate for use with the Systematic Random Sampling monitoring strategy. See Interpretation number 02-IV-02-102 for details.

Other References

U.S. DHEW/PHS/FDA Shellfish Sanitation Branch, *Proceedings Eighth National Shellfish Sanitation Workshop*, January 16-18, 1974, New Orleans, LA.

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National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2005

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Reference: Chapter IV @.02 E. (3) (a)

Key Words: Water Samples; Time Interval; Adverse Pollution Conditions; Remote Areas

Question: What is the acceptable time interval between water quality samples collected from approved growing areas when using adverse pollution condition monitoring (IV @.02 E. (3) (a)), or an approved area designated as remote (IV @.02 D. (3) (a))?

Interpretation:

In accordance with Chapter IV @.02 E. (3) (a) and Chapter IV @.02 F. (6) (a), approved areas monitored under adverse pollution conditions shall have a minimum of five (5) samples collected annually from each station in the growing area. Samples shall be collected at intervals, which distribute them over a twelve (12) month period unless it can be demonstrated through data analysis that adverse pollution conditions are represented by a shorter time period. In this case, sampling may be limited to the reduced time period and shall include a minimum of five (5) samples representative of the adverse pollution condition. Sample collection shall be timed to distribute samples over the entire reduced monitoring period.

In accordance with Chapter IV @.02 D. (3) (a), approved areas designated as remote shall have a minimum of two (2) samples collected annually from each station in the area. Ideally, sample collection shall be timed to distribute samples over a twelve (12) month period. If the two-sample minimum is incorporated by the SSCA, then sample collection shall occur at a frequency of one (1) sample every six (6) months.

It is always the option of the SSCA to collect more than the minimum number of samples required by the Model Ordinance. When the SSCA elects to collect more than the minimum requirement, it is recommended that additional samples be distributed over a twelve (12) month period.

The Model Ordinance neither intends nor implies that sample collection be performed in a manner which results in multiple samples per sampling station visit or multiple samples over several consecutive days or weeks.

Rationale:

Although the Model Ordinance is not specific concerning the time interval between sample collection for adverse pollution condition monitoring in approved areas, or for approved areas designated as remote, it is a basic premise of the NSSP to coordinate sample collection to provide data representative of water quality over time. Collection of multiple samples on the same day or over brief time intervals negates the intent of the Model Ordinance and the SSCA's ability to evaluate data associated with changing environmental conditions.

Supportive documentation is found in Chapter IV @.03 C. (3) (b) (ii), which states that for conditionally approved areas, "monthly water samples are required when the growing area is in the open status of its conditional classification." Here, emphasis is placed on the need to sample monthly, qualifying the Model Ordinance intent to sample at discrete time intervals necessary to provide representative temporal data. Chapter IV @.02 F. (6) (b) (iii), specifies the requirements for systematic random sampling, stating, "A minimum of six (6) random water samples shall be collected annually from each sample station in the growing area" and Chapter IV @.02 F. (6) (b) (ii) states that "Sample collection shall be scheduled sufficiently far in advance to support random collection with respect to environmental conditions." By design, this strategy provides for the sampling of an area over a twelve (12) month period to ensure collection under varying environmental conditions.

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Model Ordinance Reference: Chapter IV @.02 D, E, F and G

Key Words: Weighted 90th Percentile, Adverse Pollution Condition, Systematic Random Sampling, Estimated 90th Percentile

Question: What is the procedure for determining the value of the 90th percentile to be used in the analysis of sample data derived in the transition to a different MPN procedure?

Interpretation: A weighted 90th
percentile value is calculated for each set of samples derived in the transition to a different MPN procedure.

Rationale: A number of states have availed themselves of the advantages afforded by the action of the 8th National Shellfish Sanitation Workshop in allowing the use of a virtual limitless combination of tubes and dilutions in MPN procedures used in support of the National Shellfish Sanitation Program (NSSP). A change in the combination of tubes and/or dilutions from those traditionally used in the NSSP alters the precision or variability of the test and thus its associated 90th percentile. When a change in MPN procedures is instituted, new data with a different 90th percentile must be phased into the existing sample database. During this phase-in period a "hybrid" 90th percentile value must be calculated and used as the variability component of the bacteriological standard against which the variability of sample data is to be compared. This "hybrid" 90th
percentile value is calculated by weighting the relative contributions of each MPN method to the sample database. The resulting value is known as the weighted 90th percentile. Weighted 90th percentile values can be used equally effectively with either Adverse Pollution Condition (APC) or Systematic Random Sampling (SRS) regimes.

Calculations: The value of the weighted 90th
percentile from a data set derived in the transition to a different MPN procedure is calculated in the following manner:

a. Convert the 90th percentile values for both MPN procedures to their respective base 10 logarithmic values.

b. Multiply the logarithmic values for each MPN procedure by the number of samples in the database examined by that procedure.

c. Add these logarithmic values, then divide by the total number of samples examined.

d. Take the antilog of this value.

e. Round off conventionally to the nearest whole number.

f. This value is the weighted 90th percentile against which sample data is compared.

g. Recalculate the weighted 90th percentile when new data is added to the database.

h. Once all accumulated data is from the same MPN procedure and the transition in methodologies is complete, the corresponding 90th percentile value for this MPN procedure is then used for comparing sample data.

Example 1

Data was gathered for a sampling station under the APC sampling regime. The growing area which encompasses this sampling station is in the approved classification. The first ten samples in the database were examined by the traditional 5-tube, decimal dilution MPN test for **fecal coliforms**. The remaining five samples required under APC sampling were analyzed by the 12-tube, single dilution MPN test for **fecal coliforms**. The 90th percentile value for the 5-tube, decimal dilution MPN test for **fecal coliforms** is 43. The 90th
percentile value for the 12-tube, single dilution MPN test is 28. The weighted 90th percentile value which results from this data will lie somewhere between the 90th
percentile values of the MPN procedures used. Its proximity to either method's 90th percentile value will depend on the relative number of samples analyzed from each method. Since most of the samples in this example were derived from the 5-tube MPN test, the 90th percentile value calculated will be weighted toward 43.

To calculate the weighted 90th percentile for this data set:

a. The 90th
percentile values of 43 for the 5-tube, decimal dilution MPN test and 28 for the 12-tube, single dilution MPN test are converted to base 10 logarithms. This gives base 10 log values of 1.633 and 1.447 respectively.

b. The base 10 log values are then multiplied by the number of samples in the database examined by each MPN procedure used. Ten of 15 samples were analyzed by the 5-tube, decimal dilution MPN test. The remaining 5 of 15 were examined by the 12-tube, single dilution test. This gives 1.633 for the 5-tube test x 10 samples = 16.330 and 1.447 for the 12- tube, single dilution test x 5 samples = 7.235.

c. These values are added together and the resultant divided by the total number of samples in the database being used. Thus, 16.330 + 7.235 = 23.565, 23.565/15 =1.571.

d. The antilog of this value is taken. In this example, the antilog of 1.571 is 37.239.

e. The antilog value is rounded off to the nearest whole number which in this example is 37.

f. The weighted 90th percentile for this data set is 37. Thirty-seven (37) is the 90th percentile value which cannot be exceeded more than 10% of the time by the sample station data in this data set under the APC sampling regime for this station to remain in the approved classification status. When new data is added to the database of this sampling station, the value of the weighted 90th
percentile would have to be recalculated until the transition in methodologies is completed and all the data from this sampling station is derived from the same MPN procedure. At this time, the corresponding 90th percentile value of 28 for the 12-tube, single dilution MPN procedure in use will be employed in comparisons with sample data.

Example 2

Data was derived from a sampling station under the SRS sampling regime. The growing area which encompasses this sampling station is also in the approved classification for **fecal coliforms**. The first 18 of 30 samples were analyzed using the 5-tube, decimal dilution MPN test. The remaining 12 of 30 samples were examined using a 3-tube, decimal dilution MPN test. The 90th
percentile values for the 5-tube, decimal dilution test in the approved classification status is 43. That for the 3-tube, decimal dilution MPN test is 49. Again the value for the weighted 90th percentile will be somewhere between the respective 90th

percentile values of both MPN methods. Its proximity to either is a function of the number of samples in the data set contributed by each MPN procedure. In this example, a somewhat greater number of samples were derived from use of the 5-tube, decimal dilution MPN test; so that, the value of the 90th percentile will be weighted in that direction also.

To calculate the weighted 90th percentile for this data set

a. The 90th percentile values of 43 for the 5-tube, decimal dilution MPN test for **fecal coliforms** and 49 for the 3-tube, decimal dilution MPN test for **fecal coliforms** are converted to base 10 logs. This gives base 10 log values of 1.633 for the 5-tube, decimal dilution test and 1.690 for the 3-tube, decimal dilution MPN test.

b. These base 10 log values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, 18 of 30 samples were examined by the 5-tube, decimal dilution MPN test: and, 12 of 30 samples were analyzed by the 3-tube, decimal dilution MPN test. This gives 1.633 for the 5-tube, decimal dilution MPN test x 18 samples = 29.394 and 1.690 for the 3-tube, decimal dilution MPN test x 12 samples = 20.280.

c. These values are added together and the resultant divided by the total number of samples in the database being used. Thus, 29.394 + 20.280 =49.674, 49.674/30 = 1.656

d. The antilog of this value is determined. In this example, the antilog of 1.656 is 45.269.

e. This antilog value is rounded to the nearest whole number which in this example is 45.

f. The weighted 90th percentile value for this data set is 45. Forty-five (45) is the value of the 90th percentile which will be compared to the estimated 90th
percentile calculated from the data in the sample data set collected under the SRS sampling regime and examined using the two different MPN methods. To remain in the approved status the estimated 90th percentile calculated from this data set must be less than or equal to the value determined for the weighted 90th percentile of the data set. Again the weighted 90th
percentile will have to be recalculated as new data becomes available. This recalculation must continue until the transition in methodologies is completed and all the data from this sampling station has been derived from the same MPN procedure. At this time, the corresponding 90th percentile of 49 for the 3-tube, decimal dilution MPN procedure in use will be employed in comparisons to the estimated 90th percentiles calculated directly from the sampling data.

Example 3

Data in this example was collected from a sampling station under the SRS sampling regime. This sampling station is in an area classified as restricted. The first 24 of the 30 samples collected were analyzed by the 5-tube, decimal dilution MPN test for **fecal coliforms**. The remaining 6 samples of the 30 collected were analyzed using a 5-tube, fivefold dilution MPN test for **fecal coliforms**. The 90th
percentile value for each of these MPN procedures is 260 and 190 respectively. The value of the weighted 90th percentile for this data set will be somewhere between 190 and 260. The proximity to either value will depend on the respective number of samples analyzed by each MPN method. In this example, most of the samples were derived from the 5-tube, decimal dilution MPN test. Consequently, the 90th percentile value will be heavily weighted in that direction.

To calculate the weighted 90th percentile for this data set:

a. The 90th percentile values of 260 for the 5-tube, decimal dilution MPN test for **fecal coliforms** and 190 for the 5-tube, fivefold dilution MPN test for **fecal coliforms** are converted to base 10 logs. This gives a base 10 logarithmic value of 2.415 for the 5-tube, decimal dilution MPN test and 2.279 for the 5-tube, fivefold MPN test.

b. These base 10 log values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, the 5-tube, decimal dilution MPN was used in the analysis of 24 of the 30 samples while the 5-tube, fivefold dilution MPN was used to test the remaining 6 samples. Hence, 2.415, the log 90th percentile value for the 5-tube, decimal dilution MPN test is multiplied by 24, the number of samples tested by

this MPN procedure to give 57.960; and, 2.279, the log 90th percentile value for the 5-tube, fivefold dilution MPN test is multiplied by 6, the number of samples obtained using this MPN procedure to give 13.674.

c. These values are added together and subsequently divided by the total number of samples analyzed by both methods. In this example, 57.960 + 13.674 = 71.634, 71.634/30 = 2.388.

d. The antilog of this value is determined. In this example the antilog of 2.388 is 244.343.

e. This antilog is conventionally rounded to the nearest whole number which in this example is 244.

f. The weighted 90th percentile value for the data set is 244. Two hundred forty-four (244) is the value of the 90th percentile which will be compared to the estimated 90th percentile calculated from the data in the sample data set collected under the SRS sampling regime and examined using the two MPN methods. To remain in the restricted classification, the estimated 90th percentile calculated from the data set will have to be less than or equal to the value of the weighted 90th percentile obtained from the data set. This weighted 90th percentile value will need to be recalculated as more data becomes available and until such time as the transition in methodologies is completed and all the samples have been derived from the same MPN procedure. When this occurs, the corresponding 90th percentile of 190 for the 5-tube, fivefold dilution MPN procedure in use will be employed in comparisons to the estimated 90th percentile calculated directly from the sampling data.

Example 4

Data in this example was collected from a sampling station under the APC sampling regime. This sampling station is in the approved classification and 5 of 15 samples in the database were tested by the 5-tube, decimal dilution MPN test for **total coliforms**. The remaining 10 samples in the database were analyzed by the 3-tube, decimal dilution MPN test for **total coliforms**. The 90th percentile value for each of these MPN tests were 230 and 330 respectively. The value of the weighted 90th percentile will be somewhere between 230 and 330. Its proximity to either value depends on the respective number of samples analyzed by each MPN procedure. In this example, the preponderance of samples were tested by the 3-tube MPN procedure. As a result, the value of the 90th percentile will be weighted more heavily toward 330.

To calculate the weighted 90th percentile for this data:

a. The 90th percentile values of 230 for the 5-tube, decimal dilution MPN test for **total coliforms** and 330 for the 3-tube, decimal dilution MPN test for total coliforms are converted to base 10 logarithms. This gives base 10 log values of 2.362 and 2.519 respectively.

b. These base 10 log values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, 5 of 15 samples in the database were analyzed by the 5-tube, decimal dilution MPN test. The remaining 10 of 15 samples were examined by the 3-tube, decimal dilution test. Thus, the base 10 log value of 2.362, the 90th percentile of the 5-tube MPN procedure for **total coliforms** is multiplied by the 5 samples tested by this MPN method to give 11.810. In addition, the base 10 log value of 2.519, the 90th percentile of the 3-tube MPN test for **total coliforms** is multiplied by the 10 samples examined by this MPN procedure to give 25.190.

c. These values are added together and the resultant divided by the total number of samples in the database being analyzed. In this example, 11.810 + 25.190 = 37.000, 37.000/15 = 2.467.

d. The antilog of this value is determined. For this example, the antilog of 2.467 is 293.089

e. This antilog is rounded off to the nearest whole number which in this case is 293.

f. The weighted 90th percentile for this data set is 293. Two hundred ninety three (293) is the value for the 90th percentile that cannot be exceeded more than 10% of the time by this sampling station under APC for it to remain in approved classification status. The value for the weighted 90th percentile must be recalculated as more data

becomes available. This will continue until the transition in methodologies is completed and all samples in the database have been analyzed using the same MPN procedure. When this happens, the corresponding 90th percentile of 330 for the 3-tube, decimal dilution MPN procedure in use will be employed in comparisons with the sample data.

Other References:

1. *Schaum's Outline Series Theory and Problems of Statistics*, Second Edition, 1994, McGraw Hill, Inc.

2. U.S. DHEW/PHS/FDA Shellfish Sanitation Branch, *Proceedings 8th National Shellfish Sanitation Workshop*, January 16-18, 1974, New Orleans, LA.

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Model Ordinance Reference: Chapter IV @.02 F(5)
Guidance Documents, Systematic Random Sampling Monitoring Strategy

Key Words: Systematic Random Sampling, Estimated 90th Percentile, Intermittent Nonpoint Pollution Events, 12-tube, single dilution MPN

Question: Is it acceptable to apply the formula currently used in Systematic Random Sampling to calculate the estimated 90th percentile of data derived from a 12-tube, single dilution MPN test?

Interpretation: It is not acceptable to apply the formula currently used in Systematic Random Sampling to calculate the estimated 90th percentile of data derived from a 12-tube, single dilution MPN test.

Rationale:

The purpose of the estimated 90th percentile is to provide a tool to measure the impact of intermittent nonpoint pollution events on growing area water quality under the Systematic Random Sampling monitoring strategy. It does this by providing an estimate of the variability of the data. If water quality is affected by intermittent nonpoint pollution events, the effect of these events will be reflected in the variability of the data and through the use of suitable calculations this variability can be captured as the estimated 90th percentile.

Currently the procedure for calculating the estimated 90th percentile requires the use of at least 30 samples. With a data set of this size, a significant impact on the variability of the data and as a consequence, its estimated 90th percentile from the effects of intermittent nonpoint pollution events can only be detected by the occurrence of several high to very high bacterial counts in the data set. Therefore, in order to use the estimated 90th percentile as intended, the method of bacterial enumeration must be capable of operating over a wide range in counts.

A 5-tube, decimal dilution MPN test operates over a count range of <2 to >1,600. The 3-tube, decimal dilution test operates over a count range of <3 to >1,100. Both of these MPN tests have a wide count range and are capable of measuring the higher count levels necessary for the estimated 90th percentile to function. The 12-tube, single dilution MPN test on the other hand, operates over a count range of <9 to >248 for total coliforms and <2 to >50 for fecal coliforms. Both of these count ranges are quite limited and obviously are not capable of measuring the higher counts necessary for the estimated 90th percentile to function in the same manner as the 5 and 3-tube, decimal dilution MPN tests.

The *Model Ordinance* requires the use of at least 30 samples to calculate 90th percentile values when using Systematic

Random Sampling. With a data set of this size, it is impossible for the 12-tube, single dilution MPN test with its limited count range to measure bacterial densities when they occur at the levels necessary to demonstrate an impact from intermittent nonpoint pollution events. As a consequence, any significant effect on water quality that may occur as a result of these intermittent nonpoint pollution events is unlikely to be detected when using the 12-tube, single dilution MPN test for monitoring under Systematic Random Sampling. Therefore, the 12-tube, single dilution MPN test is inappropriate for use with the Systematic Random Sampling monitoring strategy. Only test procedures which generate a broad range of counts should be used to monitor for the effects of intermittent nonpoint pollution events within the context of the Systematic Random Sampling strategy. Currently these testing procedures are limited to multiple dilution MPN tests and the mTEC membrane filter procedure when filtering multiple (half log) dilutions.

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Division of Cooperative Programs
Office of Compliance

Date: March 20, 1996
Revised: December 8, 2002

Model Ordinance Chapter VIII. 03
Reference:

Key Words: Vibrio vulnificus, matrix, AMMWT

Question: What is the procedure for calculating the average monthly maximum water temperature (AMMWT) used in applying the *Vibrio vulnificus* control matrix?

Interpretation:

The state shellfish control authority shall determine, for each shellfish growing area, the AMMWT for each month using historical water temperature data for each of the previous five (5) years.

The procedure for calculating the AMMWT for each shellfish growing area is as follows:

1. List the maximum water temperature recorded for each day of the month.
2. Calculate the average maximum water temperature for the month using the daily water temperatures listed in step 1. **NOTE:**
   If water temperature data are not available for each day of the month, then use temperature data for those days it is available. These data shall be representative of water temperatures observed throughout the month.
3. Perform steps 1 and 2 for each month for each of the previous five years.
4. Determine the AMMWT by calculating the mean of the five (5) average maximum water temperatures from step 3 for each month.

Rationale:

The procedure outlined above is consistent with the intent of the 1995 ISSC to calculate the AMMWT using maximum **daily**
water temperatures, not the single warmest water temperature recorded during the month. This procedure is identical to that used to calculate average maximum monthly air temperatures (AMMAT) required under Chapter VIII. 03.

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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
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Office of Compliance

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Model Ordinance Chapter I @.02 H.(2)(c)-(e)
Reference: Chapter XI 01.B.(2) and 01.C and 01.D
Chapter XII 01.B and 01.C
Chapter XIII 01.B.(2)
Chapter XIV 01.B and 01.C

Key Words: Time/Temperature abuse, Enforcement Follow-up, Microbiological testing

Question: Is microbiological testing by the shellfish control authority a suitable means of determining whether a critical deficiency exists when a dealer fails to control shellstock or shucked product time/temperature exposure during storage or processing as specified in the above referenced sections of Chapters XI, XII, XIII, and XIV. If such a critical deficiency exists, is microbiological testing (i.e. where the product may be released if no microbiological contaminants are found at or above levels of concern) a suitable enforcement follow-up?

Interpretation:

Failure to comply with the time/temperature exposure conditions specified in the referenced sections of the Guide for the Control of Molluscan Shellfish Chapters XI, XII, XIII, and XIV constitutes a critical deficiency. Chapter X. 0l. C. (2) and (3) states that, even if processors choose to select critical limits other than those specified in these referenced sections, they must meet the conditions as components of good manufacturing practice. Violation of the temperature control requirements is a critical deficiency. When a critical deficiency is observed, product must be controlled to prevent contaminated or adulterated shellfish from reaching consumers. Microbiological testing is not a suitable means of determining whether the deficiency is a critical deficiency. There are no provisions in the NSSP for any rating other than critical for such deficiencies.

The referenced sections of Chapter I state that when a critical deficiency is detected during an inspection, the dealer must correct the deficiency during the inspection and must cease production affected by the deficiency until the deficiency is corrected. Failing that, the Shellfish Control Authority must immediately begin certification suspension or revocation proceedings. Additionally the Authority is required to ensure that contaminated or adulterated product does not reach the consumer.

A suitable correction for a time/temperature abused product is destruction or processing the product in such a way that the microbiological hazard is eliminated (e.g. thermal processing) and modifying plant operations in such a way that a reoccurrence of the deficiency is not likely (e.g. pre-chilling product, reducing the size of the shucking or finished product

containers, adding ice to the product during processing, making adjustments to or repairs to mechanical cooling systems). If these kinds of corrections are not enacted during the course of the inspection, the Shellfish Control Authority must immediately initiate certification revocation or suspension proceedings.

Microbiological testing (i.e. where the product may be released if microbiological contaminants are not found at or above levels of concern) is not a suitable means of ensuring that contaminated or adulterated product does not reach the consumer. The sample size necessary to ensure that any one microbiological contaminant is not present is prohibitively large, especially considering the low levels of organisms of concern and the typically high variability of the lot. Additionally, microbiological analysis will only provide information on the pathogen for which analysis was performed and low levels of indicator organisms is not a reliable assurance that pathogens are not present in the product.

Where the dealer fails to take the appropriate corrective action as outlined above and required by I.@.02 H.(2)(c), the shellfish Control Authority must initiate decertification procedures, as required by I.@.02 H.(2)(d), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with I.@.02 H.(2)(e).

Rationale:

Shellfish is a potentially hazardous food, particularly since it is frequently consumed raw. Consequently, controls must be in place to prevent the growth of naturally occurring pathogens as well as pathogens that may be introduced into the product during processing. Rapid chilling and holding the product at refrigeration temperature are two of the most practical and effective means of controlling the microbial hazards in raw molluscan shellfish.

Naturally occurring Vibrio sp., such as *Vibrio vulnificus* and *Vibrio parahaemolyticus*, are human pathogens found in shellfish. During periods of warm water temperature, the number of these organisms may increase to high levels and further bioaccumulate in the shellfish during processing and storage. These organisms grow rapidly at temperatures of 70 degrees F or above (one log increase in 2 hrs). Conversely, little or no growth occurs at temperatures at or below 45 degrees F. Therefore, it is critical for shellfish products to be rapidly chilled to and held at 45 degrees F or less. Further, enteric pathogens may be introduced into the shellfish through improper handling during post harvest practices (e.g. use of contaminated water for shellstock washing or wet storage) or during shucking and repacking operations. Growth of these pathogenic organisms may also be prevented by rapidly chilling the product to 45 degrees F or less.

Other References:

1. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington , DC
2. 21 Code of Federal Regulations, Part 110 - Current Good manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington , DC

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Model Ordinance
Reference: Chapter I.@.02H.(2) (c)-(e)
Chapter XI. 02. A. (2)
Chapter XI. 02. E. (4)

Key Words: Ice, sanitary quality, stored, protected, adulteration

Question:
1) What are the factors affecting the sanitary quality of ice and actions that should be taken when ice is improperly stored, protected or subject to adulteration?

Interpretation:

Ice is a regulated food which is used or intended for use on molluscan shellfish either in-shell or shucked for human consumption. Ice must be protected from adulteration as defined in the Food, Drug and Cosmetic Act §402.

In accordance with the Guide for the Control of Molluscan Shellfish any ice used in the processing, storage or transport of shellstock or shucked shellfish shall be made on-site from potable water in a commercial machine; or received from a facility sanctioned by the appropriate regulatory authority. Ice must be stored in a safe and sanitary manner to prevent its contamination.

The dealer shall use only equipment and utensils, including approved plastic ware which are: (1) constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of ice and shellfish products; and, (2) free from any exposed screws, bolts, or rivet heads on food contact surfaces. The dealer shall assure that all joints on food contact surfaces: (1) have smooth easily cleanable surfaces; and (2) for stainless steel, are welded. "Item 12 - Ice: approved source, sanitary, protected" is designated as a Swing item and identified as either a Key or Critical deficiency (NSSP Standardized Shellfish Processing Plant Inspection Form (ISSC Form 93-01(A).)

Key Deficiency: Applies when conditions may lead to adulteration of ice.

Critical Deficiency: Applies when the ice is visibly adulterated.

Key Conditions:

The following conditions are representative of Key deficiencies:

- Improperly constructed, maintained, cleaned, and sanitized walk-in coolers, insulated rooms, or other storage containers;
- Improperly constructed, cleaned, sanitized and stored totes, scoops, shovels, or other utensils used in handling ice;

- Ice making machines not maintained or protected (reservoir).

Corrective Actions:
Ice storage unit:

- Discontinue the use;
- Set a correction schedule for cleaning, repair, or replacement

Ice handling equipment:

- Discontinue use, clean and sanitize; or
- Replace with approved equipment

Ice machines:

- Shut down and initiate cleaning and/or repair.

Critical Conditions:
The following conditions are representative of Critical conditions:

- Dirt or other debris such as insulation, or paint chips observed in the ice;
- Ice is observed to be exposed to mold, slime, rust, condensate from cooler evaporator units, or other sources of adulteration.
- Ice exposed to foot traffic and observed to be used in direct contact with product;
- Stored food items in the ice.

Critical deficiency corrective action:

1. Discard ice;
2. Repair or replace ice storage units and equipment which caused the ice to be adulterated, or obtain ice from another source;
3. Destroy all product exposed to ice produced under conditions of adulteration

Where the dealer fails to take the appropriate corrective action as outlined above and required by Chapter I. @02. H. (2) (a), the shellfish Control Authority must initiate decertification procedures, as required by Chapter I. @02. H. (2) (b), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with Chapter I. @02. H. (2) (c).

Rationale:
Ice is considered a food when used in direct contact with shellfish. As a food ice must be stored and handled in the same sanitary manner as any other food product. No food product shall enter into commerce that is either injurious to health or is otherwise adulterated. Contaminated ice used in direct contact with shellfish will cause the shellfish to be adulterated. Each shellfish dealer must protect molluscan bivalves and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants. All materials used in equipment, utensils, walk in coolers, or rooms used to make or store ice must meet food contact surface requirements. A preventive or corrective measure should be used to control an identified food safety hazard to ensure that no product shall enter into commerce that is either injurious to health or is otherwise adulterated.

Other References:

1. Food and Drug Administration, "Federal Food, Drug and Cosmetic Act", Government Printing Office, Washington, DC
2. Food and Drug Administration, "1997 Food Code", Washington, DC.
3. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington, DC
4. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington, DC

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Interstate Shellfish Sanitation Conference

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
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FDA MANUAL OF INTERPRETATIONS
Interpretation Number: 05-XI-.02-101

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: January 15, 1999
Revised: December 8, 2002

Model Ordinance Chapter XI. 02. B. (1)
Reference: Chapter XI. 02. B. (2)

Key Words: Food contact surfaces, cleaning, sanitizing, equipment construction

Question: 1) What is a **food contact surface**?
2) What constitutes effective cleaning and sanitizing of a food contact surface?
3) What constitutes acceptable construction of shellstock grinders and parts thereof are considered food contact surfaces?

Interpretation:

1) A **food contact surface** means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food or liquid may drain, drip, or splash into a food; or onto a surface normally in contact with food. Food contact surfaces include, but are not limited to, equipment and utensils such as; shucking knives and handles, shucking hammers and handles, shucking blocks, ice scoops and shovels, ice bins, skimmers, blower tanks, shucking pails, shellstock grinders.
2) Food-contact surface shall be clean to sight and touch. Cleaning and sanitizing shall occur prior to use each day and any time during use when contamination may have occurred. At a minimum, food contact surfaces shall be cleaned and sanitized every four hours. More frequent cleaning may be necessary depending on the characteristics of the equipment and its use and the amount of food residue accumulation. At the end of each day, food contact equipment and utensils shall be washed and rinsed.
   Food contact surfaces shall be effectively washed to remove or completely loosen soils by manual or mechanical means such as the application of detergents; hot water; brushes; or high pressure sprays. If washing in sink compartments is impractical such as when equipment is fixed or utensils are too large, washing shall be done using an alternative manual procedure. In such instances, washing shall be facilitated by 1) disassembling equipment as necessary to allow access of the detergent solution to all parts and equipment components and 2) utensils shall be scraped or rough cleaned to remove food particle accumulation.
   The cleaning of food contact surfaces shall occur prior to sanitizing in order for the sanitizer to be effective in destroying vegetative bacteria. Sanitizers may be applied by immersion, spraying or brushing. Sanitizer concentration shall be in accordance with the manufacturer's directions on the label.
3) Parts of a shellstock grinder which are considered food contact surfaces include; the blade, the area behind the blade including the motor shaft from the blade to the motor housing, and the inside surface of the housing or cover surrounding the blade. These food contact parts shall be manufactured from high impact materials that are easily cleanable and non-corrosive. The grinder must be constructed to be easily disassembled and assembled to facilitate inspection, maintenance, cleaning, and sanitizing.

Guidelines for grinder construction:

1. The motor shaft should be of corrosion resistant material.
2. Juncture point where the motor shaft enters the blade chamber must be sealed to reduce dirt and detritus deposition around the shaft.
3. The blade must be made from a single piece of high impact non-corrosive material. Blade teeth must be an integral part of the blade, or if grinding surfaces are used instead of teeth, they must be welded to the face of the blade with all welds ground smooth.
4. The housing around the blade assembly must be constructed of material that is corrosion resistant.
5. Bolts or screws must be constructed of corrosion resistant material to prevent rust and corrosion.
6. The inside surface of the blade housing must be smooth, and if welded ground smooth for easy cleaning.
7. The blade housing must be designed with an easily removable cover that will open up the **entire blade assembly area** to facilitate inspection, cleaning, sanitizing, and maintenance.

Rationale:

Each shellfish dealer is responsible for assuring that all food contact equipment and utensils meet the design, construction, repair, and cleaning requirements of the NSSP, Guide for the Control of Molluscan Shellfish. Food contact surfaces must be cleaned and sanitized at a minimum frequency and in accordance with proper procedures to prevent contamination of shellfish by microbial pathogens and chemicals. Consistent with the FDA Food Code, cleaning and sanitizing shall occur at least every four hours and where necessary more often, depending on the accumulation of food debris or exposure to other contaminants. Under the NSSP Guide for the Control of Molluscan Shellfish and 21 CFR, Part 123, shellfish dealers are responsible for monitoring and maintaining records of the cleaning and sanitizing of food contact surfaces.

Other References:

1. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, U.S. Food and Drug Administration.
2. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, U.S. Food and Drug Administration.
3. 1997 Food Code, U.S. Food and Drug Administration.
4. Food Equipment American National Standard NSF International Standard ANSI/NSF, NSF International, Ann Arbor, MI, 48113.

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National Shellfish Sanitation Program
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FDA MANUAL OF INTERPRETATIONS
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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: February 14, 2001
Revised: December 8, 2002

Model Ordinance Chapter XV. 03. L. (1) (c)
Reference: NSSP Guidance Documents
Approved NSSP Laboratory Tests

Key Words: Sample Volume, Fecal Coliform Counts, MPN Table and Count Range

Question: What sample volume is inoculated in the 12-tube, single dilution MPN test for end product depurated shellfish samples?

How are fecal coliform counts determined using the 12-tube, single dilution MPN test for end product depurated shellfish?

Interpretation:

Two (2) mls (1 gram) of a 1:1 dilution of shellfish homogenate is inoculated into each tube of single strength lauryl tryptose presumptive broth in the 12-tube, single dilution MPN test for end product depurated shellfish samples. Inoculated tubes are incubated in an air incubator at 35°C for 24 hours. Any gas positive presumptive broth tubes are then subcultured to EC medium and incubated in a water bath at 44.5°C for 24 hours. The presence of any amount of gas or effervescence in the EC tubes constitutes a positive test. Fecal coliform counts are read from the MPN Table below and reported as MPN/100 grams.

MPN Table for End-product Depurated Shellfish Samples	
Number of Positive Tubes	**MPN/100 grams**
0	< 9.0
1	9.0
2	18
3	29
4	41
5	54
6	70
7	88
8	110
9	139
10	179

11	248
12	>248
Count range 9 to 248	

Rationale:

The use of the 12-tube, single dilution MPN test for end-product depurated shellfish was established as an acceptable method of analysis with the ISSC's adoption of the rewrite of Model Ordinance, Chapter XV, the Depuration Chapter in 1998. However, no specific guidance was provided on sample volumes to be examined or how fecal coliform counts were to be determined. Since the volume of sample inoculated in a single dilution MPN test controls the range of counts that can be determined, it is essential that an appropriate volume be inoculated to encompass the count range prescribed as the critical limits for depuration plant performance listed for all shellfish species encountered.

The inoculation of two (2) ml (yielding 1 gram) of sample from an initial 1:1 dilution of shellfish homogenate into each tube of the 12-tube, single dilution MPN produces a range of counts from 9 to 248. This range is sufficient to cover the critical limits of performance of all shellfish types listed in Chapter XV. 03. L (1) (c).

Remarks:

Comments received from the review of the draft version of Interpretation 03-XV-.03-100 indicated that the content of the Interpretation was too broad to be dealt with effectively in a single Interpretation. For this reason, this second Interpretation was developed from information presented in the first concerning the correct application of the single dilution MPN test to end product depurated shellfish.

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IX. History of The National Shellfish Sanitation Program

Introduction

The National Shellfish Sanitation Program (NSSP) was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling disease associated with the consumption of raw shellfish (oysters, clams, and mussels).

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of State regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (now the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three parties combined to form a tripartite cooperative program. The guidelines of the program have evolved into the NSSP Handbook which is managed and updated by the Interstate Shellfish Sanitation Conference (ISSC).

A Declaration of Principles

Oysters, clams and mussels are unique foods which have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. To early settlers, the food resources of the sea were one of the most valuable and readily usable of the natural resources, particularly from the estuaries. It is not surprising that shellfish were foremost among their staple food items.

The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use. Over 300 years ago in 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation, including that of New York (1715), New Jersey (1730), and Rhode Island (1734), was designed to regulate harvesting, presumably as conservation measures to guarantee a continuing supply.

Public health controls of shellfish became a national concern in the U.S. in the late nineteenth and early twentieth century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. These shellfish-associated outbreaks were also medically recorded in other parts of the world, most notably in European countries. During the winter of 1924, there occurred a widespread typhoid fever outbreak, with cases in New York, Chicago, and Washington, D.C., which was finally traced to sewage polluted oysters. Local and state public health officials, and the shellfish industry became sufficiently alarmed over this outbreak to request that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consuming public.

In accordance with this request, the Surgeon General called a conference of representatives from state and municipal health authorities, state conservation commissions, the Public Health Service and its Bureau of Chemistry (later to become the Food and Drug Administration), the Bureau of Commercial Fisheries (now National Marine Fisheries Service) and the shellfish industry. This historic conference was held in Washington, D.C. on February 19, 1925.

The members of the conference recommended eight resolutions for the sanitary control of the oyster industry. These included:

"The beds on which shellfish are grown must be determined, inspected, and controlled by some official state agency and the U.S. Public Health Service."

"The plants in which shellfish are shucked or otherwise prepared or packed by the shipper must be inspected and controlled by some official state agency and the U.S. Public Health Service."

"There must be such governmental supervision and such trade organization as will make plain the source of shellfish and will prevent shellfish from one source being substituted for those from another source. This will be chiefly a problem of

the individual state."

"The methods of shipping must be supervised, inspected, controlled and approved by the proper official federal and state agency."

"The product must conform to an established bacterial standard and must meet federal, state, and local laws and regulations relative to salinity, water content, food proportion and conform to the Pure Food Laws standards."

The conference also established a committee to develop further necessary guidelines to recommend control practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to state health officers and all others concerned. This letter set forth the following understandings:

1. The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual states; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the states, with the assistance and cooperation of the Public Health Service..."
2. In accordance with this principle, it is considered that each producing state is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other states..."
3. In order that each state may have full information concerning the measures carried out in other states, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing state, and will report thereon for the information of the authorities of other states. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane."
4. The officers of the Public Health Service assigned to this survey work will assist the state agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."
5. In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between state authorities."

To implement this program, the members of the 1925 conference agreed that the producing states would issue "Certificates," i.e., a permit to operate, to shellfish shippers that meet agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the state control programs. This clearinghouse responsibility was met initially through issuance of a periodic "Progress Report on Shellfish Sanitation" describing the shellfish sanitation program in each state. This procedure was subsequently abandoned in favor of a "program endorsement" concept. Under this concept, the Public Health Service made a continuing appraisal of each state's shellfish sanitation program to determine if the control measures were in substantial accord with the provisions of the current "Manual of Recommended Practice for Sanitary Control of the Shellfish Industry." The Public Health Service also published a list of all shellfish shippers certified by those states that maintained "satisfactory" control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Heath Service Act resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under state laws with federal technical support and industry participation. The National Shellfish Sanitation Program, now the Interstate Shellfish Sanitation Program, is dependent entirely upon the states adopting the recommended requirements and the cooperative and voluntary efforts of state regulatory agencies and the shellfish industry.

NATIONAL SHELLFISH SANITATION PROGRAM

The National Shellfish Sanitation Program (NSSP) developed from public health principles and Program controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the United States Public Health Service in 1925. These fundamental components were described in a supplement to ***Public Health Reports***, ***Report of Committee on Sanitary Control of the Shellfish Industry in the United States*** (Frost, 1925)

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of state regulatory agencies. These efforts were augmented by the assistance and advice of the Public

Health Service (replaced by the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three parties combined to form a tripartite cooperative program.

To carry out this cooperative control program, each partner accepted responsibility for certain procedures.

Each shellfish shipping state adopted adequate laws and regulations for sanitary control of the shellfish industry, completed sanitary surveys of harvest areas, delineated and patrolled restricted areas, inspected shellfish plants, and conducted such additional inspections, laboratory investigations, and control measures as were necessary to insure that the shellfish reaching the consumer had been grown, harvested and processed in a sanitary manner. The state annually issued numbered certificates to shellfish dealers who complied with the agreed-upon sanitary standards, and forwarded copies of the interstate certificates to the Food and Drug Administration (FDA).

The FDA made an annual review of each state shellfish control program including the inspection of a representative number of shellfish processing plants. On the basis of the information thus obtained, the FDA determined the degree of conformity the state control program had with the NSSP. For the information of health authorities and others concerned, the FDA published a monthly list of valid interstate shellfish shipper certificates.

The shellfish industry cooperated by obtaining shellfish from safe sources, by providing plants which met the agreed upon sanitary standards, by maintaining sanitary operating conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which showed the origin and disposition of all shellfish.

Although the basic public health principles of the NSSP have remained unchanged, program procedures have been updated and improved upon at periodic intervals. The original 1925 "Report of Committee on Sanitary Control of the Shellfish Industry in the United States" was revised and reissued in 1937 and again in 1946. The document was then divided into two parts Part II entitled "Sanitation of Harvesting and Processing of Shellfish" was issued in 1957 and in 1959, Part I, "Sanitation of Shellfish Growing Areas." The need for a specialized program of this nature was reaffirmed by the cooperating members at the First National Shellfish Sanitation Workshop held in Washington, D.C., (Jensen, 1954) and at subsequent National Shellfish Sanitation Workshops (Jensen,1956, 1958, 1961; Houser, 1964). A more complete summary of the history and evolution of the NSSP and its early approaches to resolution of shellfish sanitation issues can be found in David Clem's historical overview (Clem, 1994).

In the 1940's, the NSSP moved beyond its original 1925 objective of insuring that shellfish shipped in interstate commerce were safe for human consumption. Paralytic shellfish poison became a matter of public health concern and requirements were added to address this public health hazard. In 1957, when it was determined that shellfish could concentrate certain radionuclides, the procedures were revised to include public health controls for the pollutant. In the 1960's and 1970's, the program was again revised to address public health concern associated with heavy metals and pesticides.

Additional recommendations from the states and industry resulted in the 1965 revision of the shellfish sanitation manual. This revision was prepared in cooperation with the shellfish control authorities in all coastal states, food control authorities in the inland states, interested federal agencies, Canadian federal departments, the Oyster Institute of North America, the Pacific Coast Oyster Growers Association, and the Oyster Growers and Dealers Association of North America.

In 1968, the Sixth National Shellfish Sanitation Workshop was held (Morrison, 1969). Recommendations for further revisions to the 1965 Manual were made and accepted by Workshop participants. This Workshop was structured around 12 task forces that were assigned specific topics to examine and develop recommendations for discussion by all workshop participants. This approach to examining and discussing large numbers of issues was proved successful and was recommended for use in future Workshops.

The shellfish sanitation program responsibilities assigned to the Assistant Secretary for Health, Department of Health, Education and Welfare were delegated to the Commissioner of Food and Drugs in late 1968. The FDA continued to sponsor the National Shellfish Sanitation Workshops (Ratcliffe, 1971; Wilt, 1974, 1975 and 1977) Proceedings from these Workshops contained additional recommendations for revisions to the 1965 Manual of Operations.

On June 19, 1975, the FDA proposed National Shellfish Safety Program Regulations in the ***Federal Register*** (FDA, 1975). There was considerable discussion at the 1975 and 1977 Workshops concerning these proposed regulations. After evaluation of the comments received as a result of the proposed rules, the FDA determined that promulgating federal regulations would not likely achieve NSSP goals. Subsequently, FDA decided revision of the 1965 Manual of Operations was the best approach for strengthening the NSSP. (See Federal Register of February 26, 1985, 50 F.R. 7797)

During this period, many state shellfish control agencies began questioning the uniformity and effectiveness of shellfish programs in other states. These states and FDA began exploring methods for strengthening the NSSP that would not involve federal regulations. In reviewing other approaches, it was noted that since 1950 the National Conference of Interstate Milk Shippers (NCIMS), a successful voluntary public health program, has been successful in assuring a nationwide safe and wholesome milk supply. The NCIMS was consulted for direction and advice.

The success of the NCIMS program prompted state shellfish control officials and FDA to select the NCIMS program as a model for developing a shellfish organization. In 1982, a delegation of state officials from 22 states met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC). The ISSC is composed of state shellfish regulatory officials, industry officials, FDA, and other federal agencies.

The ISSC organization provides the forum for state regulatory officials to establish uniform national guidelines and to exchange information regarding sources of safe shellfish. The first annual meeting was held in New Orleans, Louisiana in August 1983. At this conference, the ISSC adopted the 1965 NSSP Manuals of Operation, as well as formal procedures for adopting changes to the Manuals. These documents provided the basis for an Interstate Shellfish Sanitation Program (ISSP). In March 1984, FDA entered into a Memorandum of Understanding (MOU) with the ISSC. The MOU formalized the FDA's relationship with the ISSC and established the ISSC as a federal-state-industry cooperative body. The ISSP, acknowledged in the 1984 MOU, is a set of guidelines for the sanitary control of shellfish, adequate to insure that shellfish will be safe and sanitary.

At its second annual meeting in Orlando, Florida in August 1984, the ISSC accepted for review a revision of Part I of the 1965 NSSP Manual of Operations. At the third annual meeting in Cherry Hill, New Jersey, in August, 1985, the ISSC adopted an updated Part I of the NSSP Manual of Operations (published in 1986), and accepted for review a revision of Part II of the 1965 NSSP Manual.
In preparing the draft revision of the 1965 NSSP Manual of Operations, FDA relied principally on the following sources:

1. The draft revision of the Proposed National Shellfish Safety Program Regulations, Part 951;
2. The 1965 NSSP ***Manual of Operations, Part I, Sanitation of Growing Waters; Part II, Sanitation of the Harvesting and Processing of Shellfish***; and ***Part III, Appraisal of State Shellfish Sanitation Programs***, U.S.Department of Health, Education, and Welfare, Public Health Service Publication No. 33;
3. The National Shellfish Sanitation Program Workshop Proceedings for 1968, 1971, 1973, 1974, and 1977;
4. The Environmental Protection Agency rules and regulations (40 CFR Parts 400, et seq.) concerning water pollution control and shellfish waters;
5. Other federal laws and regulations concerning quality of shellfish and shellfish growing areas;
6. Existing state rules and regulations concerning shellfish growing area control and water quality criteria;
7. Analytical methods accepted by the American Public Health Association, Association of Official Analytical Chemists, American Society of Testing Materials, and other voluntary standard-setting organizations relating to shellfish and shellfish waters; and
8. Recommendations from the Interstate Shellfish Sanitation Conference.

Developing the updated Manual was a cooperative effort between FDA and the ISSC. Initial drafts were prepared by FDA and presented to the ISSC and other interested parties for review and comment. Comments were incorporated into drafts after consultation with the ISSC, and the final revision was presented to the ISSC for formal endorsement in 1986. In updating the 1965 Manual, the harvesting and the processing of shellfish continued to be recognized as two distinct phases of operation in the shellfish industry. Therefore, the updated Manual was published in two parts; Part I: ***Sanitation of Shellfish Growing Areas*** (1986); and Part II: ***Sanitation of the Harvesting, Processing and Distribution of Shellfish*** (1987). Part I of the Manual continued as a guide for preparing state shellfish laws and regulations pertaining to sanitary control of shellfish harvest area classification, laboratory procedures, relaying, patrol operations and marine biotoxin. Part II of the Manual continued as a guide for operating, inspecting and certifying shellfish shippers, processors and depuration facilities; and for controlling interstate shipments of shellfish. Part III: *Public Health Service Appraisal of State Shellfish Sanitation Programs* was discontinued by the FDA.

In addition to setting forth the principles and requirements for the sanitary control of shellfish produced and shipped in interstate commerce in the U.S., the updated Manual was intended to be used by the states to control the harvesting and handling of shellfish for recreational and intrastate commercial use. Most coastal states believe that consumers residing in their state should be provided equal public health protection, as are consumers in other states under the interstate certification program. To accomplish this, states may apply the same water quality and harvesting restrictions on non-interstate shellfish activities as on interstate activities. Having uniform intra and interstate programs also greatly facilitates the effective implementation and regulation of all shellfish harvesting activities, and results in the most

efficient utilization of public health resources.
The updated Manual was also to be used by FDA as the basis for evaluating foreign shellfish sanitation programs. To accomplish this, FDA seeks to establish international MOUs with official agencies in those foreign countries that wish to export shellfish to the U.S. An MOU is established after the foreign government demonstrates to FDA that the government has laws or regulations equivalent to those published in the Manual, and that the foreign program was supported by trained personnel, laboratory facilities, and other resources as may be necessary to exercise control over the export shellfish industry. Once a country has an effective MOU, the shellfish control authority submits certificates of their certified shellfish dealers to the FDA. The FDA publishes the names of these certified shellfish shippers in the Interstate Certified Shellfish Shippers List as an approved source of shellfish.

In the years 1986 through 1995, under its 1984 Memorandum of Understanding with the Interstate Shellfish Sanitation Conference (ISSC), the FDA published seven revisions of the Manual. Between 1995 and 2003, the ISSC/FDA has published two revisions of the NSSP Guide for the Control of Molluscan Shellfish. The revisions were the result of the findings and recommendations from the annual meetings of the ISSC and reflected mutual FDA and ISSC concurrence. A full listing of all editions of the Manual of Operations for the National Shellfish Sanitation Program can be found in the reference portion of this section.
The intent in establishing the ISSP Program was to modify the manuals into a model ordinance format and include the ordinance with other shellfish related documents and procedures into an ISSP Handbook.

INTERSTATE SHELLFISH SANITATION PROGRAM

During development of the ISSC, FDA, state regulatory officials and the industry worked diligently to establish uniform guidelines and to exchange reliable information on sources of safe shellfish, and to provide revisions to the NSSP Manual as necessary through formal ISSC procedures. These efforts have been conducted under the umbrella of the March 1984 Memorandum of Understanding (MOU) between the FDA and the ISSC. The Memorandum formally established a FDA cooperative relationship with both the states and shellfish industry. The ISSC continues to play an important role in assuring that uniform shellfish control measures are adopted, and that those measures are enforced consistently by state regulatory authorities.

One of the foremost goals of the ISSC has been the adoption of a Model Ordinance which would embody the principles and requirements of the ISSP. Adoption of the Model Ordinance by each of the ISSC participating states implies commitment by each state to provide the necessary legal authority and resources to implement these regulatory requirements. Adoption also ensures uniformity across state boundaries and enhances public confidence in shellfish product.

Development of the Model Ordinance began in 1987 with the establishment of the ISSC Model Ordinance Committee, which included representatives of the FDA, the states and the industry. The Model Ordinance Committee worked to incorporate the NSSP Manual into the format of regulation and to resolve inconsistencies within the Manual. The initial draft Ordinance was presented to and adopted by the ISSC at its 1992 meeting. The FDA responded with comments and requested development of a strategy for the transition from the NSSP Manual to the Model Ordinance as the basis for the National Shellfish Sanitation Program and for use by FDA in reviewing state shellfish sanitation programs.

The ISSC recognized the importance of retaining many of the elements of the NSSP Manual that should not be incorporated into an ordinance. To accomplish this, the Model Ordinance Committee recommended development of the Interstate Shellfish Sanitation Program Handbook which would include, in addition to the Model Ordinance, guidance documents concerning important components of the NSSP, references, public health reasons for NSSP requirements, and procedures which support or are used in the NSSP. The ISSC Constitution, By-laws and Procedures were revised to recognize an Interstate Shellfish Sanitation Program (ISSP) and its Model Ordinance as replacing the NSSP on January 1, 1998 as the effective rules governing participation in the ISSC. However, further discussions by the ISSC Executive Board and FDA regarding recognition and identify of the Program have resulted in retention of the National Shellfish Sanitation Program title hereafter referred to as the National Shellfish Sanitation Program (NSSP).

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