

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

Page 1 of 7

Purpose.

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

Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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