

# Texas Molluscan Shellfish Rules



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**TEXAS DEPARTMENT OF HEALTH**  
**BUREAU OF FOOD AND DRUG SAFETY**  
**SEAFOOD SAFETY DIVISION**

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## MOLLUSCAN SHELLFISH

**Section 241.50. Definitions.** The following words and terms, when used in this subchapter of this title, relating to molluscan shellfish, shall have the following meanings unless the context clearly indicates otherwise.

- (1) Act - The Texas Health and Safety Code, Chapter 436, Aquatic Life.
- (2) Air gap - 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) Application process - The filing of an application for certification with the Texas Department of Health followed by an inspection by an authorized agent confirming compliance with the rules.
- (4) Approved area - A classification used to identify a harvest area where harvest for direct marketing is allowed.
- (5) Approved source - A source of molluscan shellfish acceptable to the director (commissioner of health).
- (6) Aquaculture - The cultivation of seed in natural or artificial growing or harvest areas, or the cultivation of molluscan shellstock other than seed in harvest areas.
- (7) Assure - To make certain.
- (8) Authorized agent - An employee of the Texas Department of Health who is designated by the commissioner to enforce provisions of these sections.
- (9) Backflow - 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 - 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 - A receptacle for washing shucked molluscan shellfish that uses forced air as a means of agitation.

(12) Certificate (molluscan shellfish certificate of compliance) - A numbered document issued by the commissioner which authorizes a dealer to process molluscan shellfish for sale.

(13) Certification or certify - The issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:

(A) permission from the department to conduct the activity; and

(B) initial compliance with the requirements of §§241.50 - 241.71 of this title (relating to Molluscan Shellfish).

(14) Certification number - The unique identification number issued by the commissioner 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 the following terms:

(A) shellstock shipper (SS);

(B) shucker/packer (SP);

(C) repacker (RP); and

(D) depuration processor (DP).

(15) Certified location - A plant or place of business that has been inspected by the Seafood Safety Division of the department and for which a molluscan shellfish certificate of compliance has been issued.

(16) Coliform group - All of the aerobic and facultative anaerobic, gram negative, non spore-forming, rod-shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 degrees Fahrenheit (35 degrees plus or minus 0.5 degrees Centigrade).

(17) Commingle or commingling - The act of combining different lots of molluscan shell stock or shucked molluscan shellfish.

(18) Commissioner - The commissioner of health for the State of Texas and the executive head of the department.

(19) Compliance schedule - A written schedule that provides a specific time period to correct critical, key and other deficiencies.

(20) Conditionally approved area - A classification used to identify a harvest area which meets the criteria for the approved classification except under certain conditions described in a management plan established by the SSD.

(21) Conditionally restricted area - A classification used to identify a harvest area which meets the criteria for the restricted classification except under certain conditions described in a management plan established by the SSD.

(22) Container - The physical material in contact with or immediately surrounding molluscan shellfish that confines it into a single unit.

(23) Corrosion resistant materials - 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.

(24) Critical Control Point (CCP) - 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.

(25) Critical deficiency - A condition or practice which:

(A) results in the production of a product that is adulterated, decomposed, misbranded or unwholesome; or

(B) presents a threat to the health or safety of the consumer.

(26) Critical limit - 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.

(27) Cross connection - 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 include bypass arrangements, jumper connection, removable sections, swivel or change over devices, or other devices through which backflow could occur.

(28) Cull - To remove dead or unsafe molluscan shell stock from a lot of molluscan shell stock.

(29) Dealer - A person to whom certification is issued for the activities of molluscan shell stock shipper, shucker-packer, repacker, or depuration processor.

(30) Deficiency – A condition or practice that is a violation of the Act or rules.

(31) Department - The Texas Department of Health (TDH), 1100 West 49th Street, Austin, Texas 78756, or its successor state agency, having the responsibility for the enforcement of laws concerning the safety of the food supply, including molluscan shellfish growing area classification and certification of molluscan shellfish dealers.

(32) Depletion - The removal, under the direct control of the Texas Parks and Wildlife Department, of all existing commercial quantities of market-size molluscan shellfish from a harvest area classified as prohibited.

(33) Depuration or depurate - The process of reducing the level of bacteria and viruses that may be present in molluscan shellfish by using a controlled aquatic environment as the treatment process.

(34) Depuration plant - A place where depuration of molluscan shellfish occurs.

(35) Depuration Processor (DP) - A person who harvests or receives molluscan shell stock from harvest areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such molluscan shell stock to an approved depuration process.

(36) Direct marketing - The sale for human consumption of molluscan shellfish which:

(A) does not require depuration or relaying prior to sale; or

(B) have been subjected to depuration or relaying activities.

(37) Director - The executive head (commissioner of health) of the Texas Department of Health.

(38) Dry storage - The storage of molluscan shell stock out of water.

(39) Durable material - Material with the ability to exist for several years without significant deterioration and able to withstand normal daily use associated with molluscan shellfish operations.

(40) Easily cleanable - 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.

(41) Facility - A structure.

(42) FDA - The United States Food and Drug Administration or its successor agency, the federal agency in which regulation of foods, including the Cooperative Shellfish Program, is vested.

(43) Food contact surface - An equipment surface or utensil that normally comes into direct or indirect contact with shucked molluscan shellfish.

(44) Food safety hazard - Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(45) Gatherer - Person who takes molluscan shellfish by any means from a growing area designated by the commissioner for delivery to a depuration plant.

(46) GLO - The Texas General Land Office, 1700 North Congress, Austin, Texas 78701, or its successor agency, the state agency having the responsibility for the enforcement of laws concerning all state lands, including leasing of wetland bottom for private oyster leases.

(47) Growing area - Any site that supports or could support the propagation of molluscan shell stock by natural or artificial means.

(48) HACCP - 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).

(49) HACCP Plan - A written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in Title 21, Code of Federal Regulations (CFR), §123.6.

(50) Harvest - The act of removing molluscan shell stock from growing or harvest areas and its placement on or in a manmade conveyance or other means of transport.

(51) Harvest area - An area that contains commercial quantities of molluscan shell stock and may include aquaculture sites and facilities.

(52) Harvester - A person who takes molluscan shell stock by any means from a harvest area.

(53) Heat shock - The process of subjecting molluscan shell stock 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 molluscan shellfish.

(54) ISSC - The Interstate Shellfish Sanitation Conference. The ISSC consists of agencies from molluscan shellfish producing and receiving states, FDA, the molluscan shellfish industry, and the National Marine Fisheries Service of the U.S. Department of Commerce.

(55) Key deficiency - A condition or practice that may result in adulterated, decomposed, misbranded or unwholesome product.

(56) Label - Any written, printed or graphic matter affixed to or appearing upon any package containing molluscan shellfish.

(57) License - The document issued by the Texas Parks and Wildlife Department, under the Texas Parks and Wildlife Code, Chapter 47 or Chapter 76, which authorizes a person to harvest or transport molluscan shell stock for commercial sale.

(58) Lot of molluscan shell stock - A single type of bulk molluscan shell stock or containers of molluscan shell stock of no more than one day's harvest from a single defined harvest area gathered by one or more harvesters.

(59) Lot of molluscan shell stock for depuration - Molluscan shell stock harvested from a particular area during a single day's harvest and delivered to one depuration plant.

(60) Lot of shucked molluscan shellfish - A collection of containers of no more than one day's shucked molluscan shellfish product produced under conditions as uniform as possible, and designated by a common container code or marking.

(61) Marina - 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 - Any poisonous compound produced by marine microorganisms and accumulated by molluscan shell stock. Examples of toxin producing marine microorganisms include *Alexandrium* spp. (Proto gonyaulax species) and *Karenia breves*.

(63) Market shellfish - Molluscan shellfish which are, may be, or have been harvested and/or prepared for sale for human consumption as a fresh or frozen product.

(64) Molluscan shellfish - All species of:

(A) oysters, clams or mussels, whether:

(i) shucked or in the shell;

(ii) fresh or frozen; and

(iii) whole or in part.

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

(65) Monoculture - The culture of a single molluscan shellfish species.

(66) MPN - Most probable number.

(67) Nursery products - Molluscan shellfish which do not exceed 10% of the market weight or that are six months or more growing time from market size.

(68) Open area - A molluscan shellfish growing area where the harvesting for sale, harvesting for transplant, or gathering for depuration of molluscan shellfish is allowed. An open area status may be placed on any one of the classified area designations except for a prohibited area.

(69) Open water aquaculture - The cultivation of molluscan shellfish in natural molluscan shellfish harvest areas.

(70) Other deficiency - A condition or practice that is not defined as critical or key, but is of a public health significance and, if left uncorrected, could result in a key or critical deficiency.

(71) Pack (packing) - All activities involved in placing molluscan shellfish in containers.

(72) Person - Any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, government or governmental subdivision or agency, partnership, association, corporation or other legal entity.

(73) Poisonous or deleterious substance - A toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in molluscan shellfish to protect public health.

(74) Polyculture - The cultivation of:

(A) two or more species of molluscan shellfish; or

(B) molluscan shellfish with other species in a common environment.

(75) Potable water - A water supply that is suitable for human consumption.

(76) Principal display panel - The part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of retail sale.

(77) Process batch - A quantity of molluscan shell stock 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.

(78) Process water - The water used in the scheduled depuration process.

(79) Prohibited area - A classification used to identify a harvest area where the harvest of molluscan shell stock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.

(80) Records - Written documents required to be maintained under this chapter.

(81) Relaying – Transferring of 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.

(82) Repacker (RP) - A dealer who buys, repacks and sells molluscan shellfish. Packers are not authorized to shuck shellfish.

(83) Repacking molluscan shellstock - The practice of removing molluscan shell stock from containers and placing it into other containers.

(84) Restricted area - A classification used to identify a harvest area where harvesting shall be by special license and the molluscan shell stock, following harvest, is subjected to a suitable and effective treatment process through transplanting or gathering for depuration.

(85) Safe materials - 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.

(86) Sanitation control record - Records that document the monitoring of sanitation practices and conditions.

- (87) Sanitize - 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.
- (88) Seed - Molluscan shell stock which is less than market size.
- (89) Sewage - Refuse liquids or waste matter, including hand sink drainage.
- (90) Sewer - An artificial, usually subterranean, conduit to carry off sewage and/or surface water.
- (91) Sewerage - The removal and disposal of sewage and surface water by sewers.
- (92) Shell stock - Live molluscan shellfish in the shell.
- (93) Shell stock packing - The process of placing molluscan shell stock into containers for introduction into commerce.
- (94) Shellstock Shipper (SS) - A dealer who grows, harvests, buys, or repacks and sells molluscan shell stock. They are not authorized to shuck molluscan shellfish or to repack shucked molluscan shellfish. A shellstock shipper may also ship shucked molluscan shellfish.
- (95) Shucked shellfish - Molluscan shellfish, whole or in part, from which one or both shells have been removed.
- (96) Shucker/Packer (SP) - A person who shucks and packs molluscan shellfish. A shucker-packer may act as a shellstock shipper or may repack molluscan shellfish originating from other certified dealers.
- (97) SSD - The Seafood Safety Division of the Texas Department of Health to which responsibility to classify molluscan shellfish growing areas and to regulate harvesting, processing, and/or shipping of molluscan shellfish is delegated.
- (98) Take - Catch, hook, net, snare, trap, kill, or capture by any means, including the attempt to take.
- (99) Temperature Control - The management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means that is capable of

lowering the temperature of the shellstock and maintaining it at 45 degrees Fahrenheit (7.2 degrees Centigrade) or less.

(100) TDA - The Texas Department of Agriculture, 1700 North Congress, Austin, Texas 78701, or its successor state agency having responsibility for enforcement of laws concerning licensing of aquaculture.

(101) TCEQ - The Texas Commission on Environmental Quality, 12100 Park 35 Circle, Austin, Texas 78753, or its successor state agency having the responsibility for the enforcement of laws concerning water supplies and discharges of water or wastewater in Texas.

(102) TPWD - The Texas Parks and Wildlife Department, 4200 Smith School Road, Austin, Texas 78744, or its successor state agency having the responsibility for the enforcement of laws concerning harvesting and depletion of molluscan shellfish resources.

(103) Transaction record - The form or forms used to document each purchase or sale of molluscan shellfish at the wholesale level, including molluscan shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

(104) Transplant (transplanting) - To transfer molluscan shell stock from a harvest area classified as restricted or conditionally restricted or from a conditionally approved area in the closed status to a harvest 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 molluscan shell stock, by using the ambient environment as the treatment process.

(105) Water closet - A toilet bowl and its accessories surrounded by walls or partitions.

(106) Wet storage - The temporary storage, by a dealer, of molluscan shell stock from harvest 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.

#### **Section 241.51. Adoption of National Shellfish Sanitation Program (NSSP) Model Ordinance.**

(a) The department hereby adopts by reference the National Shellfish Sanitation Program Model Ordinance, as amended. If the requirements of this chapter are more stringent than the requirements of other adopted requirements, then this chapter's requirements prevail and must be complied with.

(b) Those persons required to obtain a certificate from the department under this chapter shall comply with all of the requirements of this chapter, the Texas Aquatic Life Act, Health and

Safety Code, Chapter 436, and the requirements of the National Shellfish Sanitation Program Model Ordinance, as amended.

**Section 241.52. Growing Area Classification.** The authority conferred on the commissioner by the Health and Safety Code, §436.101 is hereby delegated pursuant to Health and Safety Code §436.003(a) to the bureau chief of the Bureau of Food and Drug Safety, or his/her designee, under the provisions of this section. The bureau chief shall:

(1) designate coastal water (as defined in the rules of the Texas Parks and Wildlife Department, 31 TAC, Chapter 51) for the purposes of taking molluscan shellfish as:

- (A) an approved area;
- (B) a conditionally approved area;
- (C) a restricted area;
- (D) a conditionally restricted area; or
- (E) a prohibited area.

(2) designate classified growing areas as open areas or closed areas.

**Section 241.53. Shell Stock Transplanting and Gathering for Depuration.**

(a) Any person who wants to transplant molluscan shell stock from a harvest area classified as conditionally approved, restricted, or conditionally restricted shall make application to the TPWD for a permit to transplant molluscan shell stock.

(b) No person may transplant molluscan shell stock without a valid transplant permit from the TPWD.

(c) Each person who transplants molluscan shell stock shall provide the following information to the department:

- (1) the source of the molluscan shell stock;
- (2) the quantity of molluscan shell stock;
- (3) the destination private oyster lease of the molluscan shell stock; and
- (4) the date the transplant permit expired or was canceled.

(d) No person shall harvest transplanted molluscan shell stock until the molluscan shell stock has been in waters meeting the approved area criteria for a minimum period of 14 consecutive days.

(e) Any person, firm, or corporation engaging wholly or part-time in the business of gathering molluscan shellfish from areas designated by the department for delivery to a controlled depuration plant shall be required to hold a current permit issued specifically for this purpose by the TPWD, with a copy in the files of the department.

(f) Permits for gathering for depuration shall be granted subject to the following conditions:

(1) all gathering and transporting of molluscan shellfish for depuration must be accomplished between the designated times for sunrise and sunset as set by the National Weather Service for that locale;

(2) all boats and vehicles used to gather or transport molluscan shellfish for depuration shall be conspicuously marked in a manner established by the TPWD. All boats or vehicles so marked shall be thoroughly cleaned and sanitized and the marking removed prior to use for harvesting or transporting treated molluscan shellfish or other molluscan shellfish approved for harvest or sale;

(3) molluscan shellfish gathered for depuration shall not be containerized in any manner resembling normal sales of molluscan shell stock from approved harvest areas. Containers used for normal sales of molluscan shell stock from approved areas shall not be stored on any boat or vehicle used to gather or transport molluscan shellfish for depuration. Containers of untreated molluscan shell stock shall be tagged or labeled as "NOT FOR HUMAN CONSUMPTION";

(4) a copy of the TPWD permit shall be kept on board the vessel at all times during gathering and transporting of molluscan shell stock for depuration;

(5) all gathering and transporting of molluscan shellfish for depuration shall be conducted under the immediate surveillance of a commissioned officer of the TPWD, or other commissioned officer as provided by law. The responsibility for obtaining this surveillance rests with the depuration plant owner or operator. A commissioned officer shall be present for every ten gatherers or gathering boats or for any portion of ten gatherers or boats working for any single depuration plant. An officer shall not concurrently serve as surveillance officer for more than one depuration plant. Separate surveillance officers shall be present for gatherers from the same plant working concurrently in more than one geographic area. The surveillance officer shall have all molluscan shell stock under his or her control at all times during transport from the gathering area to the depuration plant. The surveillance officer shall prepare a written report stating the gathering area(s), species, and quantity of molluscan shellfish gathered each day by

each gatherer under his or her surveillance. One copy of the report shall accompany the molluscan shell stock to the depuration plant and be maintained in the plant files for not less than one year from the actual date of gathering. One copy of the report shall be forwarded to the Texas Department of Health, Seafood Safety Division, 1100 West 49th Street, Austin, Texas 78756;

(6) all molluscan shellfish gathered under authority of a depuration permit shall be delivered only to the depuration plant specified in the permit, on the day gathered, and shall be depurated or disposed of as waste; and

(7) molluscan shellfish gathered for depuration shall be protected at all times during gathering and transporting to prevent contamination and undue stress.

(g) Vessels and all other equipment coming in contact with molluscan shell stock during handling or transport for transplant or depuration shall be thoroughly cleaned before the vessels or equipment are used to transport or handle molluscan shellfish for direct marketing.

#### **Section 241.54. Molluscan Shellfish Aquaculture.**

(a) The following activities are exempted from the requirements in this section:

(1) hatcheries;

(2) nursery products which do not exceed 10% of the market weight; and

(3) nursery products that are six months or more growing time from market size.

(b) Aquaculture encompasses both open water and land based monoculture and polyculture.

(c) Any person who performs open water aquaculture or operates an aquaculture facility to raise molluscan shellfish for human consumption shall obtain:

(1) a permit(s) or authorization from the department, GLO, TPWD, TDA, and/or TCEQ for the activity or for construction and functioning of his/her facility;

(2) a harvester's license; and

(3) certification as a dealer, where necessary.

(d) Molluscan shellfish aquaculture shall be practiced only in strict compliance with the provisions of the authorization issued by the department for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

(e) Prior to beginning any activity, a department approved aquaculturist shall obtain the written permission of the department for use of the site and any construction.

(f) 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.

(g) Molluscan shellfish cultured in any open water or land based system meeting the criteria for the approved classification in the open status or the open status of the conditionally approved classification of a harvest area throughout the culture period may be immediately marketed.

(h) Any molluscan 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 that 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.

(i) Only drugs sanctioned by the FDA shall be used for molluscan shellfish treatment.

(j) Harvesting, processing, storage, and shipping requirements for molluscan shellfish raised in aquaculture shall be the same as the requirements for wild molluscan shellfish specified in this subchapter of this title (relating to Molluscan Shellfish).

(k) Complete and accurate written records shall be maintained for at least two years by the aquaculturist and shall include the:

- (1) source of molluscan shellfish, including seed if the seed is from harvest areas that 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.

(l) Seed may come from any growing area, or from any harvest area in any classification, provided that:

- (1) the source of the seed is approved by the department;

(2) seed from growing areas or harvest areas in the restricted or prohibited classification has acceptable levels of poisonous or deleterious substances; and

(3) seed from growing areas or harvest areas in the prohibited classification is cultured for a minimum of six months.

**Section 241.55. Land Based Aquaculture.**

(a) Operational plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved in writing by the department 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 molluscan 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 molluscan 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 molluscan 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 harvest areas;

(10) collection of information on the microbial and chemical quality of molluscan 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 molluscan shell stock will be harvested, processed if applicable, and sold.

(b) Water systems.

(1) If the aquaculture system is of a continuous flow through design, water from a harvest area classified as approved in the open status, or in the open status of the conditionally approved classification may be used without treatment at all times molluscan shellfish are held.

(2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:

(A) not contaminate molluscan shellfish with residues that would render the product adulterated;

(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 molluscan shell stock 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 density of less than 14 MPN per 100 ml in each water sample collected from the holding tank.

(c) Molluscan shell stock quality.

(1) Molluscan shell stock cultured in any system using water meeting the criteria for the approved classification in the open status 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 molluscan shell stock may be used in direct marketing.

(3) Molluscan shell stock cultured in a closed or recirculating system which does not meet the requirements of subsection (b)(3)(A) and (B) of this section shall be relayed or depurated prior to direct marketing.

**Section 241.56. Polyculture Systems.**

(a) A polyculture system shall:

(1) meet all requirements in §241.55 of this title (relating to Land Based Aquaculture); and

(2) provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested.

(b) A polyculture system shall include in its operational plan requirements to:

(1) monitor for human pathogens, animal drugs, and/or other poisonous or deleterious substances that might be associated with polyculture activities; and

(2) subject all harvested molluscan shell stock to relaying or depuration if human pathogens, animal drugs, and/or other poisonous or deleterious substances exist at levels of public health significance.

**Section 241.57. Molluscan Shellfish Harvesting and Handling.**

(a) Harvesters. Any harvester who engages in molluscan shell stock packing as defined in this subchapter of this title (relating to Molluscan Shellfish) shall:

(1) be a dealer; or

(2) pack molluscan shell stock for a dealer.

(b) Vessels.

(1) The dealer shall not accept molluscan shell stock unless all vessels used to harvest and transport molluscan shell stock are properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the molluscan shell stock.

(A) Decks and storage bins shall be constructed and located to prevent bilge water or polluted overboard water from coming into contact with the molluscan shell stock.

(B) Bilge pump discharges shall be located so that the discharge shall not come into contact with the molluscan shell stock.

(C) Bags or other containers used for storing molluscan shell stock shall be clean and fabricated from safe materials.

(D) Boat decks and storage bins used in the harvest or transport of molluscan shell stock for direct marketing shall be:

(i) kept clean with potable water or water from a harvest area in the open status of the approved classification or in the open status of the conditionally approved classification; and

(ii) constructed so that water does not stand on the deck or in the storage bin.

(E) Coverings shall be provided on harvest boats to protect molluscan shell stock from exposure to 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 molluscan shell stock or from vessels that buy molluscan shell stock, but only into an appropriate sewage disposal system.

(2) An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

(3) Portable toilets shall:

(A) be used only for the purpose intended;

(B) be secured while on board and located to prevent contamination of molluscan shell stock by spillage or leakage;

(C) be emptied only into an appropriate sewage disposal system;

(D) be cleaned and sanitized before being returned to the boat; and

(E) be cleaned only with equipment that is not used for washing or processing food.

(4) Use of other receptacles for sewage disposal may be approved by the department if the receptacles are:

(A) constructed of impervious and cleanable materials; and

(B) meet the requirements in subsection (c)(3) of this section.

(d) Molluscan shell stock washing.

(1) Molluscan shell stock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable.

(2) The harvester shall be primarily responsible for washing the molluscan shell stock.

(3) If molluscan shell stock washing is not feasible at the time of harvest, the dealer shall assume this responsibility.

(4) Water used for molluscan shell stock washing shall be obtained from:

(A) a potable water source; or

(B) a harvest area in the:

(i) open status of the approved classification; or

(ii) open status of the conditionally approved classification.

(5) If the harvester or dealer elects to use tanks or a water system to wash molluscan shell stock, the molluscan shell stock washing system shall be constructed, operated, and maintained in compliance with an approved HACCP plan in accordance with §241.63 of this title (relating to General HACCP Requirements), and §241.64 of this title (relating to General Sanitation Requirements).

(e) Molluscan shell stock identification.

(1) Each harvester shall affix a tag to each bag or container of molluscan shell stock that shall be in place while the molluscan shell stock is being transported to a dealer.

(2) If the molluscan shell stock is harvested at more than one location, each container shall be tagged at its harvest area.

(3) When the harvester is also the dealer, the harvester has the option to tag the molluscan shellfish with a harvester's tag or a dealer's tag meeting all requirements of this section.

(4) The harvester's tags shall:

(A) be durable, waterproof and approved by the department prior to use;  
and

(B) be at least 2-5/8 by 5-1/4 inches (6.7 by 13.3 cm) in size.

(5) The harvester's tag shall contain the following indelible, legible information in the order specified:

(A) the commercial oyster boat captain's license number (issued by TPWD), the captain's name, and any one of the following:

(i) the oyster boat license number;

(ii) the boat state registration number; or

(iii) the documented boat name;

(B) the date of harvest;

(C) the most precise identification of the harvest location as is practicable including the initials of the state of harvest, and any department designation of the harvest area by indexing, administrative or geographic designation;

(D) when the molluscan shell stock has been 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)";

(E) the type and quantity of molluscan shell stock; and

(F) 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) Molluscan shell stock harvested during the period April 1 through October 31 that will not be refrigerated within the Time-To-Refrigeration guidelines required in §241.61 of this title (relating to Molluscan Shell Stock Temperature Control) shall not be harvested before

6:00 a.m. and shall be placed under refrigeration as designated in §241.61 of this title by 8:00 p.m. each day and shall be identified, stored, and processed separately from molluscan shell stock that is refrigerated within these Time-To-Refrigeration guidelines.

(7) Molluscan shell stock harvested and held exempt from the Time-To-Refrigeration guidelines in paragraph (6) of this subsection shall:

(A) be tagged with a harvester tag meeting all other requirements that shall also be over stamped on both sides with the words “FOR SHUCKING BY A CERTIFIED DEALER” in ink that shall be neon green in color in letters at least one-half inch in height. This special harvester tag shall be placed on each container of molluscan shell stock at the conclusion of harvesting of this exempt molluscan shell stock and before harvesting of any other molluscan shell stock. This special harvester tag shall remain attached to each container until the molluscan shell stock is shucked;

(B) not be commingled with any other molluscan shellfish and shall be stored separately on harvest boats and at any certified location; and

(C) be shucked and placed in containers bearing the consumer information language adopted by the ISSC, or an equivalent approved in writing by the SSD prior to use, unless the invoice and bill of lading for shipment of this exempt molluscan shell stock to another dealer both contain the following statement: “FOR SHUCKING BY A CERTIFIED DEALER.” All dealer tags attached to such molluscan shell stock shall be over stamped identical to the harvester tag.

(8) If the molluscan shell stock is removed from the original bag or container, the tag on the new bag or container shall meet all the requirements in subsection (e) of this section.

(f) Harvester records.

(1) Each harvester who harvests molluscan shell stock during the period April 1-October 31 shall maintain written records for each date molluscan shell stock is harvested that show the time the first molluscan shell stock is harvested, the time harvesting ends, and the time molluscan shell stock is unloaded from the boat.

(2) If molluscan shell stock is harvested and held exempt from the Time-To-Refrigeration guidelines in subsection (e)(6), (7), and (8) of this section, the harvester records shall also include the time that harvesting of this exempt molluscan shell stock ends and the time that harvesting of other molluscan shell stock begins.

(3) These records shall be provided to the dealer with the molluscan shell stock and shall be maintained as part of the dealer’s records.

(g) Any molluscan shellfish in the possession of a person holding a valid license issued by TPWD under Texas Parks and Wildlife Code, Chapter 47 or Chapter 76, shall be considered to be harvested for human consumption and offered for sale for food in Texas.

(h) Harvesters shall:

(1) be responsible for control of their molluscan shell stock until acceptance by a dealer;

(2) sell their molluscan shell stock only to a currently certified shellfish dealer;

(3) be required to deliver their molluscan shell stock to a dealer the same day the molluscan shell stock is harvested. Delivery of the molluscan shell stock means packing the molluscan shell stock into an approved container, transfer of the molluscan shell stock from the boat to a certified location, and acceptance of the molluscan shell stock by the dealer; and

(4) be required to transport molluscan shell stock on ice or at air temperatures of 45 degrees Fahrenheit or less if the time from unloading the boat until the product is accepted by a dealer and placed under refrigeration at a certified location will exceed two hours.

(i) If the harvester transports molluscan shell stock other than by boat to a certified location, the harvest boat captain must accompany the molluscan shell stock until acceptance by the dealer.

(j) It is illegal for harvesters to sell molluscan shell stock directly to the public.

### **Section 241.58. Certification Requirements.**

(a) No person shall engage in any activity requiring a certificate in §§241.50 - 241.71 of this title (relating to Molluscan Shellfish) without having applied for and obtained an annual numbered certificate of compliance pertaining to the particular activity from the commissioner. No certificate will be issued without a HACCP plan in accordance with §241.63 of this title (relating to General HACCP Requirements) that is acceptable to the SSD.

(b) Dealer certification.

(1) Shucker/packer. Any person who shucks molluscan shellfish shall be certified as a shucker/packer.

(2) Repacker.

(A) Any person who repacks shucked molluscan shellfish shall be certified as a shucker/packer or repacker.

(B) Any person who repacks molluscan shell stock shall be certified as a shellstock shipper, shucker/packer, or repacker.

(C) A repacker shall not shuck molluscan shellfish.

(3) Shellstock shipper. Any person who ships and receives molluscan shell stock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker/packer.

(c) Time Period for Processing and Issuing a Certificate of Compliance.

(1) The date a certificate of compliance application is received is the date the original application reaches the department.

(2) The period for processing an application begins on the date the SSD receives a compliance memo from an authorized agent of the state, which states the facility is in compliance with all applicable rules, including the HACCP requirements described in §241.63 of this title.

(3) An application for a certificate of compliance is complete when:

(A) the SSD has received, reviewed and found acceptable the application information required by §§241.50 - 241.71 of this title (relating to Molluscan Shellfish); and

(B) the SSD receives a compliance memo from an authorized agent of the state, which states the facility is in compliance with all applicable rules, including the HACCP requirements described in §241.63 of this title.

(4) A Certificate of Compliance is valid from September 1 - August 31 of each year, or part thereof.

(d) Each dealer shall have a Texas business address at which inspections of facilities, activities, equipment, or records can be made.

(e) Each dealer shall accept molluscan shellfish only if they are taken from areas approved by the department, or obtained from sources outside the State of Texas that are approved by the department. If obtained from sources outside of the State of Texas, the molluscan shellfish must be from areas approved by the appropriate state or other government authority having jurisdiction and must be obtained from dealers currently certified by the appropriate state or other government authority. Molluscan shellfish obtained from sources other than those outlined in this section shall not be sold, offered for sale, or held for sale in Texas.

(f) Prior to beginning construction of a new molluscan shellfish processing plant, or major remodeling of an existing molluscan shellfish processing plant (which includes, but is not limited to: any process new to that particular plant; any change of product flow; or any enlarging of the plant structure), complete, legible plans showing the floor plan of the building, with dimensions drawn to scale, location of equipment, doors, floor drains, etc., and written, complete operational procedures for all phases of the activity, including flow of the product, shall be submitted to the SSD for review and written approval. Additional plans of the entire premises may be required showing all structures, as well as all water wells and septic systems with related distances and a statement of specifications as to type, sizes, design, date installed, etc. Plans shall be submitted to the SSD no less than 30 days prior to initiating a new process or beginning construction. No operations shall be conducted while any construction or related activity that has the potential to contaminate the product is occurring inside the plant.

(g) A legibly written or typed application for certification on forms provided by the department must be filed with the SSD each year. The application for a shucker/packer or repacker certificate must be accompanied by a written statement of the procedure the applicant will use to determine the "SELL BY" date for molluscan shellfish packed and shipped from the location listed in the application.

(h) A certificate and unique number shall be issued by the commissioner only after an inspection of the plant by an authorized agent has determined that the plant and practices are in compliance with these sections. A certificate and unique number shall be issued to a dealer for each location at which molluscan shellfish operations are to be conducted and a certificate is required.

(i) The inspection of a previously certified plant which has had critical, key or other deficiencies cited against it, or had a certificate of compliance revoked, shall not be conducted by the SSD until written, complete operational procedures for all phases of the regulated activity, including flow of the product, are submitted to the SSD for review and written approval. An application may be refused and a certificate of compliance revoked or denied based on a history of failure to comply with the requirements of these sections in accordance with §241.60 of this title (relating to Enforcement).

(j) Molluscan shellfish operations by the dealer shall not begin until the department has issued the certificate for that location. Each certificate shall expire automatically at 11:59 p.m. on August 31st following the date of issue. Certificates shall not be transferable.

### **Section 241.59. Inspections.**

(a) After a certificate is issued, unannounced inspections may be conducted at any time the SSD has a reasonable belief that the business may be in operation, or that molluscan shellfish may be stored on the premises. Inspections may be made at such frequency as may be necessary

to assure that adequate operational and sanitary conditions are maintained, and the certificate holder is in compliance with the rules.

(1) When an inspection finds a critical deficiency, the violation shall be immediately corrected during that inspection or the plant must immediately cease production affected by the violation. If production affected by the violation does not voluntarily cease, all molluscan shellfish handled or processed while the violation exists or existed shall be detained pursuant to Health and Safety Code, §436.028. Further enforcement action may be taken as authorized under this chapter.

(2) When an inspection finds four or more key deficiencies, the dealer shall establish a correction schedule acceptable to the SSD. A follow-up inspection shall determine if the violations have been corrected or are being corrected in accordance with the scheduled correction dates noted on the previous inspection report.

(3) When an inspection detects other deficiencies or three or fewer key deficiencies, the deficiencies shall be corrected prior to the next routine inspection.

(b) All molluscan shellfish at a certified location shall be the responsibility of the dealer at that location, for the purposes of these sections.

(c) A copy of the completed inspection form, listing written descriptions of the violations observed along with any necessary explanation, shall be provided by an authorized agent of the department to the most responsible individual present at the firm at the conclusion of the inspection. If a responsible individual is not present, the form will be mailed to the firm.

(d) Any violations of the same rule requirement found on any two consecutive inspections may result in certificate suspension in accordance with §241.60(a) of this title (relating to Enforcement).

(e) Molluscan shellfish inspections and the SSD inspection forms shall comply with the requirements established in the current National Shellfish Sanitation Program.

### **Section 241.60. Enforcement.**

(a) The department may refuse to certify, suspend or revoke a certificate of compliance if the applicant or certificate holder:

(1) fails to comply with any provision of the statute;

(2) fails to comply with any provision of this subchapter;

(3) commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to this chapter;

(4) aids, abets, or permits the commission of an illegal act;

(5) fails to comply with an order of the commissioner of health or another enforcement procedure under the statute;

(6) the certificate holder or representative refuses to allow an inspection or otherwise interferes with the authorized department agent in the performance of his or her duties;

(7) fails to have a HACCP plan, has a HACCP plan unacceptable to the SSD, or fails to comply with a HACCP plan that is acceptable to the SSD;

(8) fails to provide the required application information;

(9) has any critical violations identified during the certification inspection; or

(10) has more than two key deficiencies and 3 other deficiencies identified during the certification inspection.

(b) If the department proposes to refuse to certify, proposes to suspend, or proposes to revoke a certificate of compliance, the department shall notify the applicant or certificate holder of the reasons for the proposed action and offer the person an opportunity for a hearing.

(1) If the facility chooses to request a hearing, it shall do so within 20 calendar days of receipt of the notice. Receipt of the notice is presumed to occur on the fifth calendar day after the notice is mailed to the last address known to the department unless another receipt date is reflected on a United States Postal Service return receipt.

(2) The request for a hearing shall be in writing and submitted to the Director, SSD, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.

(3) A hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health).

(4) If the facility does not request a hearing in writing within 20 calendar days of receipt of the notice, the facility is deemed to have waived the opportunity for hearing and the proposed action shall be taken.

(5) If the person fails to appear or be represented at the scheduled hearing, the person is deemed to have waived the right to a hearing and the proposed action shall be taken.

(c) If the department suspends a certificate, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. An authorized representative of the department shall investigate prior to making a determination during the time of suspension and the suspended certificate holder shall return the certificate of compliance to the department and shall not process molluscan shellfish in Texas.

(d) If the department revokes a certificate, a person may reapply for a certificate after 180 days from the date of signing of the final order of revocation. The department may refuse to issue a certificate if the reason for revocation continues to exist, or the applicant does not meet the requirements for a certificate.

(e) Upon revocation, a certificate holder shall return the certificate of compliance to the department. A dealer whose certificate has been revoked may not be issued a new certificate for 180 days after the date of signing of the final order of revocation, or before the next certification period, whichever is longer.

(f) Pursuant to Health and Safety Code, §§436.034 - 436.037, the department may assess an administrative penalty against a person who violates §436.011 of the statute or an order issued under this chapter.

(1) The penalty may not exceed \$25,000 a day for each violation. Each day of a continuing violation constitutes a separate violation.

(2) In determining the amount of an administrative penalty assessed under this section, the department shall consider:

- (A) the seriousness of the violation;
- (B) the person's previous violations;
- (C) the hazard to the health and safety of the public;
- (D) the person's demonstrated good faith; and
- (E) any other matters that justice may require.

(3) All proceedings for the assessment of an administrative penalty are subject to the Administrative Procedure Act, Government Code, Chapter 2001.

(4) If, after investigation of an alleged violation and the facts surrounding that alleged violation, the department determines that a violation has occurred, the department shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:

(A) a brief summary of the alleged violations including the statute and/or rules violated;

(B) a statement of the amount of the proposed penalty, based on the factors listed in paragraph (2) of this subsection; and

(C) a statement of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(5) The seriousness of violations for which administrative penalties are assessed may be categorized by one of the following severity levels.

(A) Severity Level I covers violations that are most significant and may have a significant negative impact on public health and safety.

(B) Severity Level II covers violations that are very significant and may have a negative impact on the public health and safety.

(C) Severity Level III covers violations that are significant, and if not corrected, could threaten public health and safety.

(D) Severity Level IV covers violations that are of more than minor public health and safety significance, but if left uncorrected could lead to more serious circumstances.

(E) Severity Level V covers violations that are of minor public health and safety significance.

(6) Not later than the 20th calendar day after the date the notice is received, the person notified may accept the determination of the department made under this section, including the recommended penalty, or make a written request for a hearing on that determination. Receipt of the notice is presumed to occur on the fifth calendar day after the notice is mailed to the last address known to the department unless another receipt date is reflected on a United States Postal Service return receipt.

(7) If the person notified of the violation accepts the determination of the department, or fails to request a hearing within 20 calendar days of the receipt of the notice, the

department shall issue an order approving the determination that a violation occurred and ordering that person to pay the recommended penalty.

(8) If a hearing is requested, the department shall refer the matter to the State Office of Administrative Hearings for a hearing.

(9) The provisions of Health and Safety Code, §§436.035 and 436.036 shall be followed in assessing and paying an administrative penalty.

### **Section 241.61. Molluscan Shell Stock Temperature Control.**

(a) For the purpose of this section, temperature control is defined as the management of the environmental temperature of shell stock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shell stock and will maintain it at 45 degrees Fahrenheit (10 degrees Centigrade) or less.

(b) The department shall establish the water temperature to be applied in Table 1 for each growing area by averaging the previous five years' maximum monthly temperatures.

Figure: 25 TAC, §241.61(b)

(c) The time to refrigeration listed in Table 1 shall be based upon the first shell stock harvested.

(d) During action levels 2, 3, and 4 listed in Table 1, the product shall be shaded.

(e) The department may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in Table 1.

### **Section 241.62. Trucks and Other Vehicles Used to Transport Molluscan Shell Stock to the Original Dealer.**

(a) The harvester or dealer who transports molluscan shell stock from the harvester to the first dealer to handle the product shall assure that all trucks used to transport molluscan shell stock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the molluscan shell stock.

(b) Storage bins on trucks or other vehicles used in the transport of molluscan shell stock for direct marketing shall be:

(1) kept clean with potable water or water from an approved area in the open status or conditionally approved area in the open status; and

(2) constructed so that water does not stand on the deck or in the storage bin.

(c) Molluscan shell stock shall be transported in air temperatures inside the truck or other vehicle of 45 degrees Fahrenheit (7.2 degrees Centigrade) or less.

(d) Mechanical refrigeration 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 degrees Fahrenheit (7.2 degrees Centigrade) or less.

(e) Any ice used to cool molluscan shell stock during transport shall be produced and handled in compliance with the sanitation standard operating procedures in accordance with 25 TAC, §241.64 of this title (relating to General Sanitation Requirements).

(f) Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where molluscan shell stock is stored.

### **Section 241.63. General HACCP Requirements.**

(a) Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of molluscan 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 the hazard will occur in the particular type of molluscan shellfish product being processed in the absence of those controls.

(b) Every dealer shall have, implement, and comply with a written HACCP plan that is acceptable to the SSD. A copy of the plan shall be provided to the SSD upon request. A HACCP plan shall be specific to:

(1) each location where molluscan shellfish products are processed by that dealer;  
and

(2) each kind of molluscan shellfish product processed by the dealer. The plan may group kinds of molluscan shellfish 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 this section are identical for all molluscan shellfish products so grouped or for all production methods so grouped.

(c) The HACCP plan shall, at a minimum:

(1) list the food safety hazards that are reasonably likely to occur, as identified in accordance with subsection (a) of this section and that must be controlled for each molluscan 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. If the dealer can demonstrate to the department through a hazard analysis that the food safety hazard is not reasonably likely to occur or is otherwise controlled, the critical control point is not required; and

(B) critical control points designed to control food safety hazards that could be introduced in the processing plant environment. If the dealer can demonstrate to the department through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required;

(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 written corrective action plans that have been developed in accordance with this section to be followed in response to deviations from critical limits at critical control points;

(6) list the verification procedures, and frequency thereof, that the dealer will use in accordance with this section. The records shall contain the actual values and observations obtained during monitoring; and

(7) 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.

(d) The HACCP plan shall be signed and dated by the most responsible individual on site at the processing facility or by a higher level official of the dealer:

(1) upon initial acceptance;

(2) upon any modification; and

(3) upon verification of the plan in accordance with subsection (g)(1)(A) of this section.

(e) Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §241.64 of this title (relating to General Sanitation Requirements), they need not be included in the HACCP plan.

(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 paragraph (2) of this subsection.

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with subsection (c)(5) of this section, 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 subparagraphs (B) and (C) of this paragraph 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;

(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; and

(E) perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with this section 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 subsection (g) of this section and the record keeping requirements of subsection (h) of this section.

(g) Verification.

(1) Every dealer 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 at least annually or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way. The reassessment shall be performed by an individual or individuals who have been trained in accordance with subsection (i) of this section. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of subsection (c) of this section. These changes may include:

(i) raw materials or source of raw materials;

(ii) product formulation;

(iii) processing methods or systems;

(iv) finished product distribution systems; or

(v) the intended use or consumers of the finished product.

(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 subsection (i) of this section, 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 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 subsection (f) of this section. This review shall occur within one 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 dealer's written procedures as specified in the HACCP plan. These reviews shall occur within one week of the day the records are made.

(2) Dealers shall immediately follow the procedures in subsection (f) of this section 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 paragraph (1)(B)(ii) and (iii) of

this subsection, shall be documented in records that are subject to the record keeping requirements of subsection (h) of this section.

(h) Records.

(1) All records required 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 shall be retained at the processing facility for at least one year after the date they were prepared in the case of refrigerated products and for at least two 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 years from the date that product is first produced using the applicable equipment or processes.

(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 producible for official review upon request by the department.

(5) All records required by subsection (h) of this section, and HACCP plans required by subsections (b) and (c) of this section shall be available for official review and copying upon request by the department.

(6) Tags on containers of molluscan shell stock are not subject to the requirements of this section unless they are used to fulfill the requirements of record keeping.

(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 molluscan shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the FDA 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 subsection (c) of this section;

(B) reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in subsection (f)(3)(E) of this section, and the HACCP plan in accordance with the verification activities specified in subsection (g)(1)(B) of this section; and

(C) performing the record review required by subsection (g)(1)(C) of this section.

(2) Job experience will qualify an individual to perform these functions if he/she has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the SSD.

(3) The trained individual need not be an employee of the dealer.

**Section 241.64. General Sanitation Requirements.**

(a) 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 §§229.211 - 229.219 of this title (relating to Current Good Manufacturing Practice and Good Warehousing Practice in Manufacturing, Packing or Holding Human Food). The requirements specified in §§229.211 - 229.219 of this title relate to the following sanitation items:

(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, or use of toxic compounds;
- (7) control of employees with adverse health conditions; and
- (8) exclusion of pests.

(b) Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by subsection (a) of this section. These records are subject to the requirements of §241.63(h) of this title (relating to General HACCP Requirements).

(c) Sanitation controls may be included in the HACCP plan, as required by §241.63(b) of this title. However, to the extent that they are monitored in accordance with subsection (a) of this section, they need not be included in the HACCP plan.

**Section 241.65. Dealer Molluscan Shell Stock Identification.**

(a) The dealer shall keep the harvester's tag affixed to each container of molluscan shell stock until the bag or container is:

- (1) shipped; or
- (2) emptied to wash, grade or pack the molluscan shell stock.

(b) Unless the dealer is also the harvester and has already placed a dealer tag on the container, the dealer shall affix his/her tag to each container of molluscan shell stock prior to shipment.

(c) The dealer's tags shall:

- (1) be durable, waterproof and approved by the department prior to use; and
- (2) be at least 2-5/8 by 5-1/4 inches (6.7 by 13.3 cm) in size.

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

- (1) the dealer's name and address;
- (2) the dealer's certification number as assigned by the department and the original shellstock shipper's certification number;

(3) the date of harvest;

(4) the most precise identification of the harvest location as is practicable including the initials of the state of harvest, and any department designation of the harvest area by indexing, administrative or geographic designation;

(5) when the molluscan shell stock has been in wet storage in a dealer's operation, the tag shall state: "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";

(6) the type and quantity of molluscan shell stock; and

(7) the following statements in bold capitalized type on each tag:

(A) "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS"; and

(B) the consumer information statement adopted by the ISSC or its equivalent as approved by the SSD.

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

(f) If the molluscan shell stock is removed from the original container, the tag on the new container shall meet the requirements of this section.

(g) When the molluscan shell stock is removed from the original container, the dealer shall:

(1) keep the harvester tag for 90 days unless records maintained as part of the HACCP plan provide the necessary information to track product to the original harvest location;

(2) track the harvest area and date of harvest for the molluscan shell stock; and

(3) maintain the lot identity of all molluscan shell stock during any intermediate stage of processing.

#### **Section 241.66. Shucked Molluscan Shellfish Labeling.**

(a) If the dealer uses reusable containers to hold or transport shucked molluscan shellfish between activities for the purpose of further processing or packing, the reusable containers are exempt from the labeling requirements in this section. When reusable containers are used, the lot shall be accompanied by a record containing:

- (1) the shucker-packer's name and certification number;
- (2) the shucking date; and
- (3) the quantity of molluscan shellfish per container and the total number of containers.

(b) 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.

(c) The dealer shall assure that each individual package containing fresh or frozen shucked molluscan shellfish meat is labeled in a legible and indelible form in accordance with applicable federal and state regulations concerning:

- (1) information on the principal display panel; and
- (2) the standard of identity.

(d) The dealer shall assure that each package containing less than 64 fluid ounces of fresh or frozen molluscan shellfish shall have:

- (1) the shucker-packer's or repacker's certification number on the label; and
- (2) a "SELL BY DATE" which provides a reasonable subsequent shelf life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen molluscan shellfish, the year will be added to the date.

(e) The dealer shall provide a "DATE SHUCKED" on all containers of shucked molluscan shellfish with a capacity of 64 fluid ounces (1873 ml) or more. The "DATE SHUCKED" shall:

- (1) for fresh molluscan shellfish, consist of the number of the day of the year (Julian date) or the month and the number of the day of the month;
- (2) for frozen molluscan shellfish, include the year; and
- (3) appear on the lid and either the sidewall or bottom of durable containers; or
- (4) appear on the lid or sidewall of disposable containers.

(f) The dealer shall label all frozen molluscan shellfish as frozen in type of equal prominence immediately adjacent to the name of the molluscan shellfish.

(g) If the dealer thaws and repacks frozen molluscan shellfish, the dealer shall label the molluscan shellfish container as previously frozen.

(h) The dealer shall provide all label information in a legible and indelible form.

(i) Shucked Molluscan Shellfish. If the dealer elects to repack molluscan shellfish, the dealer shall pack and label all molluscan shellfish in accordance with this section except that the original date of shucking shall be used as the “DATE SHUCKED” or in establishing the “SELL BY DATE.”

#### **Section 241.67. Labeling of Molluscan Shellfish Subjected to Post-Harvest Processing.**

(a) If a dealer elects to use a process to reduce the level(s) of one target pathogen, some target pathogens, or all target pathogens of public health concern in shellfish the dealer shall:

(1) have a HACCP plan approved by the SSD 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) for processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in product that has been subjected to the process shall be non-detectable (<3 MPN/gram), to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, Chapter 9.

(B) for processes that target *Vibrio parahaemolyticus*, the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).

(C) for processes that target other pathogens, the level of those pathogens in product that has been subjected to the process shall be below the appropriate FDA action level, or in the absence of such a level, below the appropriate level as determined by the Interstate Shellfish Sanitation Conference.

(D) the ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study approved by the SSD, with 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 §§241.65 - 241.67 of this title. 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 §§241.65 - 241.67 of this title; and

(3) keep records in accordance with §241.69 of this title (relating to Shipping Documents and Records).

(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), (2) or (3) of this section.

(c) For the purpose of refrigeration, if the end product is dead, the product shall be treated as shucked product. If the end product is live, the product shall be treated as shell stock.

**Section 241.68. *Vibrio vulnificus* Management Plan for Oysters.** The department will implement the requirements of the National Shellfish Sanitation Program’s *Vibrio vulnificus* Risk Management Plan for Oysters. The Texas *Vibrio vulnificus* Management Plan will be available for viewing at the SSD central office location at 2201 Donley, Suite 200, Austin, Texas 78758.

**Section 241.69. Shipping Documents and Records.**

(a) Each molluscan shellfish shipment shall be accompanied by a shipping document that contains:

- (1) the name, address, and certification number of the shipping dealer;
- (2) the name and address of the major consignee; and
- (3) the kind and quantity of the molluscan shellfish product.

(b) The receiving dealer shall:

- (1) maintain in his/her files a copy of the completed shipping document; and
- (2) make the shipping document available to the department upon request.

(c) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace their portion back to the original shipment.

(d) Each dealer shall have a business address at which transaction records are maintained.

(e) Each dealer shall maintain complete, accurate and legible records of information required by this chapter.

(f) Transaction records shall be sufficient to:

(1) document that the molluscan shellfish are from a source authorized under this subchapter of this title (relating to Molluscan Shellfish);

(2) permit a container of molluscan shellfish to be traced back to the specific incoming lot of shucked molluscan shellfish from which it was taken; and

(3) permit a lot of shucked molluscan shellfish or a lot of molluscan shell stock to be traced back to the harvest area, date of harvest, and if possible, the harvester or group of harvesters.

(g) Purchases and sales shall be recorded:

- (1) in a permanently bound ledger book; or
- (2) using other recording methods acceptable to and authorized by the department.

(h) The transaction records shall be retained:

- (1) in the case of fresh molluscan shellfish, for a minimum of one year; and

(2) in the case of frozen molluscan shellfish, for a minimum of two years or the shelf life of the product, whichever is longer.

(i) If computer records are maintained, the department shall approve the format and its use.

**Section 241.70. Tagging of Depurated Molluscan Shellfish.** All containers of treated molluscan shellfish, before being released from the molluscan shellfish treatment plant, shall be suitably tagged or labeled with a uniform tag or label bearing the following information:

- (1) the depuration processor's name and address, including at least the city and state;
- (2) the depuration processor's valid, complete certificate number issued by the SSD;
- (3) the type of molluscan shellfish;
- (4) the date on which the molluscan shellfish were released from the depuration plant;
- (5) the term "DEPURATED" in letters as large as the largest other letters printed on the tag or label; and
- (6) the lot code of the treatment process batch.

**Section 241.71. Depuration Records.**

(a) Records containing the following information shall be available at the depuration plant at all times for molluscan shellfish presently undergoing the treatment process:

- (1) name and/or location of gathering area(s);
- (2) copy of permit(s);
- (3) date received in plant;
- (4) quantity of molluscan shellfish received;
- (5) quantity of molluscan shellfish destroyed;
- (6) quantity of molluscan shellfish in tank(s); and
- (7) date and time of initiation of treatment.

(b) Records containing the following information shall be available at the depuration plant at all times for each lot of molluscan shellfish for which the treatment process has been completed for a period of one year from the date of treatment:

- (1) name and/or location of gathering area(s);
- (2) copy of permit(s);
- (3) date received in plant;
- (4) quantity of molluscan shellfish received;
- (5) quantity of molluscan shellfish destroyed;
- (6) date and time of initiation of treatment;
- (7) date and time of termination of treatment;
- (8) number of hours treated;
- (9) quantity of molluscan shellfish treated;
- (10) quantity of molluscan shellfish destroyed after treatment;
- (11) all laboratory results as specified;
- (12) date released from plant; and
- (13) quantity of molluscan shellfish released.

(c) The plant supervisor or assistant plant supervisor shall send to the Texas Department of Health, Seafood Safety Division, 1100 West 49th Street, Austin, Texas 78756, on a weekly basis, a copy of the daily records required in this section and the laboratory analysis results of all molluscan shellfish and water samples completed during each weekly period.