

TITLE 11
DEPARTMENT OF HEALTH
CHAPTER 35
SHELLFISH SANITATION

§11-35-1 Purpose.

§11-35-2 Definitions

§11-35-3 Shellfish permit

§11-35-4 Shellfish and shellfish growing water evaluation

§11-35-5 Enforcement and penalties

§11-35-6 Shellfish growing areas

§11-35-7 Artificial growing systems for shellfish

§11-35-8 Preparation of shellfish for marketing

§11-35-9 Harvesting and processing shellstock (shellstock in the shell)

§11-35-10 Shucking and packing of shellfish

§11-35-11 Repacking of shellfish

§11-35-12 Reshipping of shellfish

§11-35-13 Sale of shellfish in Hawaii

§11-35-14 Severability

Historical Note: Chapter 35 of title 11 is based substantially on Public Health Regulations Chapter 4a, Food and Food Products, Department of Health, State of Hawaii. [Eff. 3/25/78; R: SEP 18 1981]

§11-35-1 Purpose.

The purpose of this chapter is to establish sanitary controls for the shellfish industry. These provisions shall apply to the growing area and to all aspects of harvesting, processing, packaging, storing, and distributing of shellfish. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §321-11)

§11-35-2 Definitions.

"Action level" means the interim limit established for a deleterious substance present in a product or an environment, above which level control or regulatory action may be required to protect public health.

"Alert level" means the level of deleterious substance in a product or an environment indicating degradation and warranting increased monitoring and sampling.

"Approved growing area", means an area which has been approved by the department for growing and harvesting of shellfish for direct marketing.

"Artificial growing system for shellfish" means a man-made system with definite boundaries in which shellfish are grown and where supplemental material is introduced for ultimate utilization by the shellfish.

"Blower" means the tank or vat used for washing shucked shellfish, utilizing forced air as a means of agitation.

"Classes of shippers" means

- (1) reshippers (RS), persons who transship shucked stock in original containers, or shellstock, from certified shellfish shippers to other dealers or to final consumers;
- (2) repackers (RP), persons, other than the original shucker, who pack shucked shellfish into containers for delivery to the consumers;
- (3) shellstock shippers (SS), persons who grow, harvest, buy, or sell shellstock and do not shuck shellfish or repack shucked shellfish;
- (4) shucker-packers (SP), persons who shuck and pack shellfish.

"Coliform groups" means all of the aerobic and facultative anaerobic, gram-negative, non-spore-forming bacilli which ferment lactose with gas formation within forty-eight hours at 35°C.

"Culling" means the sorting and removal of dead, inferior or gaping shellfish.

"Department" means the Hawaii state department of health.

"Depuration" means the process of removing microbial contaminants from live shellfish by placing them in a water environment of low coliform, low turbidity, and free from chemicals which are detrimental to health.

"Director" means the director of health or his designee.

"Dry storage" means the storage of shellstock out of water

"Fetal coliform group" means any bacteria as defined under the coliform group which will produce gas in Escherichia coli (E.C.) medium within twenty-four hours at 44.5°C in a water bath.

"Growing area" means any offshore ocean, coastal, estuarine or fresh water area suitable for natural shellfish growth artificial shellfish propagation.

"Harvester" means a person who takes shellfish from growing areas for commercial purposes.

"Internal temperature" means the actual temperature of shucked shellfish in the container or of shellstock, as opposed to the air temperature of the refrigerator in which the shellfish may be stored.

"Lot of shellstock" means a collection of no more than one day's production of shellstock harvested from a particular growing area by one or more harvesters.

"Most probable number (MPN)" means a statistical estimate of the number of bacteria per unit volume which is determined from the number of positive results in a series of fermentation tubes.

"National Shellfish Sanitation Program" means the cooperative federal, state and industry program for the certification of interstate shellfish shippers as described in Public Health Service Publication Number 33, National Shellfish Sanitation Program Manual] of Operations, Parts I and II, (1965).

"Paralytic shellfish poisons" means poisons produced by free-swimming, one-celled marine organisms, including the dinoflagellates, *Gonvaulax catenella*, *Gonvaulax tamarensis*, *Gymnodinium breve*, which may be temporarily concentrated by shellfish.

"Pathogen" means any disease-producing microorganism or material.

"Person" means an individual, firm, partnership, company, corporation, trustee, association, or any public or private entity.

"Processor" means a repacker, shellstock shipper, or shucker-packer.

"Prohibited area" means a shellfish growing area where hazardous levels of toxic material or pathogens may be found or where a sanitary survey has not been made.

"Relaying" means the moving of market shellfish from waters classified as restricted or prohibited to an approved area for the purpose of natural purification.

"Restricted area" means a shellfish growing area subjected to moderate degrees of pollution (total coliform exceeding seventy per one hundred milliliter (ml), but not exceeding seven hundred per one hundred ml) which would make it unsafe to harvest shellfish for direct marketing but from which shellfish may be subject to depuration or relaying with approval of the department.

"Sanitary survey" means the evaluation of all factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides, and currents, and distribution and dilution of the polluting materials, and the bacteriological quality of the water.

"Shellfish" means all edible species of oysters, clams, and mussels of the molluscan class Pelecypoda. This definition excludes shellfish or products thereof which, in their final packaging have been heat-sterilized and packaged in hermetically sealed containers.

"Shellfish, market" means fresh or frozen shellfish, or parts thereof, sold for human consumption.

"Shellstock" means shellfish still in their shells.

"Shucked shellfish" means shellfish, or parts thereof, which have been removed from their shells.

"Skimmer table" means a shallow, perforated table used in washing and draining of shucked shellfish.

"Transplanting" means the moving of shellfish from one area to another for the purpose of propagation or for reharvesting after an adequate period for acclimatization and growth to market size.

"Wet storage" means the temporary storage of shellfish from approved sources intended for marketing in tanks, floats or in natural bodies of water. [Eff. SEP, 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-3 Shellfish permit.

The regulations governing the requirements for shellfish certification in their several forms (shucker-packer, shellstock-shipper, reshipper, repacker) in the State of Hawaii shall equal or exceed the requirements set forth by the Food and Drug Administration of the U.S. Department of Health and Human Services, and the National Shellfish Sanitation Program.

(a) No person in the State of Hawaii shall operate a plant or business engaged in growing, harvesting, shucking, packing, repacking, or reshipping fresh or fresh-frozen shellfish for sale to the public for human consumption without a valid permit issued by the department.

(b) Applications for permit shall be filed with the department. Each application, if necessary, shall be accompanied with sufficient written data, drawings and descriptions for the department to evaluate the operation relative to the provisions of this chapter.

(c) Authority of department to revoke or suspend a permit.

(1) Each permit issued pursuant to these regulations may be revoked or suspended by the department in accordance with Chapter 91, HRS, if for any reason the safety of the shellfish as an article of food is not assured or if the standards set forth herein are not met, or if the permit was obtained by misrepresentation, or omission of relevant information.

(2) A permit which has been previously denied, revoked or suspended, may be issued, reissued or reinstated, if violations are subsequently cleared or corrected to the satisfaction of the director.

(d) A permit issued under these regulations shall be valid for a period not to exceed one year or a portion thereof, with automatic expiration on June 30 of each year. An application for renewal of a permit shall be made on or before June 1. Permits are not transferable.

(e) Each permit holder shall notify the department immediately by telephone if there is any report or knowledge of contamination of his shellfish or of suspected illness from consumption of his shellfish. The harvesting, distribution and sale of shellfish shall cease immediately pending review of the safety of the product and approval by the department to resume operations.

(f) A person who exports shellfish certified by the department shall be listed on the Interstate Certified Shellfish Shippers List of the U. S. Public, Health Service, Food and Drug Administration. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-4 Shellfish and shellfish growing water evaluation.

(a) All collection and transportation of shellfish growing water samples and shellstock shall be performed in accordance with the "Recommended Procedures for the Examination of Sea Water and Shellfish" (APHA, 4th ed., 1970).

(b) Analyses of these samples for bacteriological, toxicological, chemical and physical parameters shall be performed by a laboratory approved by the department and in accordance with methods recommended in the "Recommended Procedures for the Examination of Seawater and Shellfish" (APHA, Fourth Edition, 1970), "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC, Thirteenth Edition, 1980), and "Standard Methods for Examination of Water and Wastewater" (APHA, 14th ed., 1975). [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-5 Enforcement and penalties.

(a) The taking of any shellfish from public waters is under the jurisdiction of the state department of land and natural resources, division of fish and game, and is subject to that department's regulations, enforcement and penalties.

(b) Any person who violates any provision of these regulations shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$500 or imprisoned not more than one year or both, as provided in §§321-18, HRS. Each and every violation of the provision of these regulations shall constitute a separate offense. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-6 Shellfish growing areas.

(a) No person shall buy sell, offer for sale, receive, keep, transport, deliver, or take any shellfish not declared by the department to be approved or otherwise fit for direct marketing.

(b) A sanitary survey shall be made by the department of each shellfish growing area prior to its classification as "approved," "restricted," or "prohibited." A sanitary survey shall evaluate all sources of actual and potential pollution in the area including but not limited to pesticides, industrial wastes and sewage effluent. In addition, the effect of wind action, water flow and currents in distributing polluting materials over a growing area shall be considered.

(c) Growing areas shall be designated as approved after the sanitary survey conducted by the department indicates that pathogenic microorganisms, paralytic shellfish poisons, heavy metals and pesticides are not present in dangerous concentrations as specified below. This classification of the growing area shall be verified by laboratory tests whenever the sanitary survey indicates the need. Shellfish from approved areas may be harvested for direct marketing.

(1) Water standards.

(A) Fecal coliform median MPN - The fecal coliform median MPN of the water samples shall not exceed fourteen per one hundred milliliters (ml) and not more than ten percent of the samples shall exceed an MPN of forty-three for a five-tube decimal dilution test. The fetal coliform standard shall be used as the primary bacteriological standard to evaluate a growing area. The sampling frequency shall be determined by the director, based on past history of data collected and the results of the sanitary survey.

(B) Total coliform median MPN - The total coliform median MPN should not exceed seventy per one hundred ml, and not more than ten per cent of the samples exceed an MPN of two hundred thirty per one hundred ml for a five-tube decimal dilution test. The total coliform median MPN of the water samples shall be used as an alert level indicator of possible fecal pollution.

(C) There shall be no continual or periodic occurrence of environmental indicators of a potential paralytic shellfish poisoning such as an algal bloom ("red tide"), animal mortality (e.g., fish kills, bird kills), intoxicated/sluggish animals, or irritating/burning aerosols in water.

(2) Shellfish meat standards.

(A) Fecal coliform - Shellfish meats from an approved growing area should not exceed a fetal coliform MPN median of one hundred thirty per one hundred grams and a 35°C plate count of one hundred thousand per gram of shellfish meat.

(B) Paralytic shellfish poisons (PSP)-PSP content of the edible portion of shellfish meat shall not exceed eighty micrograms of toxin per one hundred grams of meat as established in the "Recommended Procedures for the Examination of Seawater and Shellfish" (APHA, Fourth Edition, 1970).

(C) Heavy metals-Mercury has an action level of one part per million. The alert levels for zinc, copper, cadmium, lead and chromium shall be as stated in the "Proceedings-Seventh National Shellfish Sanitation Workshop, 1971" as listed below.

Elements	Shellfish (in parts per million)
Zinc	1,500
Copper	100.00
Cadmium	2.00

Lead	2
Chromium	2.00

(D) Pesticides - The levels of pesticides in shellfish in an approved growing area should not exceed the proposed standards as stated in appendix D of the "Proceedings-Sixth National Shellfish Sanitation Workshop, 1968," and as listed in the following table.

Shellfish	Pesticide (in parts per million)
Aldrin	0.20
BHC (Benzenehexachloride)	0.20
Chlordane	0.03
DDT)	
DDE) Any one or all not to exceed	1.50
DDD)	
Dieldrin	0.20
Endrin	0.20
Heptachlor	0.20
Heptachlor Epoxide	0.20
Lindane	0.20
Methoxychlor	0.20
2,4-D(2,4-dichlorophenoxy-acetic acid)	0.50

(b) Areas shall be classified as restricted when a sanitary survey indicates a moderate potential for pollution which would make it unsafe to harvest shellfish for direct marketing.

(1) The total coliform median MPN of the water samples exceeds seventy per one hundred ml but does not exceed seven hundred per one hundred ml and not more than ten per cent of the samples exceed an MPN of two thousand three hundred per one hundred ml.

(2) The fecal coliform median MPN of the water samples exceeds fourteen per one hundred ml and more than ten per cent of the samples exceeds an MPN of forty-three for a five-tube decimal dilution test.

(c) Areas shall be classified as prohibited if the sanitary survey indicates that the total coliform median MPN of the water exceeds seven hundred per one hundred ml or more than ten per cent of the samples have a total coliform MPN in excess of two thousand three hundred per one hundred ml.

(d) Growing areas in which sanitary surveys have not been made shall be automatically classified as prohibited.

(e) The taking of shellfish from prohibited areas for direct marketing shall be prohibited. [Eff. SEP 18 1981] (Auth: HRS §§321-09, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-7 Artificial growing systems for shellfish.

(a) Artificial growing systems for shellfish shall meet the performance criteria of natural growing water systems as stated in §11-35-6(c). The operator of an artificial growing system shall be issued a shellstock shipper's certificate. Harvesting, processing, packing, storing and shucking operations shall be the same as for shellfish reared in natural waters (see subsequent sections).

(b) Consultation with the department is strongly advised prior to the construction and operation of an artificial growing system to discuss construction details, flow diagrams, and sanitary requirements.

(c) System construction guidelines.

(1) Artificial growing systems shall be so constructed that they are not subject to storm waters and contamination from pollution surces.

(2) Wastewater from washing-culling operations shall not contaminate approved growing areas.

(c) Water system.

(1) The quality of the water used in the artificial growing system shall meet the approved growing area standards.

(2) Hydraulic appurtenances used in an artificial system shall be corrosion-resistant and non-toxic to humans and shellfish.

(3) There shall be a routine monitoring program by the certificate holder to assure proper functioning of the water system. This program shall include the monitoring of temperature, salinity, and focal and total coliforms of source and effluent waters.

(d) Food production of shellfish.

(1) Any algal food production facility used in conjunction with an artificial growing system shall be monitored to insure that the final shellfish product meets market standards as set forth in §11-35-13.

(2) Monitoring shall include the identification of algae species and the densities of paralytic poison producing forms.

(e) An artificial growing system shall have a program of sanitation, maintenance and supervision approved by the director to prevent the contamination of the final shellfish product. Plumbing and sewage disposal shall be as expressed for a packing facility of shellstock. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-8 Preparation of shellfish for marketing.

(a) Relaying.

- (1) The relaying of market-size shellfish from a prohibited or restricted area to an approved area shall be conducted only with the written permission and under the supervision of the department.
- (2) Shellfish from public waters shall only be relaid with the permission of the department of land and natural resources.
- (3) Shellfish relaid from a prohibited or restricted area to an approved area shall be kept in such an area for at least fourteen consecutive days and shall be harvested only with the written consent from the department and under its supervision. Such an area shall be located and marked so that it may be readily identified to prevent accidental harvesting and to prevent shellfish in adjacent approved areas from contamination. Further need for holding shall be determined by laboratory tests and evaluation of such data by the department.

(b) Depuration.

- (1) Shellfish from prohibited areas shall not be depurated.
- (2) Shellfish from a restricted area shall only be harvested with the permission of the department of land and natural resources (if public waters) and shall be subjected to an effective depuration process.
- (3) The department shall monitor the sanitary quality of all harvesting, transporting and depurating operations of shellfish from restricted growing areas. Shellfish from a restricted area shall be depurated for not less than forty-eight hours to achieve fifty fecal coliforms or less per one hundred grams of meat.
- (4) An effective depuration facility shall be available in artificial growing systems if human pathogens have been demonstrated to occur in the growing waters. All shellfish lots to be marketed shall be depurated at least twenty-four hours immediately after harvesting. Subsequent lots of shellfish shall be depurated until the department is satisfied by available monitoring data or a sanitary evaluation that the sources of contamination are absent.
- (5) Construction of a depuration facility.
 - (A) Consultation with the department is advised prior to the construction and operation of a depuration plant.
 - (B) Plants in which shellfish are depurated shall be so located that they are not subject to flooding by high tides, storm waters, and other pollution sources.

(C) A depuration facility shall be so constructed that depurated shellstock are not recontaminated or are not accidentally commingled with shellstock to be depurated.

(D) Process tanks and shellstock containers used for depuration purposes shall be of sufficient size and shape, constructed of corrosion-resistant material, kept in good repair at all times, and not subject to external contamination.

(E) Regulations for storage, processing, sewage facilities shall be in accordance with §11-35-9.

(6) Seawater system.

(A) Hydraulic appurtenances shall be corrosion-resistant and non-toxic to shellfish and humans.

(B) Water used in a depuration facility shall meet approved growing water standards and should favor maximum physiological activity of the shellfish so as to achieve purification.

(C) Water used in the depuration facility shall be subjected to an effective sterilization process such as ultraviolet (UV) light or ozonization unless the water is obtained from a protected well source and if the fecal coliform is less than two per one hundred ml.

(7) Plant operations.

(A) Washing and culling-shellfish shall be washed to remove matter which would contaminate the water of the depuration facility, and culled to provide proper disposal of broken-shelled, dead or gaping shellfish. After the depuration process, shellstock shall be washed to remove the feces produced by the shellfish during the process and culled to dispose of dead or gaping shellfish which may have been missed on the first washing and culling.

(B) Process tanks and shellstock containers shall be cleaned and sanitized after each depuration process.

(C) Monitoring of plant operations-Accurate and up-to-date records of the quality and the flow rate of the water shall be kept. Physiochemical parameters of untreated and treated water should be monitored so as to determine the efficiency of the treatment units.

(D) A record shall be kept of the amount of shellfish depurated, the period of time the shellfish were depurated and the person to whom the shellfish were sold. Such records shall be made available to the director upon request. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-9 Harvesting and processing shellstock (shellfish in the shell).

(a) Harvesting and transporting of shellstock.

(1) All boats and trucks used in connection with a shellfish business shall be constructed, operated, and maintained to prevent contamination or deterioration of the shellfish, and shall be kept clean.

- (2) No boat shall discharge sewage overboard in areas in which shellfish are grown for public consumption.
- (3) All shovels, wheelbarrows, containers, or other equipment used in the harvesting and transporting of shellfish shall be cleaned prior to use.
- (4) Shellstock shall be protected from the sun to prevent spoilage and shall be refrigerated within six hours after harvesting.
- (5) Harvesters shall sell shellstock only to certified dealers and provide them with the following information:

Area where shellfish were harvested.

Amount of shellstock harvested.

Date of harvesting.

Packing and shipping of shellstock.

A shellstock-shipper shall deal only in shellfish which are still in the shell. The holder of such a certificate shall not shuck shellfish or repack shucked shellfish.

Shellstock shall be washed free of bottom sediments and detritus as soon after harvesting as practicable. Water used for shellstock washing shall be obtained from an approved growing area, or from other sources approved by the department.

- (3) Dry storage of shellstock.

(A) The floor of the storage area shall be constructed of materials impervious to water, be of a smooth surface and graded to drain.

(B) Walls of shellstock storage rooms and hoppers shall be smooth and of material which will not deteriorate under repeated washing.

(C) Shellstock storage areas shall be constructed so that they will not receive floor drainage water from other portions of the plant. The shellstock shall be stored on racks to prevent them from coming into contact with the floor or with water which might accumulate on the floor. Shell-stock from different sources shall be kept separated from each other. Shellstock storage areas shall be protected against sewage backflow by the installation of an airgap in the waste line or by provision of a separate drainage system.

(D) Conveyances or devices used in the transport of shellstock shall be constructed so that they may be easily cleaned and sanitized.

(E) Shellstock kept in storage overnight or for a longer period prior to packing (or shucking) shall be refrigerated to a temperature of at least 45°F (7°C).

Wet storage. Shellfish in wet storage shall be protected against fecal contamination. Wet storage shall not be used by a shipper unless a written request is made to the department annually. The request for approval shall include a sketch, drawn to scale, showing the

location of the storage area, floats or the water intake for the wet-storage tanks, and a discussion of the potential hazards to which the stored shellfish may be exposed. A sanitary survey of the wet storage facility shall be made by the department prior to approval.

The certificate holder shall keep records of purchases and sales, and tag shellstock shipments so that they can be identified. The tag shall be securely fastened to each shipping container and bear the number of the license holder, his name and address, and the kind and quantity of shellstock in the container. Tags shall be at least two and one-half by five inches in size and shall be made of substantial, waterproof material. Bulk shipments of shellstock to a certified shipper require only a single tag or bill of lading. The necessary information may be printed on the shipping container rather than on a tag.

(6) The provisions of §11-35-10, Shucking and packing of shellfish, are also applicable to the packing and shipping of shellstock, specifically (a)(7)(A), (a)(8)(A,D,F,G,H,I,K), (a)(9), (a)(12)(A,C), (b)(1)(A,B), (c)(1), and (d). [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-10 Shucking and packing of shellfish.

(a) Facilities.

(1) Plant arrangement.

(A) Plants in which shellfish are shucked and packed shall be located so that they will not be subject to flooding. Any shellstock subjected to flooding shall be relayed, depurated or destroyed.

(B) Shucking and packing operations shall be conducted in separate rooms. A window shall be installed in the partition between the shucking and packing rooms. The window shall be equipped with a corrosion-resistant shelf draining toward the shucking room and, if necessary, curbed on the packing room side. Fly control screening may be accepted in lieu of a solid wall between the shucking and packing rooms, provided that the packing room is situated so that there is no likelihood of the shucked product or packing room equipment being contaminated by splash from the shucking room.

(C) Packing rooms shall be large enough to permit sanitary handling of shellfish and thorough cleaning of equipment.

(D) A separate room or rooms, or lockers shall be provided for storing employees' street clothing and personal articles.

(2) Wet and dry storage of shellfish prior to shucking shall meet the requirements of §11-35-9(b)(3) and (b)(4).

(3) The floors of all rooms in which shellfish are shucked or packed, or in which utensils are washed, shall be constructed of materials impervious to water, well maintained, and graded to drain.

(4) The interior surfaces of rooms in which shellfish are shucked or packed, or in which utensils are washed, shall be smooth, washable, light-colored, durable, and well maintained.

(5) Natural or artificial light shall be provided in all working and storage rooms to produce at least the intensity indicated below:

Foot Candles of Illumination	Type of Area (measured as incident light)
Working surfaces in packing rooms.	25
Shucking benches and utensil washing areas.	15
Storage rooms, including cold-storage rooms.	5

(5) Light shields shall be provided to protect workers and food stuff from shattered glass.

(6) Working rooms shall be ventilated to reduce condensation and mold.

(7) Water supply.

(A) The water supply shall be adequate and of safe and sanitary quality.

(B) All shellstock storage rooms, shucking and packing rooms, and utensil washrooms shall be provided with sufficient water outlets.

(C) An automatically regulated hot water system which has sufficient capacity to furnish water with a temperature of at least 130°F (54°C), during all hours of plant operation shall be provided.

(D) Sufficient water shall be available for all plant needs. Non-pressure supplies shall not constitute compliance.

(E) Hot (at least 100°F) (38°C) and cold water outlets shall be provided at each sink compartment, except that warm water may be acceptable at handwashing sinks.

(8) Plumbing and related facilities.

(A) Plumbing shall be installed in compliance with local plumbing codes.

(B) There shall be no cross-connection between the approved pressure water supply and water from a non-approved source, and no fixtures or connections through which the approved pressure supply might be contaminated by back-siphonage.

(C) Conveniently located, separate toilets shall be provided for each sex. Separate facilities are not required in family operations or when the plant has fewer than ten employees.

(D) Hand-washing facilities shall be convenient to the work areas, and so located that the person responsible for supervision can readily observe that employees wash their hands before beginning work after each interruption.

(E) The lavatories shall be provided with hot water (at least 100°F) (38°C).

(F) Supplies of soap and single-service hand towels shall be available near the lavatory.

(G) The toilet rooms shall be kept clean and in good repair.

(H) Toilet doors shall be tight-fitting and self-closing.

(I) A supply of toilet paper shall be available in the toilet rooms.

(J) At least five-foot-candle illumination (natural or artificial light) shall be provided in toilet rooms, and toilet rooms shall be ventilated by direct opening to the outer air, or by a mechanical ventilating system. Air vents should be screened or have self-closing louvers.

(K) No drainpipes or wastepipes shall be located over food processing or storage areas, or over areas in which containers or utensils are stored or washed.

(9) Sewage shall be discharged into public sewers wherever possible. Where private sewage-disposal systems must be utilized, they shall be constructed and operated according to the applicable public health regulations and county ordinances, rules and regulations. All sewage disposal facilities shall be constructed and maintained so that waste will be inaccessible to flies and rodents.

(10) Construction of shucking benches and tables.

(A) Shucking benches and contiguous walls to a height of at least two feet above the bench tops shall be of smooth concrete, corrosion-resistant metal or other durable, non-absorbent material, free from cracks.

(B) Benches shall drain completely and rapidly, and drainage shall be directed away from any shellfish on the benches.

(C) Shucking stools and blocks shall be constructed so as to be easily cleaned.

(11) Construction of utensils and equipment.

(A) All utensils and equipment coming into contact with shucked shellfish, or ice used for direct cooling of shellfish, shall be of corrosion-resistant, non-absorbent, non-toxic and smooth material.

(B) There shall be no exposed screw, bolt, or rivet heads in the parts touching or draining to the food, and all joints shall be welded or soldered flush and have a smooth surface.

(C) Tanks, tubs and shucked shellfish storage containers shall be so located that their top rim is at least two feet above the floor.

(D) All utensils and equipment shall be in good repair.

(E) The blower drain shall not be directly connected to a sewer.

(12) Vermin control measures.

(A) The plant shall be constructed and maintained so as to prevent rodent entrance and infestation.

(B) All outer openings to toilet and washrooms, shucking and packing rooms, storage rooms and locker rooms shall be screened or constructed to prevent the entrance of vermin. Effective in-plant vermin control measures shall be used to eradicate vermin which may enter the plant despite the screening. Doors should open outward and be self-closing.

(C) Only such toxic materials as are required to maintain sanitary conditions shall be used in a shellfish plant.

These toxic materials shall be identified, stored and used in such a manner as to prevent contamination of the product or ingredients, and to cause no health hazards to employees.

(b) Sanitation.

(1) General cleanliness.

(A) Premises shall be kept clean and free of litter and rubbish. Miscellaneous and unused equipment and articles which are not necessary to plant operations shall not be stored in rooms used for shellstock storage, shucking, packing or repacking.

(B) No animals shall be permitted in a shellfish processing plant.

(C) Shellstock storage, shucking, and packing portions of the plant, when in operation, shall be restricted to the handling of shellfish.

(D) Shuckers shall not go into or through the packing room without wearing a clean apron and washing hands thoroughly.

(2) Cleaning of buildings and equipment.

(A) Wash sinks shall be large enough to permit the complete immersion of the largest utensil to be sink-washed. A second compartment shall be provided in the sink for clear-water rinsing between washing and bactericidal treatment, unless some other method, such as a spray rinse, is provided.

(B) All shelves, tables, and other equipment in the shucking and packing rooms shall be clean.

(C) Wash tanks, blowers, and shellfish meat containers should be flushed or spray-rinsed with tap water after each emptying. Periodic clean-water flushing of shucking benches, utensils, table surfaces, and other equipment during working periods is recommended.

(3) Bactericidal treatment of utensils and equipment.

(A) All utensils and equipment in the shucking and packing rooms which come into contact with shucked shellfish shall be subjected to an effective bactericidal process at the end of each day's operation.

(B) Returnable shipping containers shall be subjected to an effective bactericidal treatment process prior to reuse.

(C) All utensils and other equipment shall be treated by a method of bactericidal treatment approved by the department.

(4) Equipment and utensils which have been cleaned and given bactericidal treatment shall be stored so as to be protected against contamination.

(c) Shucking and packing processes.

(1) All shellfish to be shucked shall be obtained from a source conforming to the provisions of these regulations.

(2) Shucking of shellfish.

(A) Shellstock shall be reasonably free of mud when shucked. Water used in washing shellstock shall be from an approved source.

(B) Only live shellstock shall be shucked.

(C) Shucking knives shall be cleaned and sanitized prior to use and after any prolonged break (e.g., lunch breaks).

(D) Empty shells shall not accumulate and shall be removed promptly from the shucking room.

(3) Sorting and packing of shucked shellfish.

(A) Shucked shellfish shall be graded, sized and packed in accordance with Title 21 Code of Federal Regulations (CFR) §161.350-161.145.

(B) Shucked shellfish shall not remain on the shucking bench for more than one hour.

(C) Skimmer tables shall be located so that they do not receive drainage from the delivery window.

(D) Shuckers shall not place shucking containers on the skim met tables.

(E) Shucking containers shall be rinsed with running tap water before each filling.

(F) Shucked shellfish shall be packed in clean containers without exposing them to contamination.

(G) Each individual package or container of fresh or frozen shucked shellfish shall have recorded on the package or label to be easily visible, the name and address of the packer, repacker, or distributor and certification number, and the date of packing-repacking.

(4) Refrigeration of shucked shellfish. Shucked shellfish shall be cooled to an internal temperature of 45°F (7°C) or less within two hours after packing, and stored and shipped under similar temperature conditions. Packaged shellfish to be frozen shall be properly stacked to insure rapid freezing and shall be frozen at an ambient air temperature of 0°F (-18°C) or less. The packages should be frozen solid within twelve hours after the start of freezing. Frozen shellfish shall be handled in such a manner to remain frozen solid and held at 0°F (-18°C) or less at all times.

(5) Ice shall be obtained from a source approved by the department and shall be stored and handled in a clean manner.

(d) Each shucker-packer, repacker, shellstock shipper or reshipper shall establish and maintain a record system satisfactory to the department indicating from whom shellfish were purchased, the date of purchase, the area of harvest and the names and addresses of persons or firms to whom the shellfish were sold.

(e) Personnel.

- (1) A person known to be infected with any communicable disease or who has an infected wound or open lesion on any exposed portion of his body, shall be excluded from the handling or processing of shellfish.
- (2) The certificate holder shall designate and identify to the department the individual who has the management responsibility for compliance with the items of these regulations having to do with plant and personnel cleanliness.
- (3) Employees shall wash their hands with soap and water before beginning work and again after each interruption. When manual handling of shucked shellfish becomes necessary, sanitized rubber gloves shall be worn, or the hands shall be washed and disinfected immediately before such manual handling.
- (4) Effective hair restraints shall be used by employees engaged in the shucking/packing of shellfish.
- (5) Employees shall not eat, drink or smoke in the shucking or packing rooms. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-11 Repacking of shucked shellfish.

When repacking (packaging of shucked shellfish in plants other than those in which they were originally shucked) is practiced, it shall be done in accordance with the requirements of §11-35-10 and the following provisions of this section:

(a) Repacking of shucked shellfish.

- (1) All shucked shellfish shall be received in containers which prevent contamination.
- (2) Shellfish shall be received from certified sources at a temperature of 45°F (7°C) or less and maintained at this temperature during repacking.
- (3) Frozen shellfish which have thawed shall not be repacked nor shall frozen shellfish be thawed during the repacking process.

(b) Returnable shipping containers shall be thoroughly cleaned and sanitized before use.

(c) A repacker may also act as a shellstock shipper if that person has the necessary facilities according to these regulations. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-12 Reshipping of shellfish.

Persons who reship shellfish from certified shellstock shippers, shucker-packers or repackers to other certified shippers or to final consumers shall be certified as reshippers. A reshipper is not permitted to shuck shellfish, nor to repack shucked shellfish. If shellstock is handled, the applicable requirements for shellstock dealers in §11-35-9(b) shall be met. If only shucked shellfish is handled, the applicable requirements of "Shucking and packing of shellfish" (§11-35-10) shall be met. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-13 Sale of shellfish in Hawaii

(a) Shellfish shipped into Hawaii.

(1) Market shellfish shipped into Hawaii from outside the state shall be from approved growing areas and certified by the appropriate agency of the state or county of origin and shall be acceptable to the Hawaii state department of health.

(2) Each certified shipper shall be listed on the current issue of the Interstate Certified Shellfish Shippers List of the U.S. Public Health Service-Food and Drug Administration.

(b) Storage of shellfish

(1) Dry storage. Shellfish shall be kept in storage in their original containers properly refrigerated at a temperature of at least 45°F (7°C). Shellstock shall be kept at least four inches off the floor.

(2) Wet storage.

(A) Wet storage shall not be practiced without written approval from the department. The request for an approval shall include a sketch drawn to scale showing the location of the storage area, water source and all potential hazards to which the stored shellfish might be exposed.

(B) Approval shall be immediately terminated if any health hazard is deemed to exist.

(C) Water storage of shellfish in fill-and-draw tanks continuously recirculated, may be practiced provided the following conditions are met:

(i) Tanks are constructed of easily cleaned material and supplied with water of salinity approximately equal to that of the waters in which the shellfish were grown originally.

(ii) An approved treatment system shall be used to treat the water to meet approved growing area standards.

(iii) Water used in the tanks shall be refrigerated to a temperature of 45°F (7°C) or less

(iv) The sidewalls of such tanks shall extend at least three feet above the surrounding floor level to protect the shellfish from contamination. (v) Tanks shall be maintained in a clean and sanitary condition at all times.

(vi) The operator of such holding tanks shall provide samples of waters and shellfish meats for laboratory analysis as requested by the department.

(c) Retailing and wholesaling of shellfish.

(1) The department shall maintain a shellfish receiver agency program aimed at protecting the health of the public by the following means:

(A) Identify inventory and make periodic inspections of various wholesale and retail dealers in the State of Hawaii.

(B) Certify all shippers shipping shellfish intrastate or interstate according to their activities as reshipper, repacker, shellstock shipper, or shucker-packer, and if appropriate, place them on the U.S. Interstate Shellfish Shippers List.

(C) Develop the laboratory and inspection capabilities to sample shellfish from certified shippers arriving at wholesale markets periodically.

(D) Laboratory results of samples which are below market standards (see next section) shall be forwarded to the regional food and drug administration office and to the appropriate state control agency as quickly as possible for corrective action.

(E) If violations are found in two successive samples from the same shipper, future shipments by this shipper shall not be allowed into Hawaii until the department is satisfied that the problems at the point of origin have been eliminated.

(2) The following standards shall apply to all certified shellfish meat at the market level:

(A) Satisfactory-A fecal coliform density of not more than two hundred thirty MPN per one hundred grams and a 35°C aerobic plate count (APC) of not more than five hundred thousand per gram of sample will be acceptable.

(B) Conditional-A fecal coliform density of more than two hundred thirty MPN per one hundred grams or 35°C aerobic plate count of more than five hundred thousand per gram shall constitute a conditional sample and may be rejected by the department.

(C) Shellfish found to contain human pathogens shall not be sold.

(D) Any shellfish found to be adulterated, e.g., decomposed gaping, shall not be marketed and shall also be subject to the requirements of §11-35-13(c)(6).

(3) Shellfish shall be displayed for retail sale in a refrigerated area at a temperature of 45°F (7°C) or less or on ice. If ice is used, it shall be made from potable water and manufactured, stored, transported and/or handled in a sanitary manner. Adequate drainage shall be provided.

(4) If shellstock are repacked into trays for retail sale, a label shall accompany each tray with the following information:

(A) Name of product.

(B) Weight statement.

(C) Name of distributor or packer and his address.

(5) Adequate records shall be kept by wholesalers and retailers to verify the source of the shellfish being sold.

(6) Mislabeled, adulterated or uncertified shellfish may be subject to embargo and possible seizure in accordance with §328-25, HRS. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)

§11-35-14 Severability.

If any provision of these regulations or the application thereof to any person or circumstance, is held invalid, other applications, and the remainder of these regulations shall not be affected hereby. [Eff. SEP 18 1981] (Auth: HRS §§321-9, 321-10, 321-11, 328-21) (Imp: HRS §§321-11, 328-21)