902 KAR 45:020. Kentucky shellfish dealer standards and requirements.

RELATES TO: KRS 217.005-217.205, 217.992, 318.130
STATUTORY AUTHORITY: KRS 194A.050, 217.125
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the Cabinet for Health and Family Services to protect the public against the adulteration and misbranding of foods. This administrative regulation establishes minimum sanitary standards for shellfish dealer certification, for dealers in both interstate and intrastate commerce, based upon the National Shellfish Sanitation Program Model Ordinance.

Section 1. Definitions.

(1) "Air gap" means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture, or other device and the flood level rim of that receptacle.
(2) "AOAC" means the Association of Official Analytical Chemists.
(3) "APHA" means the American Public Health Association.
(4) "Approved" means acceptable to the cabinet or responsible regulatory authority based on a determination of conformity with principles, practices, and generally-recognized standards that protect public health.
(5) "Approved classification" means a classification used to identify a growing area where harvest for direct marketing is allowed.
(6) "Aquaculture" means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellfish other than seed in growing areas.
(7) "Assure" means to make the best efforts within reasonable limits of manpower and resources to fulfill the objective of this administrative regulation.
(8) "Backflow" means the flow of water or other liquids, mixtures. or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.
(9) "Back siphonage" means the flowing back of used, contaminated, or polluted water from a plumbing fixture, vessel, or other source into potable water supply pipes because of negative pressure in the water supply pipes.
(10) "Blower" means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.
(11) "Broker" means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.
(12) "Cabinet" is defined by KRS 217.015(3).
(13) "Certified shellfish dealer" means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
(14) "Certified shellfish dealer processing facility" means a structure or vehicle utilized by the certified shellfish dealer for postharvest shellfish processing, including shucking, packaging, repackaging, shipping, reshipping, or depuration processing.
(15) "Certification number" means the unique identification number established in Section 2(10) of this administrative regulation and issued by the cabinet to a certified shellfish dealer for each location.
(16) "Commingle" means the act of combining different lots of shellstock or shucked shellfish.
(17) "Coliform group" means of the aerobic and facultative anaerobic, gram negative, nonsporeforming, rod-shaped bacilli which ferment lactose broth with gas formation within forty-eight (48) hours at ninety-five (95) degrees Fahrenheit.

(18) "Compliance schedule" means a written schedule, approved by the cabinet, that provides a correction time period for the certified shellfish dealer to eliminate deficiencies.
(19) "Conditionally approved" means a classification used to identify a growing area which meets criteria for the approved classification except under certain conditions described in a management plan.
(20) "Container" means any bag, sack, tote, conveyance, or other receptacle used for containing shellfish for holding or transporting.
(21) "Corrosion-resistant materials" means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.
(22) "Critical control point" means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can, as a result be prevented, eliminated or reduced to acceptable levels.
(23) "Critical deficiency" means a condition or practice noted as a deficiency on the NSSP Standardized Shellfish Plan Inspection Form which:
(a) Results in the production of a product that is unwholesome; or
(b) Presents a threat to the health or safety of the consumer.
(24) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
(25) "Cross connection" means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not, or cannot be, approved as safe and potable.
(26) "Cull" means to remove dead or unsafe shellstock from a lot of shellstock.
(27) "Depuration" means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.
(28) "Depuration processor" or "DP" means a person who harvests or receives shellstock from growing areas in the approved or conditionally-approved, restricted, or conditionally-restricted classification and submits the shellstock to an approved depuration process.
(29) "Direct marketing" means the sale for human consumption of shellfish which:
(a) Does not require depuration or relaying prior to sale; or
(b) Has been subjected to depuration or relaying activities.
(30) "Dry storage" means the storage of shellstock out of water.
(31) "Easily cleanable" means a surface which is:
(a) Readily accessible; and
(b) Is made of materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.
(32) "EPA" means the United States Environmental Protection Agency.
(33) "FDA" means the US Food and Drug Administration.
(34) "Fecal coliform" means the portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within twenty-four (24) (plus two (2)) hours in a water bath maintained at 112 degrees Fahrenheit.
(35) "Food contact surface" means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.
(36) "Food safety hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
(37) "Growing area" means any site which supports, or could support, the propagation of shellstock by natural or artificial means.

(38) "HACCP" or "Hazard Analysis and Critical Control Point" means a systematic, science-based approach used in food production as a means to assure food safety.
(39) "HACCP plan" means a written document that delineates the formal procedures that a certified shellfish dealer follows to implement the HACCP requirements set forth in Section 6 of this administrative regulation.
(40) "Handwashing" means the process established in Section 11(32) of this administrative regulation.
(41) "Harvest" means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.
(42) "Harvest area" means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.
(43) "Harvester" means a person who takes shellstock by any means from a growing area.
(44) "Heat shock" means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water, or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.
(45) "ICSSL" or "Interstate Certified Shellfish Shippers List" FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign authority. The ICSSL is available on-line at the following Web address: http://vm.cfsan.fda.gov/%7Eear/shellfis.html.
(46) "Importer" means any certified shellfish dealer who introduces molluscan shellfish into domestic commerce and has ownership of the shellfish without needing physical custody of the shellfish.
(47) "Includes" or "including" means includes or including by way of illustration and not by way of limitation.
(48) "Key deficiency" means a condition or practice noted as a deficiency on the NSSP Standardized Shellfish Processing Plant Inspection Form which may result in adulterated, decomposed, misbranded, or unwholesome product.
(49) "Label" means a label as defined by KRS 217.015(26) affixed to, or appearing upon, any package containing shellfish.
(50) "Lot of shellstock" means a single type of bulk shellstock, or containers of shellstock, of no more than one (1) day's harvest from a single defined growing area gathered by one (1) or more harvesters.
(51) "Lot of shucked shellfish" means a collection of containers of no more than one (1) day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.
(52) "Lot of shucked shellfish for depuration" means shellstock harvested from a particular area during a single day's harvest and delivered to one (1) depuration plant.
(53) "Marine biotoxin" means any poisonous compound produced by marine microorganisms and accumulated by shellstock.
(54) "MPN" or "Most probable number" means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.
(55) "National Shellfish Sanitation Program" or "NSSP" means the cooperative state-FDA-Industry Program for the sanitary control of shellfish.
(56) "Other deficiency" means a condition or practice noted as a deficiency on the NSSP Standardized Shellfish Processing Plant Inspection Form that is not defined as critical, or key, and is not in accordance with the requirements of this administrative regulation.
(57) "Person" means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation, or other entity.

(58) "Point source" means any discernible, confined, and discrete conveyance including any pipe, ditch, channel, tunnel, or conduit that carries pollution.
(59) "Poisonous or deleterious substance" means a toxic substance occurring naturally, or added to, the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.
(60) "Postharvest processing" means processing of shellfish for the purpose of added safety or quality that involves hazards not addressed by controls in Sections 11 through 14 of this administrative regulation.
(61) "Potable water" means water defined as potable under the provisions of 401 KAR Chapter 8.
(62) "Principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of retail sale.
(63) "Private water system" means a water system as defined in 401 KAR Chapter 8 that is constructed, maintained, and operated pursuant to applicable requirements of the Kentucky Environmental and Public Protection Cabinet.
(64) "Process batch" means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single-process water system for a specified depuration cycle in a depuration activity.
(65) "Process water" means the water used in the scheduled depuration process.
(66) "Prohibited Classification" means a classification used to identify a growing area where the harvest of shellstock, for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.
(67) "Public water system" means a water system as defined in 401 KAR Chapter 8 that is designed, constructed, maintained, and operated pursuant to applicable requirements of the Kentucky Environmental and Public Protection Cabinet.
(68) "Raw" means shellfish that have not been thermally processed:
(a) To an internal temperature of 145 degrees Fahrenheit or greater for fifteen (15) seconds (or equivalent); or
(b) Altering the organoleptic characteristics.
(69) "Repacker" or "RP" means any person, other than the original certified shucker-packer, that repackages shucked shellfish into other containers.
(70) "Repacking shellstock" means the practice of removing shellstock from containers and placing it into other containers.
(71) "Reshipper" or "RS" means a person that purchases shucked shellfish or shellstock from certified shellfish dealers and sells the product without repacking or relabeling to other certified shellfish dealers, wholesalers, or retailers.
(72) "Safe materials" means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of, or otherwise adversely affect, the characteristics of any food.
(73) "Sanitation control record" means records that document the monitoring of sanitation practices and conditions during processing.
(74) "Sanitize" means to adequately treat food contact surfaces by a process that is effective in:
(a) Destroying vegetative cells of microorganisms of public health significance;
(b) Substantially reducing the numbers of other undesirable microorganisms; and
(c) Not adversely affecting the product or its safety for the consumer.
(75) "Semipublic water supply" means a water supply as defined in 401 KAR Chapter 8 that is constructed, maintained, and operated pursuant to applicable requirements of the Kentucky Environmental and Public Protection Cabinet.
(76) "Shellfish" means all aspects of:
(a) Oysters, clams, or mussels, whether:
1. Shucked or in the shell;

2. Raw, including postharvest processed;
3. Frozen or unfrozen;
4. Whole or in-part; and

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

(77) "Shellstock" means live molluscan shellfish in the shell.

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

(79) "Shellstock shipper" or "SS" means a certified shellfish dealer who grows, harvests, buys, or repacks and sells shellstock or ships shucked shellfish and does not shuck shellfish or repack shucked shellfish.

(80) "Shucker-packer" or "SP" means a certified shellfish dealer that shucks and packs shellfish, acts as a shellstock shipper or reshipper, or repacks shellfish originating from other certified shellfish dealers.

(81) "Swing deficiency" means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstance, is either a "critical" or "key" deficiency.

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

(83) "Wet storage" means the temporary storage, by a certified shellfish dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally-approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

(84) "Wholesale" means any sale to any other person than the ultimate consumer or his or her family.

Section 2. Shellfish Dealer Certification Requirements.

(1) A person shall not act as a shellfish dealer prior to obtaining certification from the cabinet. A person shall not engage in the wholesale handling of shellfish, operate, or conduct an establishment for the shucking, repacking, reshipping, or otherwise processing of shellfish without a certificate issued by the cabinet.

(2) Certification shall be issued only to persons who meet the established requirements for certification as established in this administrative regulation.

(3) A person making application for a shellfish dealer certification shall:

(a) Make application to the cabinet on form DFS 200 and complete the application for certification to handle oysters, clams, mussels, or scallops (DFS 255) and provide all identifying information required on each application form;

(b) Have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with Sections 6 and 7 of this administrative regulation, except for the requirement for harvester identification on a certified shellfish dealer's tag; and

(c) Have a business address at which inspections of facilities, activities, equipment, records, and vehicles can be conducted.

(4) Upon receipt of the initial application for shellfish dealer certification, accompanied by a $100 certification fee, and upon approval of the certified shellfish dealer processing facility, an initial certification shall be issued by the cabinet if the applicant meets the hazard analysis critical control point (HACCP) requirements of this administrative regulation and complies with the following inspectional requirements relative to the NSSP standardized shellfish processing plant inspection form ISSC Form 93-01(A):

(a) Hazard Analysis Critical Control Point (HACCP) requirements:

1. No critical deficiencies as identified on the ISSC Form 93-01(A);

2. Not more than two (2) key deficiencies as identified on the ISSC Form 93-01(A); and

3. Not more than two (2) other deficiencies as identified on the ISSC Form 93-01(A).

(b) Sanitation items and additional model ordinance requirements:

1. No critical deficiencies as identified on the ISSC Form 93-01(A);

2. Not more than two (2) key deficiencies as identified on the ISSC Form 93-01(A); and

3. Not more than three (3) other deficiencies as identified on the ISSC Form 93-01(A).

(c) The initial shellfish dealer certification shall include a compliance schedule to correct any deficiencies not corrected by the shellfish dealer during the inspection.

(5) Shellfish dealer certifications shall expire on December 31 following the date of certification and each December 31 thereafter.

(6) Shellfish dealer certifications are renewable annually upon submittal of application accompanied by an annual fee of $100, if the dealer is in compliance with this administrative regulation.

(7) The cabinet shall not renew the certification for any shellfish dealer until the dealer:

(a) Meets the requirements of subsection (4)a and b of this section. The number of deficiencies allowed under subsection (4)a and b of this section shall include carry-over deficiencies from an existing compliance schedule approved by the cabinet and new deficiencies identified during the certification renewal inspection; and

(b) Agrees to a compliance schedule to address any new deficiencies not corrected by the shellfish dealer during the inspection.

(8) The cabinet shall not issue certification to a shellfish dealer whose certification has been suspended or revoked until the shellfish dealer meets the requirements for initial certification as provided under this administrative regulation.

(9) A shellfish processing facility shall not operate without a valid shellfish dealer certification issued by the cabinet. The shellfish dealer certification shall not be transferable with respect to persons or locations.

(10) The cabinet shall issue only one (1) certification number to a dealer for a location. A person or dealer may obtain more than one (1) certification if each business is:

(a) Maintained as a separate entity; and

(b) Is not found at the same location.

(11) A certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two (2) letter state abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this administrative regulation using the following terms:

(a) Shellstock shipper (SS);

(b) Shucker-packer (SP);

(c) Repacker (RP);

(d) Reshipper (RS); and

(e) Depuration processor (DP).

(12) A person shall not sell, offer for sale, or have in his or her possession with intent to sell, shellfish which have been taken from a place classified as "prohibited" or otherwise closed to harvesting by the pertinent regulatory authorities or from a place condemned by authorities having supervision at the point of origin of the shellfish.

(13) A person shall not receive or accept shipment of shellfish for shucking, repacking, shipping, storage, or sale unless the Kentucky shellfish dealer holds a current certificate issued pursuant to this administrative regulation. Shellfish originating from out-of-state sources shall be received from states or countries that have received the endorsement of

the U.S. Food and Drug Administration and the shellfish dealer shall be listed in the current USFDA Interstate Certified Shellfish Shippers List.

(14) Food processing establishments handling shellstock for interstate distribution shall meet the requirements of this administrative regulation to assure the sale or distribution of shellfish from safe sources and to assure shellfish has not been adulterated during cultivating, harvesting, processing, shipping, or handling.

(15) A person who ships and receives shellstock or shucked shellfish in interstate or intrastate commerce shall be certified as a certified shellfish dealer. The type of shellfish dealer certification issued shall be as follows:

(a) A person who shucks shellfish shall be certified as a shucker-packer.

(b) A person who repacks shucked shellfish shall be certified as a shucker-packer or repacker.

(c) A person who repacks shellstock shall be certified as a shellstock shipper.

(d) A person who purchases shellstock or shucked shellfish from shellfish dealers and sells the product without repacking or relabeling to other shellfish dealers, wholesalers, or retailers shall be certified as a reshipper.

(16) After a person is certified, the cabinet shall make unannounced inspections of the shellfish dealer's facilities:

(a) During periods of activity; and

(b) At the following minimum frequencies:

1. Within thirty (30) days of beginning activities if the dealer was certified on the basis of a preoperational inspection;

2. At least quarterly for shellfish dealer activities certified as shucker-packer or repacker; and

3. At least semiannually for other shellfish dealer certifications.

(17) Inspection results shall be recorded on the NSSP Standardized Shellfish Processing Plant Inspection Form (ISSC Form 93-01A). The cabinet shall provide a copy of the completed inspection forms to the person in charge at the shellfish facility at the inspection.

Section 3. Transportation.

(1) The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that a truck used to transport shellstock is properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.

(2) Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be kept clean with potable water and provided with effective drainage.

(3) Shellstock shall be transported in refrigerated trucks if the shellstock have been previously refrigerated or if ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.

(4) Prechilled trucks or other vehicles shall be used if ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.

(5) If mechanical refrigeration units are used, the units shall be:

(a) Equipped with automatic controls; and

(b) Capable of maintaining the ambient air temperature in the storage area at temperatures of forty-five (45) degrees Fahrenheit or less.

(6) Ice used to cool shellstock during transport shall meet the requirements of Section 11(10) of this administrative regulation.

(7) There shall not be cats, dogs, and other animals in any part of the truck or other vehicle where shellstock is stored.

Section 4. Receiving Shellfish.

(1) The certified shellfish dealer shall reject or discard shellfish shipments which:

(a) Do not originate from a licensed harvester or dealer; or

(b) Are unwholesome or adulterated, inadequately protected, or whose source cannot be identified.

(2) Transportation agents or common carriers used by a certified shellfish dealer are not required to be certified.

(3) The dealer shall:

(a) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this administrative regulation;

(b) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, fifty (50) degrees Fahrenheit or less for more than two (2) hours at points of transfer such as loading docks;

(c) Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at forty-five (45) degrees Fahrenheit or less; and

(d) Ensure that frozen shellfish remain frozen.

(4) All containers used to transport shellstock shall be:

(a) Constructed to allow for easy cleaning; and

(b) Operated and maintained to prevent product contamination.

(5) All containers shall be cleaned with:

(a) Potable water; and

(b) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

(6) Containers used for storing shellfish shall be clean and fabricated from safe materials.

(7) If the entire cargo consists of shellfish products only, except for bulk shipments, shellstock shipments shall be shipped on pallets. If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

(8) If the conveyance has mixed cargos, the shellfish may be shipped as part of a mixed cargo of seafood or other food product only if:

(a) Shellfish products are protected from contamination by the other cargo;

(b) All cargo is placed on pallets; and

(c) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.

(9) Ice used to cool shellfish shall meet the requirements of Section 11(10) of this administrative regulation.

Section 5. Shipping Times.

(1) If the shipping time is four (4) hours or less, the certified shellfish dealer may provide thermal recorders during shipment, but shall comply with the following shellfish shipping requirements:

(a) Shellfish shall be shipped well iced or by using other acceptable means of refrigeration;

(b) If mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of forty-five (45) degrees Fahrenheit or less; and

(c) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

(2) If the shipping time is greater than four (4) hours, the certified shellfish dealer shall comply with the following shellfish shipping requirements:

(a) Shellfish shall be shipped in mechanically-refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of forty-five (45) degrees Fahrenheit or less; or

(b) Shipped in containers with an internal ambient air temperature maintained at or below temperatures of forty-five (45) degrees Fahrenheit or less; and

(c) Unless the certified shellfish dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.

(3) The initial certified shellfish dealer shall note the date and time on the temperature-indicating device, if appropriate.

(4) Each receiving certified shellfish dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.

(5) The final receiving certified shellfish dealer shall keep the time-temperature recording chart or other record of time and temperature in a file and shall make it available to the cabinet upon request.

(6) An inoperative temperature-indicating device shall be considered as no recording device.

Section 6. HACCP Requirements for Certified Shellfish Dealers.

(1) A certified shellfish dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed or handled by that dealer and to identify the preventive measures that the certified shellfish dealer can apply to control those hazards. The dealer shall determine food safety hazards that can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.

(2) A certified shellfish dealer shall have and implement a written HACCP plan.

(a) A HACCP plan shall be specific to each location where shellfish products are processed by that dealer and, except as specified in paragraph (b) of this subsection, each kind of shellfish product processed by the certified shellfish dealer; and

(b) The HACCP plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in subsection (3) of this section are identical for all shellfish products so grouped or for all production methods so grouped.

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

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with Section 6(1) of this administrative regulation for the following:

1. Natural toxins;
2. Microbiological contamination;
3. Chemical contamination;
4. Pesticides;
5. Drug residues;
6. Unapproved use of direct or indirect food or color additives; and
7. Physical hazards;

(b) List the critical control points for each of the identified food safety hazards, including as appropriate:

1. Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. At a minimum, the critical control points shall include those identified in Sections 11(1) through (5), 12(1) through (3), 13(1) and (2), and 14(1) through (3) of this administrative regulation;

2. Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. At a minimum, the critical control points shall include those identified in Sections 11(1) through (5), 12(1) through (3), 13(1) and (2), and 14(1) through (3) of this administrative regulation;

(c) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Sections 11 through 14 of this administrative regulation, as applicable. The critical limits identified in Sections 11 through 14 of this administrative regulation, shall be met as components of good manufacturing practices;

(d) 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;

(e) Include any corrective action plans that have been developed to be followed in response to deviations from critical limits at critical control points;

(f) 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; and

(g) List the verification procedures, and frequency thereof, that the certified shellfish dealer will use in accordance with subsection (9) of this section.

(4) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of the certified shellfish dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the certified shellfish dealer.

(5) The HACCP plan shall be signed and dated:

(a) Upon initial acceptance;

(b) Upon any modification; and

(c) Upon verification of the plan in accordance with subsection (9) of this section.

(6) If a deviation from a critical limit occurs, a certified shellfish 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 subsection (7) of this section.

(7) If a deviation from a critical limit occurs, and the certified shellfish dealer does not have a corrective action plan that is appropriate for that deviation, the certified shellfish dealer shall:

(a) Segregate and hold the affected product, at least until the requirements of paragraphs (b) and (c) of this subsection 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 been trained in accordance with subsections (19) through (21) of this section, or experience, to perform the review;

(c) Take corrective action, if 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, if 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 subsections (19) through (21) of 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.

(8) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with subsection (9) of this section and the record-keeping requirements of subsections (12) through (18) of this section.

(9) A certified shellfish 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:

(a) A reassessment of the adequacy of the HACCP plan if any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. The reassessment shall be performed by an individual who has been trained in accordance

with subsections (19) through (21) of this section. The HACCP plan shall be modified immediately if a reassessment reveals that the plan is no longer adequate to fully meet the requirements of subsection (3) of this section;

(b) Ongoing verification activities including:

1. A review of consumer complaints that have been received by the certified shellfish dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

2. The calibration of process-monitoring instruments; and

3. 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 subsections (19) through (21) of this section, of the records that document:

1. The monitoring of critical control points. This review shall ensure that the records are complete and verify that the documents reflect values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made;

2. The taking of corrective actions. This review shall ensure that the records are complete and verify that appropriate corrective actions were taken in accordance with subsections (6) through (8) of this section. This review shall occur within one (1) week of the day that the records are made; and

3. 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 certified shellfish dealer's verification activities. This review shall ensure that the records are complete, and that these activities occurred in accordance with the certified shellfish dealer's written procedures. These reviews shall occur within a reasonable time after the records are made.

(10) Certified shellfish dealers shall immediately follow the procedures in subsections (6) through (8) of this section, if any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(11) The calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing, in accordance with subsection (9)(b)2 and 3 of this section, shall be documented in records that are subject to the record-keeping requirements of subsections (12) through (18) of this section.

(12) Records required by this administrative regulation shall include:

(a) The name and location of the certified shellfish 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) If appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records when observed.

(13) Except as provided by subsection (14) of this section, records required by this administrative regulation shall be retained at the certified shellfish dealer processing facility for at least one (1) year after the date they were prepared if refrigerated products, and for at least two (2) years after the date they were prepared if frozen products.

(14) Records that relate to the general adequacy of equipment or processes being used by a certified shellfish dealer, including the results of scientific studies and evaluations, shall be retained at the certified shellfish dealer processing facility for at least two (2) years after their applicability to the product being produced at the facility.

(15) If the certified shellfish dealer processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other

reasonably-accessible location at the end of the seasonal operations, but shall be immediately returned for official review upon request.

(16) Records required by this administrative regulation, including HACCP plans, shall be available for official review and copying at reasonable times.

(17) Tags on containers of shellstock are not subject to the requirements of this administrative regulation unless they are used to fulfill the requirements of Section 8 of this administrative regulation.

(18) The maintenance of records on computers is acceptable, if appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

(19) At a minimum, the following functions shall be performed by an individual who has successfully completed an approved training curriculum in the application of HACCP principles to perform these functions:

(a) Develop a HACCP plan;

(b) Reassess and modify the HACCP plan in accordance with the corrective action procedures specified in subsection (7)(e) of this section, and verify the HACCP plan in accordance with the verification activities specified in subsection (9)(a) and (b) of this section; and

(c) Perform the record review required by subsection (9)(c) of this section.

(20) An individual described in subsection (19) of this section shall provide the cabinet, upon request, a copy of their certificate of completion of training for the application of HACCP principles for shellfish processing.

(21) Relevant job experience may qualify an individual to perform the functions specified in subsection (19) of this section. The trained individual need not be an employee of the certified shellfish dealer.

Section 7. General Sanitation Requirements.

(1) A certified shellfish dealer shall monitor eight (8) key areas of sanitation conditions and practices with of sufficient frequency to ensure, at a minimum, conformance with the applicable requirements contained within Kentucky's Food, Drug and Cosmetic Act, KRS Chapter 217, and Sections 11(6) through (54), 12(4) through (42), 13(3) through (44), and 14(4) through (33) of this administrative regulation. The eight (8) key sanitation areas to be monitored are:

(a) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(c) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(d) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(f) Proper labeling, storage, and use of toxic compounds;

(g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(h) Exclusion of pests from the food plant.

(2) A certified shellfish dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by subsection (1) of this section. These records shall comply with the requirements of Section 6(12) through (18) of this administrative regulation.

(3) A dealer shall comply with the pertinent food establishment requirements of the Kentucky Food, Drug and Cosmetic Act, KRS Chapter 217, and the physical facility requirements contained in Sections 11 through 14 of this administrative regulation that are applicable to the plant and the food being processed.

(4) Certified shellfish dealers shall adopt and follow written procedures for conducting recalls of adulterated or misbranded shellfish products including: Timely notification of the cabinet of a situation requiring a recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product.

Section 8. Shellstock Identification.

(1) The certified shellfish dealer shall buy shellfish only from sources certified by the cabinet or listed in the ICSSL.

(2) The certified shellfish dealer's tags shall be:

(a) Durable, waterproof, and approved by the cabinet prior to use; and

(b) At least two and five-eighths (2 5/8) inches by five and one-fourth (5 1/4) inches in size.

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

(a) The certified shellfish dealer's name and address;

(b) The certified shellfish dealer's certification number as assigned by the cabinet and the original shellstock shipper's certification number;

(c) The date of harvest (if depurated, the date of depuration processing);

(d) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed, an appropriate geographical or administrative designation shall be used, and if depurated, the depuration cycle or lot number shall be included;

(e) If the shellstock has been placed in wet storage in a certified shellfish 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)";

(f) The type and quantity of shellstock;

(g) The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS"

(h) Shellstock intended for raw consumption shall include a consumer advisory. The following statement, or an equivalent statement, shall be included on all shellstock: "RETAILERS INFORM YOUR CUSTOMERS" "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of food-borne illness, especially if you have certain medical conditions"; and

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

(4) If both the certified shellfish dealer and harvester tags appear on the container, the certified shellfish dealer's tag shall not be required to duplicate the information on the harvester's tag.

(5) If the shellstock is removed from the original container, the tag on the new container shall meet all applicable labeling and shellstock identification requirements of this administrative regulation.

(6) If shellstock are sold in bulk, the certified shellfish dealer shall provide a transaction record prior to shipment. This transaction record shall contain the information required in Section 10(5) through (10) of this administrative regulation with the addition of the name of the consignee.

Section 9. Shucked Shellfish Labeling.

(1) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers shall be exempt from the labeling requirements in this administrative regulation. If returnable containers are used, the shipment shall be accompanied by a transaction record containing:

(a) The original shucker-packer's name and certification number;

(b) The shucking date; and

(c) The quantity of shellfish per container and the total number of containers.

(2) If the certified shellfish dealer uses master shipping cartons, the master cartons shall be exempt from these labeling requirements if the individual containers within the carton are properly labeled.

(3) At a minimum, the certified shellfish dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with the following:

(a) 21 C.F.R. Part 101 Nutrition Labeling of Food;

(b) Federal Fair Packaging and Labeling Act, 15 U.S.C. Chapter 39;

(c) 21 C.F.R. 161.30;

(d) 21 C.F.R. 161.130; and

(e) 21 C.F.R. 161.136.

(4) The certified shellfish dealer shall assure that each package containing less than sixty-four (64) fluid ounces of fresh or frozen shellfish shall have:

(a) The shucker-packer's or repacker's certification number on the label; and

(b) A "sell by date" which provides a reasonable subsequent shelf-life or the words "Best if used by" followed by a date if 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 shellfish, the year shall be added to the date.

(5) The certified shellfish dealer shall assure that each package containing sixty-four (64) or more fluid ounces of fresh or frozen shellfish shall have:

(a) The shucker-packer's or repacker's certification number on the label; and

(b) A "Date shucked" which shall:

1. For fresh shellfish, consist of the number of the day of the year or the month and the number of the day of the month;

2. For frozen shellfish, include the year; and

3. Appear on the lid and sidewall or bottom of disposable containers.

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

(7) The certified shellfish dealer shall provide label information in a legible and indelible form.

(8) If the certified shellfish dealer elects to repack shellfish, the dealer shall pack and label shellfish in accordance with this section except that the original date of shucking shall be used in establishing the sell by date.

Section 10. Shipping Documents and Records.

(1) A shellfish shipment shall be accompanied by a shipping document.

(2) The shipping document shall contain:

(a) The name, address, and certification number of the shipping dealer;

(b) The name and address of the major consignee; and

(c) The kind and quantity of the shellfish product.

(3) The receiving certified shellfish dealer shall:

(a) Maintain in a file a copy of the completed shipping document; and

(b) Make the shipping document available to the cabinet upon request.

(4) If the shipment is subdivided to different certified shellfish dealers, a receiving certified shellfish dealer shall maintain records sufficient to trace the portion received back to the original shipment.

(5) A certified shellfish dealer shall have a business address at which transaction records are maintained.

(6) A certified shellfish dealer shall maintain complete, accurate, and legible records of the cabinet's required information.

(7) Transaction records shall be sufficient to:

(a) Document that the shellfish are from a source authorized under this administrative regulation;

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

(c) Permit a lot of shucked shellfish or a lot of shellstock to be traced back to the growing area, date of harvest, and, if possible, the harvester or group of harvesters.

(8) Purchase and sales shall be recorded:

(a) In a permanently-bound ledger book; or

(b) In retrievable electronic computer files or discs.

(9) The transaction records shall be retained as follows:

(a) If fresh shellfish, for a minimum of one (1) year; and

(b) If In the case of frozen shellfish, for at least two (2) years or the shelf-life of the product, whichever is longer.

Section 11. Requirements for Certified Shellfish Dealers Engaged in Shucking and Packing.

(1) The certified shellfish dealer shall shuck and pack only shellstock which is from sources certified by the cabinet or listed in the ICSSL; and identified with a tag on each container or a transaction record on each bulk shipment.

(2) The certified shellfish dealer shall ensure upon receipt that shellfish has been transported iced or in a conveyance maintained at or below an ambient air temperature of forty-five (45) degrees Fahrenheit.

(3) The certified shellfish dealer shall ensure that the storage of shellstock, once placed under temperature control and until sale to the processor or final consumer, shall be:

(a) Stored in ice; or

(b) Placed and stored in a storage area or conveyance maintained at forty-five (45) degrees Fahrenheit or less;

(c) Not permitted to remain without ice, mechanical refrigeration, or other approved methods of refrigeration for more than two (2) hours at points of transfer such as loading docks; and

(d) Not permitted to be placed in wet storage.

(4) The certified shellfish dealer that processes shall ensure that:

(a) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five (45) degrees Fahrenheit or less within four (4) hours of removal from refrigeration; and

(b) If heat shock is used, once heat-shocked shellstock is shucked, the shucked shellfish meats shall be cooled to forty-five (45) degrees Fahrenheit or less within two (2) hours after the heat shock process.

(5) The certified shellfish dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of forty-five (45) degrees Fahrenheit or less, or covered in ice to maintain the internal product temperature of forty-five (45) degrees Fahrenheit.

(6) The certified shellfish dealer shall provide a water supply that is potable, adequate, and from an approved public supply of a municipality or water district, if available.

(7) If a public water supply of a municipality or a water district is not available, the supply for the certified shellfish dealer processing facility shall be developed and approved pursuant to applicable requirements of 401 KAR Chapter 8, Public Water Supply.
(8) The certified shellfish dealer shall have the water supply sampled in accordance with the provisions of 401 KAR Chapter 8, as applicable, and shall maintain sample results on file at the plant.
(9) The certified shellfish dealer shall assure that steam used in food processing or that comes in contact with food contact surfaces is free from any additives or deleterious substances.
(10) Ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
(a) Be made on-site from potable water in a commercial ice machine; or
(b) Come from a facility which holds a valid permit to operate as an ice manufacturer.
(11) Water from a potable water supply shall be used to wash shellstock.
(12) If the certified shellfish dealer uses a system to wash shellstock which recirculates water, the dealer shall:
(a) Obtain approval from the cabinet for the construction or remodeling of the system by submitting construction plans for approval prior to construction or renovation;
(b) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave unacceptable residues in the shellstock; and
(c) Test bacteriological water quality daily.
(13) The certified shellfish dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(a) Prevent contamination of water supplies; and
(b) Prevent cross-connection between the pressurized potable water supply and water from an unacceptable source in accordance with 815 KAR Chapter 20, State Plumbing Code. The certified shellfish dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.
(14) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction that:
(a) Is easily accessible for cleaning and inspection;
(b) Is self-draining; and
(c) Meets the requirements for food contact surfaces in accordance with subsection (16) of this section.
(15) Except for equipment in continuous use and placed in service prior to January 1, 1989, the certified shellfish dealer shall use only equipment which conforms to the Shellfish Industry Equipment Construction Guide.
(16) Food contact surfaces of equipment and utensils used by the certified shellfish dealer, including plastic ware and finished product containers, shall be:
(a) Constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced in a manner to prevent contamination of shellfish products;
(b) Free from exposed screws, bolts, or rivet heads on food contact surfaces; and
(c) Fabricated from food grade materials.
(17) The certified shellfish dealer shall assure that all joints on food contact surfaces have smooth, easily cleanable surfaces and are welded.
(18) Shucking blocks shall be provided which are:
(a) Easily cleanable;
(b) Fabricated from safe material;
(c) Solid, one (1) piece construction; and

(d) Easily removed from the shucking bench, unless the block is an integral part of the bench.

(19) The certified shellfish dealer shall provide a temperature measuring device accurate to plus or minus two (2) degrees Fahrenheit for use in monitoring product temperatures.

(20) Equipment used in heat shock processing shall meet the requirements of subsection (15) through (17) of this section.

(21) Equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in subsections (15) through (17) of this section.

(22) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The certified shellfish dealer shall:

(a) Provide adequate cleaning supplies and equipment, including three (3) compartment sinks, brushes, detergents, and sanitizers. Hot water and pressure hoses shall be available within the plant;

(b) Sanitize equipment and utensils prior to the start-up of each day's activities and following interruption during which food contact surfaces may have been contaminated;

(c) Wash and rinse equipment and utensils at the end of each day; and

(d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use.

(23) Conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

(24) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling.

(25) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.

(26) Shucked shellfish shall be packed in clean, covered containers and stored in a manner which assures their protection from contamination.

(27) If used, the finger cots or gloves shall be:

(a) Made of impermeable materials except if the use of this material is inappropriate or incompatible with the work being done;

(b) Sanitized at least twice daily;

(c) Cleaned more often, if necessary;

(d) Properly stored until used; and

(e) Maintained in a clean, intact, and sanitary condition.

(28) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.

(29) Shucked shellfish shall be protected from contamination.

(30) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.

(31) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

(32) Handwashing shall include the following:

(a) Wetting hands and forearms with running water at a temperature of 110-120 °F;

(b) Applying antibacterial or antimicrobial soap and thoroughly distributing over hands and forearms;

(c) Rubbing hands vigorously for at least twenty (20) seconds, covering all surfaces of the hands, forearms, and fingers, paying special attention to the thumbs, backs of fingers, and spaces between the fingers;

(d) Rinsing hands and forearms thoroughly to remove residual soap;

(e) Drying hands and forearms with paper towels dispensed from a sanitary dispenser or by utilizing a hand drying device that provides heated air; and
(f) Application of an approved hand sanitizer.

(33) If the same employee works in both the shucking and packing areas, the employee shall wash their hands immediately and thoroughly after entering each work area.

(34) The certified shellfish dealer shall require all employees to wash their hands in an approved hand washing facility:
(a) Before starting work;
(b) After each absence from the work station;
(c) After each work interruption; and
(d) If their hands may have become soiled or contaminated.

(35) Hand washing facilities with warm water at a minimum temperature of 110 degrees Fahrenheit, dispensed from a hot and cold mixing or combination faucet, under pressure, shall be provided.

(36) Sewage and liquid disposable wastes shall be properly removed from the facility.

(37) Toilets shall be provided and conveniently located in accordance with 815 KAR Chapter 20, State Plumbing Code.

(38) The certified shellfish dealer shall provide toilet facilities with an adequate supply of toilet paper in a suitable holder.

(39) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.

(40) The certified shellfish dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices.

(41) Lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or shielded to prevent food contamination in case of breakage.

(42) Food contact surfaces shall be protected from contamination and adulteration by using cleaning compounds and sanitizing agents in accordance with manufacturer label directions.

(43) Ice that is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice may have been subject to contamination.

(44) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.

(45) Ventilation shall be provided to minimize condensation in areas where food is stored, processed, or packed.

(46) The certified shellfish dealer shall assure that only toxic substances necessary for plant activities are present in the certified shellfish dealer processing facility.

(47) The following categories of toxic substances shall be stored separately:
(a) Insecticides and rodenticides;
(b) Detergents, sanitizers, and related cleaning agents; and
(c) Caustic acids, polishes, and other chemicals.

(48) The certified shellfish dealer shall not store toxic substances above shellfish or food contact surfaces.

(49) If pesticides are used, the certified shellfish dealer shall apply pesticides in full compliance with the manufacturer's labeling and in a manner to prevent the contamination of any shellfish or packaging materials with residues.

(50) Cleaning compounds and sanitizing agents shall be properly labeled and used in accordance with the manufacturer's label directions.

(51) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

(52) The certified shellfish dealer shall take all reasonable precautions to assure that an employee with a communicable disease that can be transmitted through food, shall be

excluded from working in any capacity in which the employee may come in contact with shellfish or with food contact surfaces.
(53) An employee with an open, exposed, or infected wound shall keep it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion.
(54) The certified shellfish dealer shall operate the certified shellfish dealer processing facility to assure that pests are excluded.
(55) The physical certified shellfish dealer processing facility shall be maintained in good repair.
(56) The certified shellfish dealer shall operate the certified shellfish dealer processing facility to provide protection from contamination and adulteration by assuring that dirt and other filth are excluded from the facility or activities.
(57) Animals or unauthorized persons shall not be allowed in portions of the certified shellfish dealer processing facility where shellfish are stored, handled, processed or packaged, or where food handling equipment, utensils, and packaging materials are cleaned or stored.
(58) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters shall not be used.
(59) The shucking and packing operation shall be separated by use of:
(a) Separate rooms;
(b) Partitions; or
(c) Spacing which is sufficient to protect product from adulteration or cross-contamination.
(60) Manufacturing activities which could result in the contamination of shellfish shall be separated by adequate barriers.
(61) The certified shellfish dealer shall provide toilet room doors which are tight fitting, self closing, and do not open directly into a processing area.
(62) Sanitary conditions shall be maintained throughout the shellfish processing facility.
(63) Dry area floors shall be hard, smooth, easily cleanable, and in good repair.
(64) Wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
(a) Are graded to provide adequate drainage;
(b) Have even surfaces and are free from cracks that create sanitary problems and interfere with drainage; and
(c) Have sealed junctions between floors and walls to render them impervious to water.
(65) Walls, ceilings, and interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials.
(66) Grounds around the facility shall be maintained to be free from rodent attraction and harborage, and inadequate drainage conditions.
(67) Hand washing facilities shall be provided which are:
(a) Convenient to work areas;
(b) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; and
(c) Plumbed to an approved sewage disposal system in accordance with 815 KAR Chapter 20, State Plumbing Code.
(68) The certified shellfish dealer shall provide at least one (1) conveniently located hand sink in the packing room.
(69) The certified shellfish dealer shall provide at each hand washing facility:
(a) A supply of hand cleansing soap or detergent;
(b) A conveniently-located supply of single-service towels in a suitable dispenser or a hand-drying device that provides heated air;

(c) An easily cleanable, covered waste receptacle;
(d) Approved hand sanitizer; and
(e) Hand washing signs in a language understood by the employees;

(70) Plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained in accordance with 815 KAR Chapter 20, State Plumbing Code, to provide a water system that is adequate in quantity and under pressure, and includes:
(a) Cold and warm water at all sinks; and
(b) Hand washing facilities adequate in number and size for the number of employees and that are located where supervisors can observe employee use.

(71) Adequate floor drainage, including backflow preventers, such as air gaps, shall be provided if floors are:
(a) Used in shellstock storage;
(b) Used for food holding units;
(c) Cleaned by hosing, flooding, or similar methods; and
(d) Subject to the discharge of water or other liquid waste on the floor during normal activities.

(72) A safe, effective means of sewage disposal for the certified shellfish dealer processing facility shall be provided. Sewage shall be disposed of into a public sewerage system, if available. If a public sewerage system is not available, disposal shall be made into a private system designed, constructed, and operated pursuant to 902 KAR 10:060 through 110, Kentucky On-site Sewage Disposal Systems, or 401 KAR Chapter 5, Water Quality.

(73) Drainage or waste pipes shall not be installed over food processing or food storage areas, or over areas in which containers and utensils are washed or stored.

(74) Ventilation, heating, or cooling systems shall not create conditions that may cause shellfish products to become contaminated.

(75) To insure that insects and vermin are not present in the facility, the dealer shall employ necessary internal and external insect and vermin control measures including tight-fitting, self-closing doors; screening of not less than fifteen (15) mesh per inch; and controlled air currents.

(76) Disposal of waste materials, shell, and other nonedible materials shall be promptly and effectively removed from the shucking bench or table. Areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.

(77) Nonfood contact surfaces of equipment and utensils utilized by the certified shellfish dealer, including plastic ware, shall be designed and fabricated for durability under conditions of normal use and shall be resistant to denting, buckling, pitting, chipping, and crazing and be made from materials that can be cleaned, sanitized, maintained, or replaced.

(78) The certified shellfish dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct:
(a) Shucking benches and contiguous walls;
(b) Stands or stalls and stools for shuckers; and
(c) Nonfood contact surfaces in shellfish storage or handling areas.

(79) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.

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

(81) Conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

(82) The certified shellfish dealer shall:

(a) Assure that shellstock is:
1. Reasonably free of sediment; and
2. Culled;
(b) Completely empty shucking buckets at the packing room so that no overage is returned to the shucker;
(c) Inspect incoming shipments and shall reject dead or inadequately protected shellstock;
(d) Not allow the use of dip buckets for hand or knife rinsing;
(e) Not have on the premises usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source;
(f) Wash, blow, and rinse shellfish meats in accordance with 21 C.F.R. 161.130;
(g) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room;
(h) Conduct packing activities to conform to applicable food additive requirements contained in KRS Chapter 217, and 21 C.F.R. Part 170 through 189;
(i) Store packaged shellfish, if they are to be frozen, at an ambient temperature of zero degrees Fahrenheit or less, and frozen solid within twelve (12) hours following the initiation of freezing; and
(j) Not commingle shellstock during shucking.

(83) A certified shellfish dealer that uses heat shock to prepare shellstock for shucking shall:
(a) Post the schedule for the heat shock process in a conspicuous location; and
(b) Make sure responsible persons are familiar with the requirements;
(c) Cool hot-dipped shellstock immediately after the heat shock process. This cooling shall be accomplished by:
1. Dipping in an ice bath; or
2. Use of flowing potable water; and
(d) If a heat shock water tank is used, the certified shellfish dealer shall completely drain and flush the tank at three (3) hour intervals or less so that mud and debris which have accumulated in the dip tank are eliminated.

(84) An employee handling shucked shellfish shall:
(a) Wear effective hair restraints;
(b) Remove hand jewelry that cannot be sanitized or secured;
(c) Wear finger cots or gloves if jewelry cannot be removed; and
(d) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean.

(85) In an area where shellfish are shucked or packed and in an area which is used for cleaning or storage of utensils, the certified shellfish dealer shall not allow employees to:
(a) Store clothing or other personal belongings;
(b) Eat or drink;
(c) Spit; or
(d) Use tobacco in any form.

(86) A reliable, competent individual shall be designated to supervise general plant management and activities and monitor compliance with this administrative regulation.

(87) Cleaning procedures shall be developed and supervised to assure that cleaning activities do not result in contamination of shellfish or food contact surfaces.

(88) Supervisors shall be:
(a) Trained in proper food handling techniques and food protection principles; and
(b) Knowledgeable of personal hygiene and sanitary practice requirements contained within 21 C.F.R. Part 110, Current Good Manufacturing Practice in Manufacturing,

Packing, or Holding Human Food.

(89) The certified shellfish dealer shall require that supervisors:

(a) Monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and the storage of personal items or clothing;

(b) Assure that proper sanitary practices are implemented, including:

1. Plant and equipment clean-up;
2. Rapid product handling; and
3. Shellfish protection from contamination; and

(c) Require employees to:

1. Be trained in proper food handling; and personal hygiene practices; and
2. Report any symptoms of illness.

Section 12. Requirements for Certified Shellfish Dealers Engaged in Repacking of Shucked Shellfish.

(1) The certified shellfish dealer receiving shellfish shall repack only shellfish which:

(a) Originated from a certified shellfish dealer;

(b) Are identified with a label as specified in Section 8 of this administrative regulation; and

(c) Has been transported iced or in a conveyance maintained at or below an ambient air temperature of forty-five (45) degrees Fahrenheit.

(2) The certified shellfish dealer processing shellfish shall ensure that repacked shellfish:

(a) Do not exceed an internal temperature of forty-five (45) degrees Fahrenheit for more than two (2) hours during processing; and

(b) Are maintained at a temperature less than forty-five (45) degrees Fahrenheit in any portion of frozen shellfish thawed for repacking.

(3) The certified shellfish dealer shall store repacked, shucked shellfish in covered containers at an ambient air temperature of forty-five (45) degrees Fahrenheit or less, or covered in ice to maintain an internal product temperature of forty-five (45) degrees Fahrenheit or less.

(4) The certified shellfish dealer shall comply with Section 11(6) through (10), (13), (15) through (17), (19), (21), (22), (25), (27), (29), (31), (32), (34) through (58), (61) through (75), (77), (80), (81), and (84) through (89) of this administrative regulation.

(5) Shucked shellfish shall be repacked in clean containers:

(a) Fabricated from food grade materials; and

(b) Stored in a manner which assures their protection from contamination.

(6) The certified shellfish dealer shall assure that employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness.

(7) Disposal of waste materials shall not create a public health hazard or nuisance.

(8) Areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.

(9) The certified shellfish dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct nonfood contact surfaces in shellfish storage or handling areas.

(10) The certified shellfish dealer shall:

(a) Not commingle shellfish from different lots;

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number;

(c) Not have on the premises usable containers or container covers bearing a certification number different from the one issued for those premises unless

documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source;

(d) Wash, blow, and rinse shellfish meats in accordance with 21 C.F.R. 161.130;

(e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly;

(f) Conduct repacking activities to conform to applicable food additive requirement contained in KRS Chapter 217, and 21 C.F.R. Parts 170 through 189; and

(g) Store packaged shellfish, if they are to be frozen, at an ambient temperature of zero degrees Fahrenheit or less and frozen solid within twelve (12) hours following the initiation of freezing.

Section 13. Requirements for Certified Shellfish Dealers Engaged in Shellstock Shipping.

(1) The certified shellfish dealer receiving shellstock shall ship or repack only shellstock which is obtained from:

(a) Sources certified by the cabinet or listed in the ICSSL;

(b) A certified shellfish dealer who has transported the shellfish iced or in a conveyance maintained at an ambient air temperature at or below forty-five (45) degrees Fahrenheit;

(c) A licensed harvester who has:

1. Harvested the shellstock from an approved or conditionally-approved area in the open status as identified by the tag; and

2. Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or

(d) A certified shellfish dealer who has identified the shellstock with a tag on each container.

(2) The certified shellfish dealer storing shellstock shall ensure that once placed under temperature control and until sold to the processor or final consumer, shellstock shall be:

(a) Iced; or

(b) Placed in a storage area or conveyance maintained at forty-five (45) degrees Fahrenheit or less;

(c) Not permitted to remain without ice, mechanical refrigeration, or other approved methods of refrigeration, as required in paragraphs (a) and (b) of this subsection for more than two (2) hours at points of transfer such as loading docks; and

(d) Not permitted to be placed in wet storage.

(3) The certified shellfish dealer shall comply with Section 11(6) through (17), (19), (21), (22), (25), (27) through (32), (34) through (57), (61) through (67), (69), (70) through (75), (77), (80), (81), and (85) through (89) of this administrative regulation.

(4) Shellstock shall be packed in clean containers.

(5) The certified shellfish dealer shall operate the certified shellfish dealer processing facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from the certified shellfish dealer processing facility.

(6) Disposal of waste materials shall not create a public health hazard or nuisance.

(7) Areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.

(8) The certified shellfish dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct any nonfood contact surfaces in shellstock storage or handling areas.

(9) The certified shellfish dealer shall:

(a) Assure that shellshock is:

1. Alive;

2. Reasonably free of sediment; and

3. Culled; and

(b) Not commingle shellstock during repacking.

(10) The certified shellfish dealer shall inspect incoming shipments and shall reject dead or inadequately-protected shellstock.

(11) A certified shellfish dealer whose activity consists of trucks or docking facilities only shall:

(a) Have a permanent business address at which records are maintained and inspections can be performed; and

(b) Not repack shellstock.

(12) A certified shellfish dealer who stores or repacks shellstock shall have:

(a) A facility for proper storage or repacking of shellstock; or

(b) Arrangements with a facility approved by the cabinet for the storage or repacking of shellstock.

Section 14. Requirements for Certified Shellfish Dealers Engaged in Reshipping.

(1) The certified shellfish dealer shall reship only shellfish received which at receiving:

(a) Are from sources certified by the cabinet or listed in the ICSSL;

(b) Are identified with a tag as specified in Section 8 of this administrative regulation or a label as specified in Section 9 of this administrative regulation; and

(c) Originated from a certified shellfish dealer who has transported the shellstock iced or in a conveyance maintained at or below an ambient air temperature of forty-five (45) degrees Fahrenheit.

(2) The certified shellfish dealer shall ensure that, once placed under temperature control and until sold to the processor or final consumer, shellstock shall be:

(a) Iced; or

(b) Placed in a storage area or conveyance maintained at forty-five (45) degrees Fahrenheit or less;

(c) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration, as required in paragraphs (a) and (b) of this subsection, for more than two (2) hours at points of transfer such as loading docks; and

(d) Not permitted to be placed in wet storage.

(3) The certified shellfish dealer shall store shucked shellfish at a temperature of forty-five (45) degrees Fahrenheit or less.

(4) The certified shellfish dealer shall comply with Section 11(6), (7), (8), (10), (13), (28), (29), (31), (32), (34) through (43), (45) through (57), (61) through (67), (69) through (75), (77), (78), (80), (81), and (85) through (89) of this administrative regulation.

(5) Equipment used to handle ice shall be kept clean and stored in a sanitary manner and shall meet the construction requirements in Section 11(15) through (17) of this administrative regulation.

(6) Disposal of waste materials shall not create a public health hazard or nuisance.

(7) Areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.

(8) The certified shellfish dealer shall:

(a) Buy shellfish only from sources holding a valid certification issued by the cabinet or listed in the most current ICSSL; and

(b) Add the dealer's name and certification number to the package.

(9) The certified shellfish dealer shall not:

(a) Commingle, sort, or repack shellstock or shucked shellfish; or

(b) Remove or alter any existing tag or label.

(10) A certified shellfish dealer whose activity consists of trucks only shall have:

(a) A facility for the storage of shellfish; or

(b) Arrangements with a facility that meets the minimum sanitation requirements for a refrigerated or frozen food storage warehouse in accordance with KRS Chapter 217; and

(c) A permanent business address at which records are maintained and inspections can be performed.

Section 15. Plan Review of Future Construction. If a certified shellfish dealer processing facility is constructed or extensively remodeled, or plumbing relocated, or additional plumbing added, or if an existing structure is converted for use as a certified shellfish dealer processing facility; properly prepared plans and specifications for the construction, renovation, or alteration; showing layout, arrangements, size, location and type of facilities and a plumbing riser diagram shall be submitted to the cabinet for approval before work is begun.

Section 16. Denial, Suspension, Revocation or Nonrenewal of Shellfish Dealer Certification.

(1) The cabinet, after notice to the applicant, shall deny initial shellfish dealer certification for failure to comply with the requirements of this administrative regulation.

(2) The cabinet, after notice to a certificate holder, and after an opportunity for a conference, may suspend, permanently revoke, or deny certificate renewal for failure to comply with the requirements of this administrative regulation. Following conference proceedings, a certificate holder may request a formal hearing pursuant to KRS Chapter 13B.

(3) If the cabinet has substantial reason to believe that an imminent public health hazard exists, or if the certificate holder has interfered with the cabinet in the performance of its duties, after the cabinet agents have duly and officially identified themselves, the certification shall be suspended immediately upon notice to the certificate holder without a conference. In this event, the certificate holder may request a conference on form DFS-212. If requested, the conference shall be granted as soon as practical, or in any event, not to exceed seven (7) days.

(4) In all other cases, a shellfish dealer's certification shall not be renewed or reinstated until the shellfish dealer complies with the requirements for initial certification found in Section 2 of this administrative regulation and is able to demonstrate substantial compliance with other pertinent requirements of this administrative regulation specific to the particular type of certification being sought.

(5) If an inspection reveals the presence of a critical deficiency as identified on the ISSC Form 93-01(A):

(a) The deficiency shall be corrected during that inspection; or

(b) The certified shellfish dealer shall cease production in areas of the facility affected by deficiency.

(6) If the certified shellfish dealer fails to comply with subsection (5) of this section, the cabinet shall immediately begin actions to suspend or revoke the certified shellfish dealer's certification.

(7) If the cabinet has reason to believe that a critical deficiency may have resulted in product contamination, the cabinet shall take appropriate action to prevent contaminated or adulterated product from reaching consumers. If necessary the cabinet shall:

(a) Quarantine undistributed lots of shellfish that may have been adulterated;

(b) Coordinate with the certified shellfish dealer a recall of distributed shellfish; and

(c) Immediately notify the appropriate federal and state health authorities where the product was distributed and the ISSC.

(8) If an inspection detects any key or other deficiencies as identified on the ISSC Form 93-01(A) that are not already covered in a compliance schedule, the cabinet, working

with the certified shellfish dealer, shall develop a compliance schedule to correct the new key or other deficiencies.

(9) If a certified shellfish dealer has failed to meet a compliance schedule for the correction of objectionable conditions noted during a previous inspection, the cabinet shall:

(a) If unique circumstances prevail, consider revising the compliance schedule;

(b) Seek suspension or revocation of the shellfish dealer's certification; or

(c) Seek other administrative remedies as provided by KRS Chapter 217.

(10) If an inspection detects four (4) or more new key deficiencies as identified on the ISSC Form 93-01(A), the cabinet shall initiate the following enforcement action towards the certified shellfish dealer:

(a) Revise the existing compliance schedule;

(b) Suspend or revoke the shellfish dealer's certification; or

(c) Seek other administrative remedies as provided by KRS Chapter 217.

(11) Any shellfish dealer whose shellfish dealer certification has been suspended may make a request in writing for reinstatement of the certification.

Section 17. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Appendix B.1., Mulluscan Shellfish Model Ordinance-Shellfish Industry Equipment Construction Guide", 2003;

(b) "DFS-200, Facility Profile", 7-01;

(c) "DFS-255, Application for Certification to Handle Oysters, Clams, Mussels or Scallops", 2005;

(d) "Shellfish Dealer Certification", 2005;

(e) "DFS-220, Food Plant Inspection Form", 04-04;

(f) "ISSC Form 93-01 (A), NSSP Standardized Shellfish Processing Plant Inspection Form", 2000;

(g) "DFS-214, Enforcement Notice", 8-96;

(h) "DFS-212, Request for Conference";

(i) "DFS-213, Notice of Conference"; and

(j) "DFS-215, Application for Reinstatement of Shellfish Dealer Certification", (2-95).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(FDC-6; 1 Ky.R. 534; eff. 3-12-1975; 20 Ky.R. 1413; 1843; eff. 1-10-1994; 22 Ky.R. 2450; eff. 8-1-1996; 32 Ky.R. 1155; 1405; eff. 3-2-2006; Crt eff. 11-5-2019; TAm eff. 3-20-2020; Crt eff. 9-2-2026.)