

901:3-8-01

**Criteria and definitions for shellfish processing.**

(A) All food processing establishments handling shellstock for interstate distribution shall meet the requirements of Chapter 901:3-8 of the Administrative Code and Chapter ~~901:3-1~~ 901:3-17 of the Administrative Code 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.

(B) Definitions.

As used in Chapter 901:3-8 of the Administrative Code:

- (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) "Approved" means acceptable to the director or responsible regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.
- (3) "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.
- (4) "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.
- (5) "Blower" means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.
- (6) "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.
- (7) "Certification" means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:
  - (a) Approval from the director to conduct the activity; and
  - (b) Compliance with the requirements of this chapter.
- (8) "Certification number" means the unique identification number issued by the director to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter state abbreviation

and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this chapter using the following terms:

- (a) Shellstock shipper (ss);
  - (b) Shucker-packer (sp);
  - (c) Repacker (rp);
  - (d) Reshipper (rs); and
  - (e) Depuration processor (dp).
- (9) "Commingle" means the act of combining different lots of shellstock or shucked shellfish.
- (10) "Compliance schedule" means a written schedule that provides a correction time period to eliminate deficiencies.
- (11) "Container" means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.
- (12) "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.
- (13) "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.
- (14) "Critical deficiency" means a condition or practice which:
- (a) Results in the production of a product that is unwholesome; or
  - (b) Presents a threat to the health or safety of the consumer.
- (15) "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.
- (16) " 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.

- (17) "Cull" means to remove dead or unsafe shellstock from a lot of shellstock.
- (18) "Dealer" means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
- (19) "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.
- (20) " Depuration processor" means a person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.
- (21) "Director" means the director of the Ohio department of agriculture.
- (22) "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.
- (23) "Dry storage" means the storage of shellstock out of water.
- (24) "Easily cleanable" means a surface which is:
  - (a) Readily accessible; and
  - (b) Is made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.
- (25) "Facility" means a structure.
- (26) "FDA" means the United States food and drug administration.
- (27) "Food contact surface" means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.
- (28) "Food safety hazard" means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

- (29) "HACCP" is an acronym that stands for hazard analysis and critical control point, a systematic, science-based approach used in food production as a means to assure food safety.
- (30) "HACCP plan" means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in Chapter 901:3-7 of the Administrative Code.
- (31) "Harvest" means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.
- (32) "Harvest area" means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.
- (33) "Harvester" means a person who takes shellstock by any means from a growing area.
- (34) "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.
- (35) "ICSSL" is an acronym that stands for Interstate Certified Shellfish Shippers List, an FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign authority.
- (36) "Importer" means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.
- (37) "Label" means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.
- (38) "Lot of shellstock" means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters.
- (39) "Lot of shucked shellfish for depuration" means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.
- (40) "Lot of shucked shellfish" means a collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

- (41) "Person" means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation or other entity. Person includes the federal government, the state, and any other public or private entity.
- (42) "Point source" means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.
- (43) "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.
- (44) "Potable water" means a water supply which meets the requirements of the Ohio environmental protection agency or the local board of health, as applicable.
- (45) "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.
- (46) "Private water system" as defined in Chapter 3701-28 of the Administrative Code means any water system, other than a public water supply system, for the provision of water for human consumption, if the system has fewer than fifteen service connections and does not regularly serve an average of at least twenty-five individuals daily at least sixty days each year.
- (47) "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.
- (48) "Process water" means the water used in the scheduled depuration process.
- (49) "Public water system" means as defined in Chapter 6109. of the Revised Code a system, for the provision to the public of water for human consumption through pipes or other constructed conveyances if the system has at least fifteen service connections or regularly serves at least twenty-five individuals.
- (50) "Repacker" means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers.
- (51) "Repacking shellstock" means the practice of removing shellstock from containers and placing it into other containers.

- (52) "Reshipper" means a person who purchases shucked shellfish or shellstock from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.
- (53) "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.
- (54) "Sanitation control record" means records that document the monitoring of sanitation practices and conditions during processing.
- (55) "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.
- (56) "Shellfish" means all aspects of:
- (a) Oysters, clams, or mussels, whether:
    - (i) Shucked or in the shell;
    - (ii) Fresh or frozen; and
    - (iii) Whole or in part; and
  - (b) Scallops in any form, except when the final product form is the adductor muscle only.
- (57) "Shellstock" means live molluscan shellfish in the shell.
- (58) "Shellstock packing" means the process of placing shellstock into containers for introduction into commerce.
- (59) "Shellstock shipper" means a dealer who grows, harvests, buys, or repacks and sells shellstock. A shellstock shipper may also ship shucked shellfish. A shellstock shipper is not authorized to shuck shellfish nor to repack shucked shellfish.

- (60) "Shucker-packer" means a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.
- (61) "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.
- (62) "Wet storage" means the temporary storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

Effective: 6/25/2020

Five Year Review (FYR) Dates: 11/14/2019 and 06/25/2025

CERTIFIED ELECTRONICALLY

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Certification

06/15/2020

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Date

Promulgated Under: 119.03  
Statutory Authority: 3715.021  
Rule Amplifies: 3715.021 , 3715.02  
Prior Effective Dates: 06/16/2003

901:3-8-03

**General requirements for dealers.****(A) General HACCP requirements.**

- (1) Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.
- (2) Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:
  - (a) Each location where shellfish products are processed by that dealer; and
  - (b) Except as specified in paragraph (A)(2)(c) of this rule, each kind of shellfish product processed by the dealer.
  - (c) The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in paragraph (A)(3) of this rule 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 paragraph (A)(1) of this rule for the following:
    - (i) Natural toxins;
    - (ii) Microbiological contamination;
    - (iii) Chemical contamination;
    - (iv) Pesticides;
    - (v) Drug residues;
    - (vi) Unapproved use of direct or indirect food or color additives; and
    - (vii) Physical hazards;

- (b) List the critical control points for each of the identified food safety hazards, including as appropriate:
    - (i) Critical control points designed to control food safety hazards 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 paragraph (A) of rule 901:3-8-04, paragraph (A) of rule 901:3-8-05, paragraph (A) of rule 901:3-8-06, and paragraph (A) of rule 901:3-8-07 of the Administrative Code, as applicable;
    - (ii) 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 paragraph (A) of rule 901:3-8-04, paragraph (A) of rule 901:3-8-05, paragraph (A) of rule 901:3-8-06, and paragraph (A) of rule 901:3-8-07 of the Administrative Code, as applicable.
  - (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 rules 901:3-8-04, 901:3-8-05, 901:3-8-06, and 901:3-8-07 of the Administrative Code, as applicable. The critical limits identified in rules 901:3-8-04, 901:3-8-05, 901:3-8-06, and 901:3-8-07 of the Administrative Code, 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.
  - (g) List the verification procedures, and frequency thereof, that the dealer will use in accordance with paragraph (A)(6) of this rule.
- (4) Signing and dating the HACCP plan.
- (a) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official

of the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer.

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

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with paragraph (A)(6) of this rule.

(5) Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(i) Following a corrective action plan that is appropriate for the particular deviation, or

(ii) Following the procedures in paragraph (A)(5)(b) of this rule.

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

(i) Segregate and hold the affected product, at least until the requirements of paragraph (A)(5)(b)(ii) and paragraph (A)(5)(b)(iii) of this rule are met;

(ii) 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 paragraph (A)(8) of this rule, or experience, to perform such a review;

(iii) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(iv) Take corrective action, when necessary, to correct the cause of the deviation;

(v) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with paragraph (A)(8) of this rule, 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.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with paragraph (A)(6) of this rule and the record keeping requirements of paragraph (A)(7) of this rule.

(6) Verification.

(a) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(i) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. The reassessment shall be performed by an individual or individuals who have been trained in accordance with paragraph (A)(8) of this rule. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of paragraph (A)(3) of this rule;

(ii) Ongoing verification activities including:

(a) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(b) The calibration of process-monitoring instruments; and

(c) At the option of the dealer, the performing of periodic end product or in-process testing.

(iii) A review, including signing and dating, by an individual who has been trained in accordance with paragraph (A)(8) of this rule, of the records that document:

(a) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are

complete and to verify that they document values that are within the critical limits. This review shall occur within one week of the day that the records are made;

(b) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with paragraph (A)(5) of this rule. This review shall occur within one week of the day that the records are made; and

(c) The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the dealer's verification activities. The purpose of these reviews shall be to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) Dealers shall immediately follow the procedures in paragraph (A)(5) of this rule whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraph (A)(6)(a)(ii)(b) and paragraph (A)(6)(a)(ii)(c) of this rule shall be documented in records that are subject to the record keeping requirements of paragraph (A)(7) of this rule.

#### (7) Records.

(a) All records required by paragraph (A) and paragraph (B) of this rule shall include:

(i) The name and location of the dealer;

(ii) The date and time of the activity that the record reflects;

(iii) The signature or initials of the person performing the operation; and

(iv) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

- (b) All records required by paragraph (A) and paragraph (B) of this rule shall be retained at the processing facility for at least one year after the date they were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen products.
  - (c) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two years after their applicability to the product being produced at the facility.
  - (d) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.
  - (e) All records required by paragraph (A) and paragraph (B) of this rule and HACCP plans required by paragraph (A)(2) and paragraph (A)(3) of this rule shall be available for official review and copying at reasonable times.
  - (f) Tags on containers of shellstock are not subject to the requirements of this rule unless they are used to fulfill the requirements of paragraph (E) of this rule.
  - (g) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.
- (8) Training.
- (a) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing to perform these functions:
    - (i) Developing a HACCP plan;
    - (ii) Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in paragraph (A)(5)(b)(v) of this rule, and the HACCP plan in accordance with the verification activities specified in paragraph (A)(6)(a)(i) of this rule; and
    - (iii) Performing the record review required by paragraph (A)(6)(a)(iii) of this rule.

- (b) An individual described in paragraph (A)(8) of this rule shall provide the director, upon request, a copy of their certificate of completion of training for the application of HACCP principles for shellfish processing.
- (c) Job experience may qualify an individual to perform these functions specified in paragraph (A)(8) of this rule. The trained individual need not be an employee of the dealer.

(B) General sanitation requirements.

- (1) Each dealer shall monitor general sanitation conditions and practices that are both appropriate to the plant and the food being processed to ensure, at a minimum, conformance with the applicable requirements specified in Chapter ~~901:3-1~~901:3-17 of the Administrative Code; and paragraph (B) of rule 901:3-8-04, paragraph (B) of rule 901:3-8-05, paragraph (B) of rule 901:3-8-06, and paragraph (B) of rule 901:3-8-07 of the Administrative Code. The requirements specified in these rules relate to the following sanitation items:
  - (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) Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (B)(1) of this rule. These records are subject to the requirements of paragraph (A)(7) of this rule.

(C) Physical facilities.

Each dealer shall comply with the requirements in Chapter ~~901:3-1~~901:3-17 of the Administrative Code and the physical facility requirements contained in paragraph (C) rule 901:3-8-04, paragraph (C) of rule 901:3-8-05, paragraph (C) of rule 901:3-8-06, and paragraph (C) of rule 901:3-8-07 of the Administrative Code that are applicable to the plant and the food being processed.

(D) Certification requirements.

(1) General.

- (a) No person shall act as a dealer prior to obtaining certification from the director.
- (b) Any person who wants to be a dealer shall:
  - (i) Make application to the director for certification or recertification and provide all identifying information required on the application form;
  - (ii) Have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with Chapter 901:3-7 of the Administrative Code, except for the requirement for harvester identification on a dealer's tag.
- (c) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.
- (d) Upon receipt of such application and upon approval of the facilities and sanitary condition of the establishment or area, a certification shall be issued by the director.
- (e) All shellfish certifications shall expire on December thirty-first of each year and shall be renewed. In no case shall a shellfish processing establishment operate without a valid certification issued by the director. The certification shall not be transferable with respect to persons or locations.

- (f) Current certifications shall be kept on file and open to inspection by the director.
- (g) The director, after notice and hearing, held in accordance with Chapter 119. of the Revised Code may refuse to issue or may revoke the certification for failure to comply with this chapter and applicable provisions of Chapter 901:3-7 of the Administrative Code pertaining to shellfish.
- (h) If the director determines that an emergency exists that presents a clear and present danger to the public health, the director may suspend a certification, effective without a hearing. Thereafter, without delay, the director shall afford the shellfish operator an opportunity for a hearing. On determining that there is no longer a clear and present danger to the public health, the director may rescind the suspension without a hearing.

(2) Types of certification.

- (a) Any person who shucks shellfish shall be certified as a shucker-packer.
- (b) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker.
- (c) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker.
- (d) Any person who ships and receives the shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.
- (e) Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers shall be certified as a reshipper.
- (f) A repacker shall not shuck shellfish.

(E) Shellstock identification.

- (1) The dealer shall buy shellfish only from sources certified by the director or listed in the ICSSL.
- (2) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:
  - (a) Shipped; or

(b) Emptied to wash, grade, or pack the shellstock.

(3) Tags.

(a) The dealer's tags shall:

(i) Be durable, waterproof, and sanctioned by the director prior to use; and

(ii) Be at least two and five eighths inches by five and one-fourth inches in size.

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

(i) The dealer's name and address;

(ii) The dealer's certification number as assigned by the director and the original shellstock shipper's certification number;

(iii) The date of harvest;

(iv) 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 then an appropriate geographical or administrative designation must be used;

(v) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement: "This product is a product of (name of state) and was wet stored at (facility certification number) from (date) to (date)";

(vi) The type and quantity of shellstock; and

(vii) The following statement in bold capitalized type on each tag "This tag is required to be attached until container is empty or is retagged and thereafter kept on file for ninety days";

(viii) All 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 foodborne illness, especially if you have certain medical conditions".

- (c) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.
  - (d) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in paragraph (E)(2) of this rule.
- (4) Tagging of a lot of shellstock during intermediate processing.
- (a) When the shellstock is removed from the original container, the dealer shall:
    - (i) Keep the harvester tag for ninety days;
    - (ii) Keep track of the growing area and date of harvest for shellstock; and
    - (iii) Maintain the lot identity of all shellstock during any intermediate stage of processing.
  - (b) A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the director to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.
  - (c) In order for a dealer to tag a lot container of shellstock in lieu of meeting the requirement in paragraph (E)(2) of this rule for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the director which establishes the procedures the dealer shall use to tag the lot during the washing, packing or staging of shellfish.
- (5) If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in paragraph (G)(2) of this rule with the addition of the name of the consignee.

(F) Shucked shellfish labeling.

(1) Shellfish labeling.

- (a) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in

this rule. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:

- (i) The original shucker-packer's name and certification number;
  - (ii) The shucking date; and
  - (iii) The quantity of shellfish per container and the total number of containers.
- (b) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.
- (c) At a minimum, the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with 21 CFR 161.30 and 21 CFR 161.136 (2018).
- (d) The dealer shall assure that each package containing less than sixty-four fluid ounces of fresh or frozen shellfish shall have:
- (i) The shucker-packer's or repacker's certification number on the label; and,
  - (ii) A "Sell by date" which provides a reasonable subsequent shelf-life or the words "Best if used by" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year will be added to the date.
- (e) The dealer shall assure that each package containing more than sixty-four fluid ounces of fresh or frozen shellfish shall have:
- (i) The shucker-packer's or repacker's certification number on the label; and,
  - (ii) A "Date shucked" which shall:
    - (a) 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;
    - (b) For frozen shellfish, include the year; and,

- (c) Appear on the lid and sidewall or bottom of disposable containers.
  - (f) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.
  - (g) The dealer shall provide all label information in a legible and indelible form.
- (2) If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with paragraph (F) of this rule except that the original date of shucking shall be used in establishing the sell by date.

(G) Shipping documents and records.

(1) Shipping documents.

- (a) Each shellfish shipment shall be accompanied by a shipping document.
- (b) The shipping document shall contain:
  - (i) The name, address, and certification number of the shipping dealer;
  - (ii) The name and address of the major consignee; and
  - (iii) The kind and quantity of the shellfish product.
- (c) The receiving dealer shall:
  - (i) Maintain in a file a copy of the completed shipping document; and
  - (ii) Make the shipping document available to the director upon request.
- (d) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace the portion received back to the original shipment.

(2) Transaction and shipping records.

- (a) Each dealer shall have a business address at which transaction records are maintained.
- (b) Each dealer shall maintain complete, accurate, and legible records of the director's required information in a form authorized by the director.
- (c) Transaction records shall be sufficient to:

- (i) Document that the shellfish are from a source authorized under this chapter;
  - (ii) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
  - (iii) Permit a lot of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, and if possible, the harvester or group of harvesters.
- (d) Purchase and sales shall be recorded:
- (i) In a permanently bound ledger book; or
  - (ii) Using other recording methods acceptable to and authorized by the director.
- (e) The transaction records shall be retained:
- (i) In the case of fresh shellfish, for a minimum of one year; and
  - (ii) In the case of frozen shellfish, for at least two years or the shelf-life of the product, whichever is longer.
- (f) If computer records are maintained, the director shall approve the format and its use.

Effective: 6/25/2020

Five Year Review (FYR) Dates: 11/14/2019 and 06/25/2025

CERTIFIED ELECTRONICALLY

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Certification

06/15/2020

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Date

Promulgated Under: 119.03  
Statutory Authority: 3715.02, 3715.021  
Rule Amplifies: 3715.02, 3715.021 , 3715.52, 3715.59, 3715.60,  
3715.61  
Prior Effective Dates: 06/16/2003

901:3-8-04

**Shucking and packing.**

## (A) Critical control points.

- (1) The dealer shall shuck and pack only shellstock which is from sources certified by the director or listed in the ICSSL; and identified with a tag on each container or a transaction record on each bulk shipment.
- (2) The dealer shall ensure that the storage of shellstock once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
  - (a) Iced; or
  - (b) Placed and stored in a storage area or conveyance maintained at forty-five degrees Fahrenheit or less;
  - (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than two hours at points of transfer such as loading docks; and
  - (d) Not permitted to be placed in wet storage.
- (3) The dealer that processes shall ensure that:
  - (a) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five degrees Fahrenheit or less within four hours of removal from refrigeration.
  - (b) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to forty-five degrees Fahrenheit or less within two hours after the heat shock process.
- (4) The dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of forty-five degrees Fahrenheit or less.

## (B) Sanitation.

- (1) Safety of water supply for processing and ice production.
  - (a) Water supply.

The dealer shall provide a water supply approved by the applicable regulatory agency:

- (i) For a public water system, the Ohio environmental protection agency;  
or
  - (ii) For a private water system, the local board of health.
- (b) The dealer shall have the water supply sampled in accordance with the approval of the Ohio environmental protection agency or the local board of health as applicable, and shall maintain sample results on file at the plant.
- (c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances.
- (d) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
  - (i) Be made on-site from potable water in a commercial ice machine; or
  - (ii) Come from a facility approved by the director or the appropriate regulatory agency.
- (e) Shellstock washing.
  - (i) Water from a potable water supply shall be used to wash shellstock.
  - (ii) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
    - (a) Obtain approval for the construction or remodeling of the system from the director.
    - (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 any unacceptable residues in the shellstock; and
    - (c) Test bacteriological water quality daily.
- (f) Plumbing and related facilities.
  - (i) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

- (a) Prevent contamination of water supplies;
        - (b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.
    - (ii) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
      - (a) Is easily accessible for cleaning and inspection;
      - (b) Is self-draining; and
      - (c) Meets the requirements for food contact surfaces.
- (2) Condition and cleanliness of food contact surfaces.
  - (a) Equipment and utensil construction for food contact surfaces.
    - (i) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to the shellfish industry equipment construction guide in Appendix A of this rule.
    - (ii) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
      - (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 any exposed screws, bolts, or rivet heads on food contact surfaces; and
      - (c) Fabricated from food grade materials.
    - (iii) The dealer shall assure that all joints on food contact surfaces have smooth easily cleanable surfaces; and are welded.
    - (iv) Shucking blocks shall be provided which are:
      - (a) Easily cleanable;



- (v) Shucked shellfish shall be packed in clean containers and stored in a manner which assures their protection from contamination.
- (vi) If used, the finger cots or gloves shall be:
  - (a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
  - (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.

(3) Prevention of cross contamination.

(a) Protection of shellfish.

- (i) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.
- (ii) Shucked shellfish shall be protected from contamination.
- (iii) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.
- (iv) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

(b) Employee practices.

- (i) Where the same employees work in both the shucking and packing activities, the employees shall wash their hands thoroughly after entering.
- (ii) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
  - (a) Before starting work;
  - (b) After each absence from the work station;

(c) After each work interruption; and

(d) Any time when their hands may have become soiled or contaminated.

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities.

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

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

(c) An adequate number of conveniently located toilets shall be provided.

(d) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.

(5) Protection from adulterants.

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

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

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

(d) Protection of ice used in shellfish processing.

(i) Ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination.

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

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

(6) Proper labeling, storage, and use of toxic compounds.

(a) Storage of toxic compounds.

- (i) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.
- (ii) Each of 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.
- (iii) The dealer shall not store toxic substances above shellfish or food contact surfaces.

(b) Use and labeling of toxic compounds.

- (i) When pesticides are used, the dealer shall apply pesticides in accordance with Chapter 921. of the Revised Code and the rules adopted thereunder to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues.
- (ii) Cleaning compounds and sanitizing agents shall be properly labeled and used only in accordance with the manufacturer's label directions.
- (iii) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

(7) Control of employees with adverse health conditions.

- (a) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces.
- (b) An employee with an infected wound shall keep it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion.

- (8) The dealer shall operate the facility to assure that pests are excluded from the facility and processing activities.

(C) Physical facilities.

(1) Plants and grounds.

(a) General.

- (i) The physical facilities shall be maintained in good repair.
- (ii) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored.
- (iii) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed.

(b) Separation of operations.

- (i) Facilities for shucking and packing activities shall be separated by use of:
- (a) Separate rooms;
- (b) Partitions; or
- (c) Sufficient spacing.
- (ii) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers.

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

(d) Plant interior.

- (i) Sanitary conditions shall be maintained throughout the facility.
- (ii) All dry area floors shall be hard, smooth, easily cleanable;

- (iii) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
  - (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.
- (iv) 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.
- (e) Grounds around the facility shall be maintained to be free from rodent attraction and harborage, and inadequate drainage conditions which can result in shellfish contamination.

(2) Plumbing and related facilities.

- (a) Hand washing facilities shall be provided which are:
  - (i) Convenient to work areas;
  - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; and
  - (iii) Directly plumbed to an approved sewage disposal system.
- (b) The dealer shall provide at least one hand sink in the packing room.
- (c) The dealer shall provide at each hand washing facility:
  - (i) A supply of hand cleansing soap or detergent;
  - (ii) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;
  - (iii) An easily cleanable waste receptacle; and
  - (iv) Hand washing signs in a language understood by the employees;

- (d) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure , and includes:
    - (i) Cold and warm water at all sinks; and
    - (ii) Hand washing facilities adequate in number and size for the number of employees, and that are located where supervisors can observe employee use;
  - (e) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
    - (i) Used in shellstock storage;
    - (ii) Used for food holding units;
    - (iii) Cleaned by hosing, flooding, or similar methods; and
    - (iv) Subject to the discharge of water or other liquid waste on the floor during normal activities.
  - (f) A safe, effective means of sewage disposal for the facility shall be provided;
  - (g) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.
- (3) Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- (4) 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 but not limited to tight fitting, self-closing doors; screening of not less than fifteen mesh per inch; and controlled air currents.
- (5) Disposal of waste materials, shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.
- (6) Equipment construction for non-food contact surfaces.

- (a) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced.
- (b) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct:
  - (i) Shucking benches and contiguous walls; and
  - (ii) Stands or stalls and stools for shucker;
  - (iii) Any non-food contact surfaces in shellfish storage or handling areas.
- (c) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.

(7) Cleaning non-food contact surfaces.

- (a) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.
- (b) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

(8) Shellfish storage and handling.

The dealer shall:

- (a) Assure that shellstock is:
  - (i) Reasonably free of sediment; and,
  - (ii) 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 any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source.
  - (f) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161.130 (2018).
  - (g) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room.
  - (h) Conduct packing activities so as to conform to applicable food additive regulations.
  - (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 hours following the initiation of freezing.
  - (j) Not commingle shellstock during shucking.
- (9) A 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 all responsible persons are familiar with the requirements.
  - (c) Cool all hot dipped shellstock immediately after the heat shock process. This cooling shall be accomplished by:
    - (i) Dipping in an ice bath; or
    - (ii) Use of flowing potable water.
  - (d) If a heat shock water tank is used, the dealer shall completely drain and flush the tank at three hour intervals or less so that all mud and debris which have accumulated in the dip tank are eliminated.
- (10) Any employee handling shucked shellfish shall be required to:
- (a) Wear effective hair restraints;
  - (b) Remove any hand jewelry that cannot be sanitized or secured;
  - (c) Wear finger cots or gloves if jewelry cannot be removed;

- (d) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean; and
- (e) In any area where shellfish are shucked or packed and in any area which is used for cleaning or storage of utensils, the dealer shall not allow employees to:
  - (i) Store clothing or other personal belongings;
  - (ii) Eat or drink;
  - (iii) Spit; or
  - (iv) Use tobacco in any form.

(11) Supervision.

- (a) A reliable, competent individual shall be designated to supervise general plant management and activities.
- (b) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.
- (c) All supervisors shall be:
  - (i) Trained in proper food handling techniques and food protection principles; and
  - (ii) Knowledgeable of personal hygiene and sanitary practices.
- (d) The dealer shall require:
  - (i) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing;
  - (ii) Supervisors to assure that proper sanitary practices are implemented, including:
    - (a) Plant and equipment clean-up;
    - (b) Rapid product handling; and,
    - (c) Shellfish protection from contamination.

- (iii) Employees to be trained in proper food handling and personal hygiene practices, and to report any symptoms of illness to their supervisor.

Effective: 6/25/2020

Five Year Review (FYR) Dates: 11/14/2019 and 06/25/2025

CERTIFIED ELECTRONICALLY

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Certification

06/15/2020

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Date

Promulgated Under: 119.03  
Statutory Authority: 3715.02, 3715.021  
Rule Amplifies: 3715.02 , 3715.021, 3715.52, 3715.59, 3715.60  
Prior Effective Dates: 06/16/2003

901:3-8-05

**Repacking of shucked shellfish.****(A) Critical control points.**

- (1) The dealer receiving shellfish shall repack only shellfish which:
  - (a) Originated from a dealer; and
  - (b) Are identified with a label as specified in paragraph (E) of rule 901:3-8-03 of the Administrative Code.
- (2) The dealer processing shellfish shall ensure that repacked shellfish are:
  - (a) Maintained at an internal temperature of forty-five degrees Fahrenheit or less; and
  - (b) Maintained at a temperature less than forty-five degrees Fahrenheit in any portion of frozen shellfish thawed for repacking.
- (3) The dealer shall store repacked, shucked shellfish in covered containers at an ambient air temperature of forty-five degrees Fahrenheit or less.

**(B) Sanitation.**

- (1) Safety of water supply for processing and ice production.
  - (a) The dealer shall provide a water supply approved by the applicable regulatory agency:
    - (i) For a public water system, the Ohio environmental protection agency;  
or
    - (ii) For a private water system, the local board of health.
  - (b) The dealer shall have the water supply sampled in accordance with the approval of the Ohio environmental protection agency or the local board of health as applicable, and shall maintain sample results on file at the plant.
  - (c) The dealer shall assure that any steam used in food processing or that comes in contact with food surfaces is free from any additives or deleterious substances.
  - (d) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

- (i) Be made on-site from potable water in a commercial ice machine; or
- (ii) Come from a facility approved by the director or the appropriate regulatory agency.

(2) Plumbing and related facilities.

- (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

- (i) Prevent contamination of water supplies;
- (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.

(3) Condition and cleanliness of food contact surfaces.

- (a) Equipment and utensil construction for food contact surfaces.

- (i) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to the shellfish industry equipment construction guide as specified in appendix A of rule 901:3-8-04 of the Administrative Code.
- (ii) The dealer shall use only equipment and utensils, including approved plastic ware which is:
  - (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 any exposed screws, bolts, or rivet heads on food contact surfaces; and
  - (c) Fabricated from food grade materials.
- (iii) The dealer shall assure that all joints on food contact surfaces have smooth, easily cleanable surfaces; and are welded.
- (iv) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in

paragraph (B)(2)(a)(i) of rule 901:3-8-04, paragraph (B)(2)(a)(ii) of rule 901:3-8-04, and paragraph (B)(2)(a)(iii) of rule 901:3-8-04 of the Administrative Code.

(b) Cleaning and sanitizing of food contact surfaces.

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

- (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers. Hot water and pressure hoses shall be available within the plant;
- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and
- (iii) Wash and rinse equipment and utensils at the end of each day.

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

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

- (i) Fabricated from food grade materials; and
- (ii) Stored in a manner which assures their protection from contamination.

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

- (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
- (ii) Sanitized at least twice daily;
- (iii) Cleaned more often, if necessary;
- (iv) Properly stored until used; and
- (v) Maintained in a clean, intact, and sanitary conditions.

(4) Prevention of cross contamination.

(a) Protection of shellfish.

- (i) Shucked shellfish shall be protected from contamination;
  - (ii) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.
- (b) Employee practices.
  - (i) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness.
  - (ii) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
    - (a) Before starting work;
    - (b) After each absence from the work station;
    - (c) After each work interruption; and
    - (d) Any time when their hands may have become soiled or contaminated.
- (5) Maintenance of hand washing, hand sanitizing, and toilet facilities.
  - (a) Hand washing facilities with warm water at a minimum temperature of one hundred ten degrees Fahrenheit, dispensed from a hot and cold mixing or combination faucet, shall be provided.
  - (b) Sewage and liquid disposable wastes shall be properly removed from the facility.
  - (c) An adequate number of conveniently located toilets shall be provided.
  - (d) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.
- (6) Protection from adulterants.
  - (a) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.
  - (b) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed

shall be of the safety type or protected to prevent food contamination in case of breakage.

- (c) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with the manufacturer's label directions.
  - (d) Ice used in shellfish processing which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.
  - (e) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.
- (7) Proper labeling, storage, and use of toxic compounds.
- (a) Storage of toxic compounds.
    - (i) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.
    - (ii) Each of 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.
    - (iii) The dealer shall not store toxic substances above shellfish or food contact surfaces.
  - (b) Use and labeling of toxic compounds.
    - (i) When pesticides are used, the dealer shall apply pesticides in accordance with Chapter 921 of the Revised Code and the rules adopted thereunder to control insects and rodents in such a manner to prevent the contamination of any shellfish or repackaging materials with residues.

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

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

(8) Control of employees with adverse health conditions.

(a) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces.

(b) An employee with an infected wound shall keep it covered with proper bandage, an impermeable barrier, and a single-use glove for a hand lesion.

(9) The dealer shall operate the facility to assure that pests which may be a source of shellfish contamination are excluded from the facility.

(C) Physical facilities.

(1) Plants and grounds.

(a) General.

(i) The physical facilities shall be maintained in good repair.

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

(iii) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed.

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

(c) The dealer shall provide toilet room doors which are tight fitting, self closing, and do not open directly into a processing area.

(d) Plant interior.

- (i) Sanitary conditions shall be maintained throughout the facility;
- (ii) All dry area floors shall be hard, smooth, easily cleanable; and
- (iii) All wet area floors used in areas to process food and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
  - (a) Are graded to provide adequate drainage;
  - (b) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;
  - (c) Have sealed junctions between floors and walls to render them impervious to water.
- (iv) 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.
- (v) Grounds around the facility shall be maintained to be free from rodent attraction and harborage, and inadequate drainage conditions which can result in shellfish contamination.

(2) Plumbing and related facilities.

- (a) Hand washing facilities shall be provided which are:
  - (i) Convenient to work areas;
  - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; and
  - (iii) Directly plumbed to an approved sewage disposal system.
- (b) The dealer shall provide at least one hand sink in the packing room.
- (c) The dealer shall provide at each hand washing facility:
  - (i) A supply of hand cleansing soap or detergent;
  - (ii) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;

- (iii) An easily cleanable waste receptacle; and
    - (iv) Hand washing signs in a language understood by the employees.
  - (d) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
    - (i) Cold and warm water at all sinks; and
    - (ii) Hand washing facilities adequate in number and size for the number of employees and that are located where supervisors can observe employee use.
  - (e) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
    - (i) Used for food holding units;
    - (ii) Cleaned by hosing, flooding, or similar methods; and
    - (iii) Subject to the discharge of water or other liquid waste on the floor during normal activities.
  - (f) A safe, effective means of sewage disposal for the facility shall be provided.
  - (g) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.
- (3) Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- (4) 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 but not limited to tight fitting, self-closing doors; screening of not less than fifteen mesh per inch; and controlled air currents.
- (5) Disposal of other wastes.
  - (a) Disposal of waste materials shall not create a public health hazard or nuisance.

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

(6) Equipment construction for non-food contact surfaces.

- (a) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and
- (b) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas.

(7) Cleaning non-food contact surfaces.

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

(8) Shellfish storage and handling.

(a) The dealer shall:

- (i) Not commingle shellfish from different lots;
- (ii) Repack shucked shellfish meats only into containers labeled with the authorized certification number;
- (iii) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source.
- (iv) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161.130 (2018).
- (v) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly;

- (vi) Conduct repacking activities so as to conform to applicable food additive regulations;
- (vii) Store packaged shellfish, if they are to be frozen, at an ambient temperature of zero degrees Fahrenheit or less and frozen solid within twelve hours following the initiation of freezing.

(9) Any employee handling shucked shellfish shall be required to:

- (a) Wear effective hair restraints;
- (b) Remove any hand jewelry that cannot be sanitized or secured;
- (c) Wear finger cots or gloves if jewelry cannot be removed;
- (d) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean;
- (e) In any area where shellfish are shucked or packed and in any area which is used for cleaning or storage of utensils, the dealer shall not allow employees to:
  - (i) Store clothing or other personal belongings;
  - (ii) Eat or drink;
  - (iii) Spit; or
  - (iv) Use tobacco in any form.

(10) Supervision.

- (a) A reliable, competent individual shall be designated to supervise general plant management and activities;
- (b) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.
- (c) All supervisors shall be:
  - (i) Trained in proper food handling techniques and food protection principles; and
  - (ii) Knowledgeable of personal hygiene and sanitary practices.

(d) The dealer shall require:

(i) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing.

(ii) Supervisors to assure that proper sanitary practices are implemented, including:

(a) Plant and equipment clean-up;

(b) Rapid product handling; and

(c) Shellfish protection from contamination.

(iii) Employees to:

(a) Be trained in proper food handling and personal hygiene practices; and

(b) Report any symptoms of illness to their supervisor.

Effective: 6/25/2020  
Five Year Review (FYR) Dates: 11/14/2019 and 06/25/2025

CERTIFIED ELECTRONICALLY

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Certification

06/15/2020

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Date

Promulgated Under: 119.03  
Statutory Authority: 3715.02, 3715.021  
Rule Amplifies: 3715.02, 3715.021 , 3715.52, 3715.59, 3715.60  
Prior Effective Dates: 06/16/2003