

901:3-7-01

Criteria and definitions for fish and fishery products.

(A) Food processing establishments processing fish and fishery products shall comply with Chapter 901:3-7 and the applicable provisions of Chapter 901:3-17 of the Administrative Code. The rules in this chapter do not apply to all of the following:

- (1) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
- (2) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
- (3) The operation of a retail food establishment or food service operation as defined in Chapter 3717. of the Revised Code.
- (4) A non-profit organization exempt from federal income taxation pursuant to section 501 (c)(3) of the Internal Revenue Code, 26 U.S.C.A., or senior centers created under section 173.11 of the Revised Code, that do both of the following:
 - (a) Moves fish or fishery products from a food processing establishment to another location under their control; and,
 - (b) Serves the food to the end consumer, without charge.

(B) Definitions.

As used in Chapter 901:3-7 of the Administrative Code:

- (1) "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.
- (2) "Corrective action plan" means a plan that describes the steps to be taken and assigns responsibility for those steps as they pertain to a particular deviation from the HACCP plan.
- (3) "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.
- (4) "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.

- (5) "Fish" means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life and the roe of such animals, including but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin and all mollusks, where such animal life is intended for human consumption. Fish does not include birds or mammals.
- (6) "Fishery product" means any human food product in which fish is a characterizing ingredient.
- (7) "Food safety hazard" means any biological, chemical, or physical property determined through experience, illness data, scientific reports, or other information, that may cause a food to be unsafe for human consumption.
- (8) "Food processing establishment" has the same meaning as defined in section 3715.021 of the Revised Code.
- (9) "HACCP" means hazard analysis and critical control point.
- (10) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.
- (11) "Preventive measure" means physical, chemical, or other factors that can be used to control an identified food safety hazard.
- (12) "Process-monitoring instrument" means an instrument or device used to indicate conditions during processing at a critical control point.
- (13) "Processing of fish or fishery products" means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding of fish or fishery products.
- (14) "Processor" means any person engaged in commercial, custom, or institutional processing of fish or fishery products. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

- (15) "Scombroid toxin-forming species" means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.
- (16) "Shellfish control authority" means a federal, state, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.
- (17) "Shellstock" means raw, in-shell molluscan shellfish.
- (18) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.
- (19) "Smoked or smoke-flavored fishery products" means the finished food prepared by:
- (a) Treating fish with salt (sodium chloride), and
 - (b) Subjecting the fishery product to the direct action of smoke from burning wood, sawdust, or similar material or imparting to the fishery product the flavor of smoke by a means such as immersing the fishery product in a solution of wood smoke.
- (20) "Tag" means a record of harvesting information attached to a container of shellstock by the harvester or processor.

901:3-7-02

Hazard analysis and hazard analysis critical control point (HACCP) plan.

(A) Hazard analysis.

Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. These food safety hazards include those that can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. Controls shall be established for those food safety hazards that are reasonably likely to occur.

(B) The HACCP plan.

(1) Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (A) of this rule. A HACCP plan shall be specific to:

(a) Each location where fish and fishery products are processed by that processor; and

(b) Each kind of fish and fishery product processed by the processor.

(2) The HACCP plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (C) of this rule are identical for all fish and fishery products so grouped or for all production methods so grouped.

(C) The contents of the HACCP plan.

The HACCP plan shall, at a minimum do all of the following:

(1) List the food safety hazards that are reasonably likely to occur that must be controlled for each fish and fishery product including as appropriate:

(a) Natural toxins;

(b) Microbiological contamination;

- (c) Chemical contamination;
 - (d) Pesticides;
 - (e) Drug residues;
 - (f) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
 - (g) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
 - (h) Unapproved use of direct or indirect food or color additives; and
 - (i) Physical hazards.
- (2) List the critical control points for each of the identified food safety hazards, including as appropriate:
- (a) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
 - (b) 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.
- (3) List the critical limits that must be met at each of the critical control points.
- (4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.
- (5) Include any corrective action plans that have been developed in accordance with paragraph (B) of rule 901:3-7-03 of the Administrative Code, to be followed in response to deviations from critical limits at critical control points.
- (6) List the verification procedures, and frequency thereof, that the processor will use in accordance with paragraph (A) of rule 901:3-7-04 of the Administrative Code.

- (7) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(D) Signing and dating the HACCP plan.

- (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

- (2) The HACCP plan shall be dated and signed:

- (a) Upon initial acceptance;

- (b) Upon any modification; and

- (c) Upon verification of the plan in accordance with paragraph (A)(1) of rule 901:3-7-04 of the Administrative Code.

(E) Products subject to other rules.

For fish and fishery products that are subject to the requirements of Chapter 901:3-3 or 901:3-5 of the Administrative Code, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(F) Sanitation.

Sanitation controls that are monitored in accordance with paragraph (A) of rule 901:3-7-07 of the Administrative Code need not be included in the HACCP plan.

901:3-7-03

Corrective actions.

- (A) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:
- (1) Following a corrective action plan that is appropriate for the particular deviation, or
 - (2) Following the procedures in paragraph (C) of this rule.
- (B) If a written corrective action plan is developed, it shall become part of the HACCP plans in accordance with paragraph (C)(5) of rule 901:3-7-02 of the Administrative Code, by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan shall ensure that:
- (1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
 - (2) The cause of the deviation is corrected
- (C) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
- (1) Segregate and hold the affected product, at least until the requirements of paragraphs (C)(2) and (C)(3) of this rule are met;
 - (2) Perform or obtain a review by an individual or individuals who have been trained in accordance with rule 901:3-7-06 of the Administrative Code to determine the acceptability of the affected product for distribution;
 - (3) 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;
 - (4) Take corrective action, when necessary, to correct the cause of the deviation;
 - (5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with rule 901:3-7-06 of the Administrative Code, 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.

- (D) All corrective actions taken in accordance with this rule shall be fully documented in records that are subject to verification in accordance with paragraph (A)(3)(b) of rule 901:3-7-04 of the Administrative Code and the record keeping requirements of rule 901:3-7-05 of the Administrative Code.

901:3-7-04

Verification.

(A) Overall verification.

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:

- (1) 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 rule 901:3-7-06 of the Administrative Code. 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 (C) of rule 901:3-7-02 of the Administrative Code.
- (2) Ongoing verification activities including:
 - (a) A review of any consumer complaints that have been received by the processor 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 processor, the performing of periodic end-product or in-process testing.
- (3) A review of the records, including signing and dating, by an individual who has been trained in accordance with rule 901:3-7-06 of the Administrative Code, that document:
 - (a) The monitoring of critical control points to ensure, at a minimum, 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 to ensure, at a minimum, that the records are complete and to verify that appropriate corrective actions were taken in accordance with rule 901:3-7-03 of the Administrative Code. This review shall occur within one week of the day that the records are made; and

- (c) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities.

(B) Corrective actions.

Processors shall immediately follow the procedures in rule 901:3-7-03 of the Administrative Code whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(C) Reassessment of the hazard analysis.

Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. The reassessment shall be performed by an individual or individuals who have been trained in accordance with rule 901:3-7-06 of the Administrative Code.

(D) Record keeping.

The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (A)(2)(b) to (A)(2)(c) of this rule shall be documented in records that are subject to the record keeping requirements of rule 901:3-7-05 of the Administrative Code.

901:3-7-05

Records.

(A) General requirements.

All records required by this chapter shall include:

- (1) The name and location of the processor or importer;
- (2) The date and time of the activity that the record reflects;
- (3) The signature or initials of the person performing the operation; and
- (4) When applicable, the identity of the product and the production code. Processing and other information shall be entered on records at the time that it is observed.

(B) Record retention.

- (1) All records required by this chapter 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, preserved, or shelf-stable products.
- (2) 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.
- (3) If the processing facility is closed for a prolonged period between seasonal packs, 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 pack but shall be immediately returned for official review upon demand.

(C) Official review.

All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(D) Tags.

Tags as defined in paragraph (B)(20) of rule 901:3-7-01 of the Administrative Code are not subject to the requirements of this rule unless they are used to fulfill the

requirements in paragraph (C) of rule 901:3-7-09 of the Administrative Code.

(E) Records maintained on computers.

The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

901:3-7-06

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 fish and fishery product processing.
- (1) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor in order to meet the requirements in paragraph (B) of rule 901:3-7-02 of the Administrative Code.
 - (2) Reassessing and modifying the HACCP plan in accordance with the:
 - (a) Corrective action procedures specified in paragraph (C)(5) of rule 901:3-7-03 of the Administrative Code;
 - (b) Verification activities specified in paragraph (A)(1) of rule 901:3-7-04 of the Administrative Code; and
 - (c) Hazard analysis in accordance with the verification activities specified in paragraph (C) of rule 901:3-7-04 of the Administrative Code.
 - (3) Performing the record review required in paragraph (A)(3) of rule 901:3-7-04 of the Administrative Code.
- (B) An individual described in paragraph (A) of this rule shall provide the director, upon request, a copy of their certificate of completion for the application of HACCP principles for fish and fishery product processing.
- (C) Job experience may qualify an individual to perform the functions specified in paragraph (A) of this rule. The trained individual need not be an employee of the processor.

901:3-7-07

Sanitation control procedures.

(A) Sanitation monitoring.

Each processor shall monitor the sanitary conditions and practices during processing. Each processor shall correct in a timely manner any sanitary conditions and practices that are not met to ensure, at a minimum, conformance with those sanitary conditions and practices specified in Chapter 901:3-17 of the Administrative Code that are both applicable to the plant and the food being processed and relate to the following:

- (1) Safety of the water that comes into contact with food or food contact surfaces or is used in the manufacture of ice;
- (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
- (3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
- (4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- (5) 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;
- (6) Proper labeling, storage, and use of toxic compounds;
- (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
- (8) Exclusion of pests from the food plant.

(B) Sanitation control records.

Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (A) of this rule. These records are subject to the requirements of rule 901:3-7-05 of the Administrative Code.

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901:3-7-08

Smoked and smoke-flavored fishery products-process controls.

Processors of smoked and smoke-flavored fishery products, except those subject to the requirements of Chapters 901:3-3 and 901:3-5 of the Administrative Code, shall include in their HACCP plans how they are controlling the formation of the toxin by *Clostridium botulinum* for, at a minimum, the shelf life of the product under normal and moderate abuse conditions.

901:3-7-09

Raw molluscan shellfish-source controls.

- (A) Processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (B), (C), and (D) of this rule are met in order to meet the requirements of rules 901:3-7-01 to 901:3-7-10 of the Administrative Code as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards.
- (B) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the federal government.
- (C) To meet the requirements of paragraph (B) of this rule, processors who receive shellstock shall accept only shellstock from a harvester who is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor who is certified by a shellfish control authority. Each container of shellstock received by a processor shall have a tag affixed on which shall bear, at a minimum, the information required in rule 901:3-7-10 of the Administrative Code. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in rule 901:3-7-10 of the Administrative Code. Processors shall maintain records that document that all shellstock have met the requirements of this rule. These records shall document:
- (1) The date of harvest;
 - (2) The location of harvest by state and site;
 - (3) The quantity and type of shellfish;
 - (4) The date of receipt by the processor; and
 - (5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.
- (D) To meet the requirements of paragraph (B) of this rule, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with rule 901:3-7-10 of the Administrative Code. Processors shall maintain records that document that all shucked molluscan

shellfish have met the requirements of this rule. These records shall document:

- (1) The date of receipt;
- (2) The quantity and type of shellfish; and
- (3) The name and certification number of the packer or repacker of the product.

901:3-7-10

Raw molluscan shellfish tags.

- (A) Except as provided in paragraph (B) of this rule, all shellstock shall bear a tag that discloses the following information:
- (1) The date of harvest;
 - (2) The location of harvest by state and site;
 - (3) The quantity and type of shellfish; and
 - (4) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.
- (B) In place of a tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in paragraph (A) of this rule.
- (C) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.
- (D) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear the information required by paragraphs (A), (B), and (C) of this rule shall be subject to detention, embargo, condemnation or destruction, in accordance with section 3715.55 of the Revised Code.

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901:3-7-11

Adulteration.

Failure of a processor to have and implement the HACCP plan as specified in rule 901:3-7-02 of the Administrative Code shall render the fish or fishery products of that processor adulterated under section 3715.59 of the Revised Code.