









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 may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 123.11(b) they need not be included in the HACCP plan, and vice versa.
- (g) *Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

#### § 123.7 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 section.
- (b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

- (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 section are met;
    - (2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;
    - (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 § 123.10, 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 correction actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

## § 123.8 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) *Reassessment of the HACCP plan.* 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. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 123.6(c).
  - (2) *Ongoing verification activities.* Ongoing verification activities including:
    - (i) 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;
    - (ii) The calibration of process-monitoring instruments; and,
    - (iii) At the option of the processor, the performing of periodic end-product or in-process testing.
  - (3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:
    - (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
    - (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within 1 week of the day that the records are made; and
    - (iii) 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. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.
- (b) *Corrective actions.* Processors shall immediately follow the procedures in § 123.7 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. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems,

or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

- (d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of § 123.9.

### § 123.9 Records.

- (a) *General requirements.* All records required by this part 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) 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) *Record retention.*

- (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 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 or the importer's place of business in the United States for

at least 2 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) *Public disclosure.*

- (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

- (2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

- (e) *Tags.* Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

- (f) *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.

### § 123.10 Training.

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 at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

- (a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);
- (b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and
- (c) Performing the record review required by § 123.8(a)(3); The trained individual need not be an employee of the processor.

### § 123.11 Sanitation control procedures.

- (a) *Sanitation SOP.* Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.
- (b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those con-

ditions and practices specified in part 110 of this chapter and in subpart B of part 117 of this chapter that are both appropriate 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.

The processor shall correct in a timely manner, those conditions and practices that are not met.

- (c) *Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.



(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

[60 FR 65197, Dec. 18, 1995, as amended at 80 FR 56167, Sept. 17, 2015]

### § 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a) *Importer verification.* Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including

writing the importer's verification procedures on the importer's behalf.

- (c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.
- (d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

## Subpart B—Smoked and Smoke-Flavored Fishery Products

### § 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

### § 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

## Subpart C—Raw Molluscan Shellfish

### § 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

### § 123.28 Source controls.

- (a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, 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 section are met.
- (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 section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in § 1240.60(b) of this chapter. 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 §

1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. 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 section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with § 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. 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.

## **PART 1240 – CONTROL OF COMMUNICABLE DISEASES**

1. The authority citation for 21 CFR Part 1240 continues to read as follows:

Authority: Secs 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

2. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t) and (u) to read as follows:

### **§ 1240.3 General Definitions.**

- a. *Molluscan Shellfish*. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.
  - b. *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.
  - c. *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.
  - d. *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.
3. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

## § 1240.60 Molluscan Shellfish

- a. A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.
- b. All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.
- 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 all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

[40 FR 5620, Feb. 6, 1975, as amended at 60 FR 65202, Dec. 18, 1995]

**NOTES:**