RULES AND REGULATIONS PRESCRIBING MINIMUM STANDARDS FOR PROCESSING, STORAGE AND TRANSPORTATION OF FISH AND FISHERY PRODUCTS

[R21.27; 21-31; 23-1-FFP]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

April 1971

***AS AMENDED*:**

January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

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INTRODUCTION

These amended *Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products*[1] [*R21-27; 21-31; 23-1-FFP*] are promulgated pursuant to the authority set forth in Chapters 21-27, 21-31 and 23-1 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum standards for assuring the safety of fish and fishery products that are comparable to those established by the U.S. Food and Drug Administration (FDA) pursuant to 21 CFR 123.

A complete replacement of the 1971 regulations concerning seafood products was deemed necessary due to advances in science and technology, and in order to provide the industry with requirements consistent with existing federal mandates under the Code of Federal Regulations.

Processing and handling of molluscan shellfish is regulated pursuant to the *Rules and Regulations Pertaining to the Processing and Distribution of Shellfish* [*R21-14-SB*]. Therefore, molluscan shellfish are not subject to the *Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products.*

Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at these amended regulations:

(1) Alternative approaches to the regulations;

(2) Duplication or overlap with other state regulations; and

(3) Significant economic impact on small business.

Based on the available information, no known overlap, duplication or alternative approach was identified.

Upon promulgation of these amendments, these Regulations shall supersede all previous *Rules and Regulations Prescribing Minimum Standards for Seafood Processing, Storage and Transportation* promulgated by the Department of Health and filed with the Secretary of State.

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[1] All editions of the *Rules and Regulations Prescribing Minimum Standards for Seafood Processing, Storage and Transportation* prior to January 2012 were promulgated solely pursuant to authority under Chapter 23-1 of the General Laws of Rhode Island, as amended. Beginning with the January 2012 edition, the *Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products* are promulgated pursuant to authority under Chapters 21-27, 21-31 and 23-1 of the General Laws of Rhode Island, as amended. Furthermore, the title of the Regulation was changed to reflect the expansion of the Regulation's scope to include all fish and fishery products.

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Section 1.0 ***Definitions***

Wherever used in these Regulations, the following terms shall be construed as follows:

1.1 ***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.

1.2 ***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.

1.3 ***Department*** means the Rhode Island Department of Health.

1.4 ***Director*** means the Director of the Rhode Island Department of Health or his or her duly authorized designee.

1.5 ***FDA*** means the U.S. Food and Drug Administration.

1.6 ***Fish*** means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

1.7 ***Fishery product*** means any human food product in which fish is a characterizing ingredient.

1.8 ***Food safety hazard*** means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

1.9 ***Fresh*** means recently made, produced, or harvested; not stale or spoiled; not preserved, as by canning, smoking, or freezing

1.10 ***Importer*** means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier or the steamship representative.

1.11 ***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.

1.12 ***Operational plan*** means a written description of the design and activities of the facility specific to, but not limited to, the species of fish or fishery product to be processed, the source of the fish or fishery product to be processed, how the fish or fishery product will be processed, and how the required records will be maintained.

1.13 ***Preventive measure*** means physical, chemical, or other factors that can be used to control an identified food safety hazard.

1.14 ***Process-monitoring instrument*** means an instrument or device used to indicate conditions during processing at a critical control point.

1.15 ***Processing*** means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.

1.16 ***Processor*** means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. Processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

1.17 ***RIGL*** means the General Laws of Rhode Island, as amended.

1.18 ***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.

1.19 ***Smoked or smoke-flavored fishery products*** means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

1.20 ***These Regulations*** mean all parts of Rhode Island *Rules and Regulations for Processing, Storage and Transportation of Fish and Fishery Products* [*R21-27; 21-31; 23-1-FFP*].

Section 2.0 ***Registration of a Fish or Fishery Product Processing Facility***

2.1 **General Requirement.** No person shall operate a fish or fishery product processing facility unless the person is registered with the Department under the provisions of §2.0 of these Regulations.

2.2 **Registration Application**

(a) An applicant for registration of a fish or fishery product processing facility shall submit a completed application to the Department on forms provided by the Department. The application shall include all the required information on the form.

(b) **Additional Information**. An applicant for registration of a fish or fishery product processing facility shall also submit the following information for review by the Department at least thirty (30) days prior to the scheduled first use of the facility:

(1) Plans and Specifications:

(i) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(ii) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities and installation specifications;

(iii) Intended type(s) of fish or fishery product(s) to be processed;

(iv) Anticipated volume of fish or fishery product(s) to be processed and stored; and

(v) Other information that may be required by the Department for the proper review of the proposed construction, conversion or modification to ensure compliance with the requirements of these Regulations.

(2) HACCP Plan. A properly prepared HACCP plan as specified in §4.0 of these Regulations.

(3) Operational Plan. A properly prepared Operational Plan as specified in §1.12 of these Regulations.

2.3 **Notification of Changes**

(a) Any person registered to operate a fish or fishery product processing facility pursuant to §2.0 of these Regulations shall notify the Department in writing before making any change which would render the information[2] contained in their application for registration no longer accurate.

(b) Any registration to operate a fish or fishery product processing facility issued pursuant to §2.0 of these Regulations shall apply only to those type(s) of fish or fishery product(s) identified in the application. Any proposed changes in the type(s) of fish or fishery product(s) being processed shall require written notification to, and approval by, the Department before the changes can be implemented.

(c) **Updated Facility Plan.** Any person registered to operate a fish or fishery product processing facility pursuant to §2.0 of these Regulations shall submit an updated HACCP Plan (if applicable), an updated operational plan (if applicable) and properly prepared plans and specifications to the Department, for review and approval, at least thirty (30) days before:

(1) The construction of a structure for use as a fish or fishery product processing facility;

(2) The conversion of an existing structure for use as a fish or fishery product processing facility; or

(3) The remodeling of a fish or fishery product facility or a change of type(s) of fish or fishery product(s) being processed, if the Department determines that plans and specifications are necessary to assure compliance with these Regulations.

2.4 **Issuance and Renewal of a Registration**

(a) **Issuance of a Registration**. Pursuant to the provisions of RIGL §21-27-10, the Department shall grant a registration to operate a fish or fishery product processing facility to an applicant who meets the registration requirements set forth in these Regulations, and upon receipt of the registration fee established by RIGL §21-27-10(e)(1) and as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. The registration period shall be for twelve (12) months, unless sooner suspended or revoked for cause, commencing on October 1st, and the registration fee shall be at the full annual rate regardless of the date of application or the date of issuance of registration.

(b) **Renewal of Registration.** A person may request renewal of a registration for a fish or fishery product processing facility by submitting a completed renewal application, as provided by the Department, and the registration renewal fee established by RIGL §21-27-10(e)(1) and as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*. The renewed registration shall be valid for a period of twelve (12) months, unless sooner suspended or revoked for cause, commencing on October 1st.

[2] For example, type(s) of fish or fish product being processed, name, mailing address or phone number.

Section 3.0 ***Exemptions***

3.1 The following operations are not subject to these Regulations:

(a) Processing and handling of molluscan shellfish. However, these activities are regulated pursuant to the *Rules and Regulations Pertaining to the Processing and Distribution of Shellfish* [*R21-14-SB*][3].

(b) Harvesting fish or fishery products, without otherwise engaging in processing.

(c) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(d) The operation of a retail establishment offering for sale to the consumer only fish or fishery product which have been obtained from persons registered to operate a fish or fishery product processing business.

Section 4.0 ***Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan***

4.1 **Hazard Analysis.** Every fish or fishery product 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 or fishery product processed by that processor and to identify the preventive measures that the processor 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. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

4.2 **The HACCP Plan.** Every fish or fishery product 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 §4.1 of these Regulations. A HACCP plan shall be specific to:

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

(b) Each kind of fish or fishery product processed by the processor. The plan may group kinds of fish or 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 §4.3 of these Regulations are identical for all fish or fishery products so grouped or for all production methods so grouped.

4.3 **The Contents of the HACCP Plan.** The HACCP plan shall, at a minimum:

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with §4.1 of these Regulations, and that thus must be controlled for each fish or fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

[3] Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: http://www.sos.ri.gov/rules/

(1) Natural toxins;

(2) Microbiological contamination;

(3) Chemical contamination;

(4) Pesticides;

(5) Drug residues;

(6) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(7) 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;

(8) Unapproved use of direct or indirect food or color additives; and

(9) Physical hazards;

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

(1) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(2) 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;

(c) List the critical limits that must be met at each of the critical control points;

(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 in accordance with §5.0 of these Regulations, to be followed in response to deviations from critical limits at critical control points;

(f) List the verification procedures, and frequency thereof, that the processor will use in accordance with §6.1 of these Regulations;

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

4.4 **Signing and Dating the HACCP Plan**.

(a) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the fish or fishery product 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.

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

(1) Upon initial acceptance;

(2) Upon any modification; and

(3) Upon verification of the plan in accordance with §6.1(a) of these Regulations.

4.5 **Products Subject to Other Regulations**. For fish or fishery products that are subject to the requirements of 21 CFR Part 113 *Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers* or Part 114 *Acidified Foods*, 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 or fishery products shall address any other food safety hazards that are reasonably likely to occur.

4.6 **Sanitation.** Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §9.2 of these Regulations they need not be included in the HACCP plan, and vice versa.

4.7 **Legal Basis.** Failure of a fish or fishery product processor to have and implement a HACCP plan that complies with §4.0 of these Regulations 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 RIGL §21-31-10. Whether a fish or fishery product processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processor's overall implementation of its HACCP plan, if one is required.

Section 5.0 ***Corrective Actions***

5.1 Whenever a deviation from a critical limit occurs, a fish or fishery product processor shall take corrective action either by:

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

(b) Following the procedures in §5.3 of these Regulations.

5.2 Fish or fishery product processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §4.3(e) of these Regulations, 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:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(b) The cause of the deviation is corrected.

5.3 When a deviation from a critical limit occurs and the fish or fishery product processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(a) Segregate and hold the affected product, at least until the requirements of §§5.3(a) and (b) of these Regulations are met;

(b) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §8.0 of these Regulations;

(c) 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;

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

(e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §8.0 of these Regulations, 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.

5.4 All corrective actions taken in accordance with §5.3 of these Regulations shall be fully documented in records that are subject to verification in accordance with §6.1(c)(2) of these Regulations and the recordkeeping requirements of §7.0 of these Regulations.

Section 6.0 *Verification*

6.1 **Overall Verification.** Every fish or fishery product 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:

(a) **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 §8.0 of these Regulations. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §4.3 of these Regulations.

(b) **Ongoing Verification Activities.** Ongoing verification activities including:

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

(2) The calibration of process-monitoring instruments; and,

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

(c) **Records Review.** A review, including signing and dating, by an individual who has been trained in accordance with §8.0 of these Regulations, of the records that document:

(1) 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 (1) week of the day that the records are made;

(2) 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 §5.2 of these Regulations. This review shall occur within one (1) week of the day that the records are made; and

(3) 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 fish or fishery product 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.

6.2 **Corrective Actions.** Fish or fishery product processors shall immediately follow the procedures in §5.0 of these Regulations whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

6.3 **Reassessment of the Hazard Analysis.** Whenever a fish or fishery product 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 §8.0 of these Regulations.

6.4 **Recordkeeping.** The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with §§6.1(b)(2) through (b)(3) of these Regulations shall be documented in records that are subject to the recordkeeping requirements of §7.0 of these Regulations.

Section 7.0 ***Records***

7.1 **General Requirements.** All records required by these Regulations shall include:

(a) The name and location of the fish or fishery product processor or importer;

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

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

(d) 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.

7.2 **Record Retention**

(a) All records required by these Regulations shall be retained at the fish or fishery product processing facility or importer's place of business in the United States for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(b) 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 two (2) years after their applicability to the product being produced at the facility.

(c) If the fish or fishery product 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.

7.3 **Official Review.** All records required by these Regulations and all plans and procedures required by these Regulations shall be available for official review and copying at reasonable times.

7.4 **Public Disclosure**

(a) Subject to the limitations in §7.4(b) of these Regulations, all plans and records required by these Regulations are not available for public disclosure unless they have been previously disclosed to the public as defined in 21 CFR §20.81 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 21 CFR §20.61.

(b) 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.

7.5 **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.

Section 8.0 *Training*

8.1 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 or 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 §4.2 of these Regulations;

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in §5.3(e) of these Regulations, the HACCP plan in accordance with the verification activities specified in §6.1(a) of these Regulations, and the hazard analysis in accordance with the verification activities specified in §6.3 of these Regulations; and

(c) Performing the record review required by §6.1(c) of these Regulations. The trained individual need not be an employee of the processor.

Section 9.0 *Sanitation Control Procedures*

9.1 **Sanitation SOP.** Each fish or fishery product 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 or fishery products are produced. The SSOP should specify how the fish or fishery product processor will meet those sanitation conditions and practices that are to be monitored in accordance with §9.2 of these Regulations.

9.2 **Sanitation Monitoring.** Each fish or fishery product processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in the Rhode Island *Rules and Regulations Pertaining to Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food* (*R21-27; 21-31; 23-1-GMP*) that are both appropriate to the plant and the food being processed and relate to the following:

(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;

(c) 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;

(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.

9.3 **Other Process Controls**

(a) **Packing of Fish and Fishery Products**

(1) Filleted fish or fishery products shall be packed without exposing them to contamination.

(2) Fish and fishery products shall be packed and shipped in clean, single-service containers of impervious material, or in clean, properly designed, returnable containers so sealed that tampering can be detected. Returnable containers will be accepted only for interplant shipment of seafood.

(3) The room used for the picking of lobster, crab or whelk meat shall be separated from other rooms or areas in the building by a suitable full partition or walls. Doors to such rooms shall be self-closing.

(4) Packing rooms shall be large enough to permit sanitary handling of fish and fishery products and for the proper arrangement and thorough cleaning of equipment.

(b) **Open Air Processing.** Open air processing of fish and fishery products shall not be allowed. Fish and fishery products shall only be processed within a registered fish and fishery products facility maintained in accordance with these Regulations.

9.4 **Sanitation Control Records.** Each fish or fishery product processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by §9.2 of these Regulations. These records are subject to the requirements of §7.0 of these Regulations.

9.5 **Relationship to HACCP Plan.** Sanitation controls may be included in the HACCP plan, required by §4.2 of these Regulations. However, to the extent that they are monitored in accordance with §9.2 of these Regulations, they need not be included in the HACCP plan, and vice versa.

9.6 **Trucks or Other Vehicles Used to Transport Fish or Fishery Product.** All trucks or other vehicles used to transport fish and fishery products shall be constructed, operated and maintained to prevent contamination, adulteration, cross-contamination, decomposition and deterioration of the fish or fishery product.

(a) Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.

(b) Refrigeration trucks or other vehicles shall be:

(1) Equipped with automatic controls; and

(2) Capable of maintaining the ambient air temperature in the storage area at temperatures of 41°F (5°C) or less.

(c) Any ice used during transport shall:

(1) Be made on-site from potable water in a commercial ice machine; or

(2) Come from a facility sanctioned by the Department or the appropriate regulatory Agency.

(d) Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where fish or fishery product is stored.

9.7 **Transportation Containers.**

(a) All containers used to transport fish or fishery product shall be:

(1) Constructed to allow for easy cleaning; and

(2) Operated and maintained to prevent product contamination.

(b) All containers shall be cleaned with:

(1) Potable water; and

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

Section 10.0 *Labeling*

10.1 All fish and fishery products offered for sale shall be clearly identified by specie or generic name.

10.2 No fish or fishery product shall be stored in a frozen state for more than twelve (12) successive months except by permission of the Director. Immediately upon being frozen, fish and fishery products shall be clearly labeled with the date of freezing and such label shall accompany said product at all times and shall not be removed or defaced.

10.3 **Designation as Fresh Fish or Fishery Product.** No person shall sell, or represent for the purpose of sale, or imply as fresh, fish or fishery product which:

(a) has been frozen at any time; or

(b) does not otherwise meet the specification in §1.9 of these Regulations.

10.4 Fish or fishery product so-labeled as to deceive shall be deemed to be misbranded pursuant to RIGL §21-31-2(13)(iv).

Section 11.0 *Shipping Documents*

11.1 Each fish or fishery product shipment shall be accompanied by a shipping document which shall contain:

(a) The name, address, of the shipper;

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

(c) The kind and quantity of fish or fishery product(s).

11.2 The receiving business shall:

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

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

11.3 If the shipment is subdivided to different businesses, each receiving business shall maintain records sufficient to trace their portion back to the original shipment.

Section 12.0 ***Special Requirements for Imported Products***

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

12.2 **Importer Verification.** Every importer of fish or fishery products shall either:

(a) 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

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

(1) Product specifications that are designed to ensure that the product is not adulterated within the meaning of RIGL §21-31-10 because it may be injurious to health or have been processed under insanitary conditions, and,

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

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

(ii) 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 these Regulations;

(iii) 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 these Regulations;

(iv) 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 these Regulations;

(v) 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 these Regulations; or

(vi) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of these Regulations.

12.3 **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 §10.2(b) of these Regulations, including writing the importer's verification procedures on the importer's behalf.

12.4 **Records.** The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in §10.2(b)(2) of these Regulations. These records shall be subject to the applicable provisions of §7.0 of these Regulations.

12.5 **Determination of Compliance.** There must be evidence that all fish or fishery products offered for entry into the United States have been processed under conditions that comply with these Regulations. 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 these Regulations, the product will appear to be adulterated and will be denied entry.

Section 13.0 ***Specific Requirements - Smoked and Smoke-Flavored Fishery Products***

13.1 **General.** §13.0 augments the requirements in §§1.0 through 11.0 of these Regulations by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

13.2 **Process Controls.** In order to meet the requirements of §§1.0 through 11.0 of these Regulations, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of 21 CFR Part 113 or Part 114, 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.

Section 14.0 ***Specific Requirements – Clam Juice***

14.1 **Pasteurization.** No clam juice intended for human consumption shall be sold or offered for sale without first being pasteurized. Clam juice is to be heated for at least thirty (30) minutes at no less than 143°F (62°C), or equivalent process approved by the Department, to insure proper pasteurization.

Section 15.0 ***Variances Procedure***

15.1 The Department may grant a variance upon request of the applicant from the provisions of these Regulations, if it finds in specific cases, that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest.

15.1.1 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made, citing the relevant regulation and the alternative(s).

Section 16.0 ***Compliance and Enforcement***

16.1 **General Obligation.** A fish or fishery product processing facility shall correct, in a timely manner, those conditions and practices that are not in compliance with these Regulations. However, any violation identified in an inspection report issued shall be corrected within the time frame for correction specified by the Department.

16.2 **Ceasing Operations and Reporting: Imminent Health Hazard**

(a) Except as specified in §16.2(b), a fish or fish product processing facility shall immediately discontinue operations and notify the Department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health.

(b) A fish or fish product processing facility need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

(c) **Resumption of Operations.** If operations are discontinued as specified under §16.2(a) of these Regulations or otherwise according to law, the fish or fish product processing facility shall obtain approval from the Department before resuming operations.

16.3 **Enforcement Options**.

(a) The Director may pursue any combination of the following administrative and judicial enforcement actions, depending upon the circumstances and gravity of each case:

(1) Confiscation of food pursuant RIGL §21-27-4;

(2) Notice to cease business pursuant RIGL §21-27-5;

(3) Penalties for violations pursuant to RIGL §21-27-9 and/or RIGL §21-31-5;

(4) Administrative fines pursuant RIGL §21-27-11.11;

(5) Embargo, condemnation and destruction of adulterated food pursuant RIGL §21-31-6;

(6) Penalties for obstruction of inspections or examinations pursuant to RIGL §23-1-19;

(7) Compliance orders pursuant to RIGL §23-1-20;

(8) Immediate compliance orders pursuant to RIGL §23-1-21;

(9) Enforcement of compliance orders pursuant to RIGL §23-1-23;

(10) Criminal penalties pursuant to RIGL §23-1-25; and

(11) Revocation, suspension, or other disciplinary action pursuant to RIGL §21-27-10(c) regarding a registration issued in accordance with RIGL §21-27-10.

(b) The imposition of one or more remedies and/or penalties provided in §16.3(a) of these Regulations shall not prevent the Director from jointly exercising any other remedy or penalty available to him or her by statute or regulation.

(c) **Consent Agreement/Order**. Nothing in these Regulations shall preclude the Director from resolving outstanding violations or penalties through a Consent Agreement or Consent Order at any time he or she deems appropriate.

16.4 **Grounds for Discipline Without Hearing.** The Director may temporarily suspend the registration of a fish or fish product processing facility without a hearing if the Director finds that evidence in his or her possession substantiates that continuation in practice would constitute an immediate danger to the health, safety, and welfare of the public. In the event that the Director temporarily suspends the registration of a fish or fish product processing facility without a hearing, a hearing by the Department shall be held within ten (10) days after the suspension has occurred.

16.5 All hearings and reviews required under the provisions of RIGL §21-31-7, RIGL §22-1-22 or these Regulations shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health* (*R42-35-PP*).

Section 17.0 ***Severability***

17.1 If any provision of these Regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.

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