Department of Health

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Notice of Community Review Meeting

Proposed amendments to

***Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products* [*R21-27; 21-31; 23-1-FFP*]**

This regulation will replace the existing *Rules and Regulations Prescribing Minimum Standards for Seafood Processing, Storage and Transportation*, and will establish 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 10 CFR 123.

Proposed promulgation of

***Rules and Regulations Pertaining to Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food* [*R21.27; 21-31; 23-1-GMP*]**

This new regulation will establish minimum standards for manufacturing, packing or holding human food that are comparable to those established by the U.S. Food and Drug Administration (FDA) pursuant to 10 CFR 110.

The Rhode Island Department of Health will hold a community review meeting to receive input regarding these proposed regulations on **Tuesday, 22 November 2011** at **10:00 AM** in the Auditorium of the Cannon Building (on the lower level). Any person who wishes to offer comments on this matter is welcome to attend.

If you have any questions about these proposed regulations, or wish to submit written comments in advance of the meeting, please direct them to Ernest Julian, Ph.D., Chief, Office of Food Protection: e-mail to Ernest.Julian@health.ri.gov or by calling 401-222-2750.

Copies of the proposed amendments are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, by calling 401-222-7767 or e-mail to Bill.Dundulis@health.ri.gov.

Please feel free to circulate additional copies of this document, as needed, to any interested person.

The Department of Health is accessible to the handicapped. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

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)

November 2011 (Proposed)

COMPILER'S NOTES:

Proposed Additions: **The proposed amendments supersede the April 1971 edition of these Regulations in its entirety. Therefore, changes are not specifically indicated.**

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 November 2011 were promulgated solely pursuant to authority under Chapter 23-1 of the General Laws of Rhode Island, as amended. Beginning with the November 2011 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). 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). 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:

(1) Natural toxins;

[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/

(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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Thursday, 10 November 2011

RULES AND REGULATIONS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING OR HOLDING HUMAN FOOD

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

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

November 2011 (Proposed)

COMPILER'S NOTES:

Proposed Additions: **The proposed regulations are new in their entirety. Therefore, changes are not specifically indicated.**

INTRODUCTION

These *Rules and Regulations Pertaining to Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food* [*R21.27; 21-31; 23-1-GMP*] 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 safety standards for manufacturing, packing or holding human food that are comparable to those established by the U.S. Food and Drug Administration (FDA) pursuant to 21 CFR 110.

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 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.

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Section 1.0 ***Definitions***

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

1.1 ***Acid foods or acidified foods*** means foods that have an equilibrium pH of 4.6 or below.

1.2 ***Adequate*** means that which is needed to accomplish the intended purpose in keeping with good public health practice.

1.3 ***Batter*** means a semi-fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

1.4 ***Blanching, except for tree nuts and peanuts,*** means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

1.5 ***Critical control point*** means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

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

1.7 ***Director*** means the Director of the Rhode Island Department of Health or a subordinate to whom the Director has assigned his or her functions.

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

1.9 ***Food*** means:

(1) Articles used for food or drink for man or other animals;

(2) Chewing gum;

(3) Articles used for components of any such article; and

(4) Includes raw materials and ingredients.

1.10 ***Food-contact surfaces*** are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food-contact surfaces includes utensils and food-contact surfaces of equipment.

1.11 ***Lot*** means the food produced during a period of time indicated by a specific code.

1.12 ***Microorganisms*** means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms[1] that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of RIGL §21-31-10.

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[1] These Regulations may also use the adjective "microbial" instead of using an adjectival phrase containing the word "microorganism".

1.13 ***Pest*** refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

1.14 ***Plant*** means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

1.15 ***Processed food*** means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as washing, canning, cooking, freezing, dehydration, or milling.

1.16 ***Quality control operation*** means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of RIGL §21-31-10.

1.17 ***Rework*** means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

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

1.19 ***Safe and suitable*** means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

1.20 ***Safe-moisture level*** is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

1.21 ***Sanitize*** means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

1.22 ***These Regulations*** mean all parts of 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*]

1.23 ***Water activity (a_w)*** is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Section 2.0 *Current Good Manufacturing Practice*

2.1 **Applicability and Scope.** The criteria and definitions in these Regulations shall apply in determining whether a food is adulterated:

(a) Within the meaning of RIGL §21-31-10(1)(iii) in that the food has been manufactured under such conditions that it is unfit for food; or

(b) Within the meaning of RIGL §21-31-10(1)(iv) in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

2.2 The criteria and definitions in these Regulations also apply in determining whether a food is in violation of §361 of the Public Health Service Act (42 U.S.C. 264).

2.3 Food covered by specific current good manufacturing practice regulations is also subject to the requirements of those regulations.

Section 3.0 ***Personnel***

3.1 The plant management shall take all reasonable measures and precautions to ensure the following:

(a) **Disease Control.** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) **Cleanliness.** All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing clean garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces or food-packaging materials.

(5) Using utensils or wearing gloves for food handling if product is ready to eat and maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable nonlatex material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco. Additional restrictions concerning use of tobacco are contained in the Rhode Island *Rules and Regulations Pertaining to Smoke-free Public Places and Workplaces* [*R23-20.10-SMOKE*][2]

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) **Education and training.** Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) **Supervision.** Responsibility for assuring compliance by all personnel with all requirements of these Regulations shall be clearly assigned to competent supervisory personnel.

Section 4.0 *Plant and Grounds*

4.1 **Grounds.** The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(a) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(b) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(c) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(d) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(e) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in §§4.1(a)-(c) of these Regulations, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

4.2 **Plant Construction and Design.** Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(a) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

[2] 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/

(b) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(c) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(1) Using protective coverings.

(2) Controlling areas over and around the vessels to eliminate harborages for pests.

(3) Checking on a regular basis for pests and pest infestation.

(4) Skimming the fermentation vessels, as necessary.

(d) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(e) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(f) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials and food-contact surfaces.

(g) Provide tight fitting doors and outer openings and, where necessary, adequate screening or other protection against pests.

Section 5.0 ***Sanitary Operations***

5.1 **General Maintenance.** Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of RIGL §21-31-10. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

5.2 **Substances Used in Cleaning and Sanitizing - Storage of Toxic Materials**.

(a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(1) Those required to maintain clean and sanitary conditions;

(2) Those necessary for use in laboratory testing procedures;

(3) Those necessary for plant and equipment maintenance and operation; and

(4) Those necessary for use in the plant's operations.

(b) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use or holding of these products shall also be followed.

5.3 **Pest Control.** No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

5.4 **Sanitation of Food-Contact Surfaces.** All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(a) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(b) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(c) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(d) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(e) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

5.5 **Storage and Handling of Cleaned Portable Equipment and Utensils.** Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

Section 6.0 ***Sanitary Facilities and Controls***

6.1 Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) **Water Supply.** The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. The facility shall comply with requirements regarding water quality, and the site and location of the source of the water supply as specified in RIGL Chapter 46-13 (*Public Drinking Water Supply*) and the *Rhode Island Rules and Regulations Pertaining to Public Drinking Water* [*R-46-13-DWQ*].

(1) Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality.

(2) Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) **Plumbing.** A plumbing system shall be designed, constructed and installed according to all applicable federal, state and local requirements. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) **Sewage Disposal.** Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) **Toilet Facilities.** Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) **Hand-Washing Facilities.** Hand-washing facilities shall be adequate and convenient and be furnished with running water at a temperature of at least 100°F (38°C). Hand-washing sinks shall be designated for hand-washing only and shall not be used for other purposes. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unproteced food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) **Rubbish and Offal Disposal**. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Section 7.0 *Equipment and Utensils*

7.1 All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.

(a) The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(b) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(c) Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

7.2 Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

7.3 Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

7.4 Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

7.5 Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring

device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

7.6 Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

7.7 Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Section 8.0 ***Production and Process Controls***

8.1 All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.

(a) Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Foods shall also be produced and labeled to comply with 21 CFR Part 101 *Food Labeling* and the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

(b) Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function.

(c) All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.

(d) All food that has become contaminated to the extent that it is adulterated within the meaning of RIGL §21-31-10 shall be rejected, or if permissible, treated or processed to eliminate the contamination.

8.2 **Raw Materials and Other Ingredients**

(a) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration.

(1) Raw materials shall be washed or cleaned as necessary to remove soil or other contamination.

(2) Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality.

(3) Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.

(4) Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(b) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause

the product to be adulterated within the meaning of RIGL §21-31-10. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(c) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with RIGL §21-31-13, these Regulations and applicable action levels/regulations for poisonous or deleterious substances promulgated by the FDA before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(d) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with the provisions of §10.0 of these Regulations regarding defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(e) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of RIGL §21-31-10. Material scheduled for rework shall be identified as such.

(f) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of RIGL §21-31-10.

(g) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

8.3 **Manufacturing Operations.**

(a) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(b) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(c) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of RIGL §21-31-10. Compliance with this requirement may be accomplished by any effective means, including:

(1) Maintaining refrigerated foods at 41°F (5°C) or below as appropriate for the particular food involved.

(2) Maintaining frozen foods in a frozen state.

(3) Maintaining hot foods at 140°F (60°C) or above.

(4) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(d) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of RIGL §21-31-10.

(e) Work-in-process shall be handled in a manner that protects against contamination.

(f) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.

(1) When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food.

(2) Food transported by conveyor shall be protected against contamination as necessary.

(g) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(h) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(i) Food, raw materials, and other ingredients that are adulterated within the meaning of RIGL §21-31-10 shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of RIGL §21-31-10 before being incorporated into other food.

(j) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(k) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food (from 135°F (57°C) to 70°F (21°C) within two (2) hours, and from 135°F (57°C) to 41°F (5°C) within a total of six (6) hours) or passing it to subsequent manufacturing without delay.

(1) Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.

(2) Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(l) Batters, breading, sauces, gravies, dressings, spices and other similar preparations shall be treated or maintained in such a manner that they are safe and protected against contamination.

Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(1) Using ingredients free of contamination and verified by testing.

(2) Employing adequate heat processes where applicable.

(3) Using adequate time and temperature controls minimizing time food is in temperature danger zone of 41°F (5°C) to 140°F (60°C).

(4) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(5) Cooling to an adequate temperature within an appropriate time frame [from 135°F (57°C) to 70°F (21°C) within two (2) hours, and from 135°F (57°C) to 41°F (5°C) within a total of six (6) hours] during manufacturing.

(6) Disposing of batters at appropriate intervals to protect against the growth of micro-organisms.

(m) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(1) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(2) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(3) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in these Regulations.

(4) Providing physical protection from contamination, particularly airborne contamination.

(5) Using sanitary handling procedures.

(n) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(1) Monitoring the a_w of food.

(2) Controlling the soluble solids-water ratio in finished food.

(3) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(o) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(1) Monitoring the pH of raw materials, food in process, and finished food.

(2) Controlling the amount of acid or acidified food added to low-acid food.

(p) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in these Regulations.

(q) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

Section 9.0 *Warehousing and Distribution*

9.1 Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Section 10.0 *Natural or Unavoidable Defects In Food For Human Use That Present No Health Hazard - Defect Action Levels*

10.1 Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action[3].

10.2 Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

10.3 Compliance with defect action levels does not excuse violation of the requirement of RIGL Chapter 21-31 that food not be prepared, packed, or held under unsanitary conditions or the requirements of these Regulations that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of RIGL §21-31-10, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

10.4 The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of RIGL §21-31-10, regardless of the defect level of the final food.

[3] The current Defect Action Levels handbook may be downloaded from the FDA Center for Food Safety and Applied Nutrition website: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm.

Section 11.0 ***Adoption by Reference***

11.1 Federal Food, Drug, and Cosmetic Act : §413 [21 USC §350b - *New Dietary Ingredients*] and §703 [21 USC §373 - *Records of Interstate Shipment*] are adopted by reference except where provisions of these Regulations may specify different requirements.

11.2 Code of Federal Regulations: 21 CFR Parts 1, 7, 70, 73, 74, 81, 82, and 100-199, excluding Parts 171 and 179, are adopted by reference, except where provisions of these Regulations may specify different requirements.

Section 12.0 ***Compliance and Enforcement***

12.1 **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 §12.1(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.

12.2 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 13.0 ***Severability***

13.1 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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Friday, 04 November 2011

~~RULES AND REGULATIONS PRESCRIBING MINIMUM STANDARDS FOR SEAFOOD PROCESSING, STORAGE AND TRANSPORTATION~~

~~[R23-1-SF]~~

~~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)~~

November 2011 (Proposed to be superceded)

COMPILER'S NOTES:

Proposed Deletions: **This regulation is proposed to be superceded in its entirety. Therefore, all of the regulatory text is shown as ~~to be deleted~~.**

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~~**Authority:** Chapters 23-1, 21-27 and 21-31, of the General Laws of 1956 as amended~~

~~R23-1-SF1~~ ~~**PERMITS**~~

~~A. No person shall conduct within this state any seafood processing business without a permit from the Director of the Department of Health.~~

~~B. The Director shall, upon receipt of application for a permit to conduct a seafood processing business, cause the applicant's seafood processing business facilities to be investigated, and, if they are found to comply with these regulations, shall issue a permit. All permits shall expire on December thirty-first of the year issued unless sooner suspended or revoked for cause. Permits issued hereunder may be suspended or revoked for violation of any provision of these regulations.~~

~~R23-1-SF2~~ ~~**DEFINITIONS**~~

~~A. The word "department" shall be construed to mean the state Department of Health.~~

~~B. The word "director" shall be construed to mean the director of the state Department of Health or his duly appointed agents.~~

~~C. The work "person" shall be construed to mean any individual, firm, co-partnership, association, or private or municipal corporation.~~

~~D. The work "approved" shall be construed to mean approved by the director.~~

~~E. The word "fish" shall be construed to mean any aquatic animal, including amphibians or part thereof capable of use as human food.~~

~~F. The words "process," "processed," "processing" with respect to fish or fishery products mean to harvest, handle, store, prepare, produce, manufacture, process, pack, transport, or hold such products.~~

~~G. The word "gurry" shall be construed to mean fish offal.~~

~~H. "Sanitize" means adequate bactericidal treatment of cleaned food-contact surfaces by a process that is generally recognized as effective in destroying microorganisms including pathogens.~~

~~I. The word "adequate" shall mean in conformance with local, state and Federal requirements or recommendations. In the absence of such requirements or recommendations, "adequate" means in keeping with good public health practice.~~

~~J. The words "corrosion-resistant material" shall mean a material that maintains its original surface characteristic under repeated and prolonged exposure to food products, food ingredients, cleaning compounds, and sanitizing solutions to which it is normally subjected.~~

~~K. The words "easily cleanable" shall mean easily accessible and of such design, material, and finish that residues from or caused by processing operations may be completely removed by normal, safe cleaning methods.~~

~~L. The word "plant" shall be construed to mean the building or buildings, or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or storage of human food.~~

~~M. The term "vessel" means any watercraft of any description which is engaged primarily in the processing of fish for human consumption in this state, and any such craft used for harvesting and/or transporting seafood.~~

~~N. The word "fresh" shall mean any seafood that has been newly gathered; has not been preserved in any manner except by refrigeration; has not been frozen and has not had its original qualities or characteristics impaired.~~

~~O. The word "Whelk" (conches, winkles) shall be construed to mean Channeled Whelks and/or Knobbed Whelks.~~

~~P. The word "lobster" shall mean a sea product of the species "Homarus americanus."~~

~~Q. "Seafood product" shall mean any animal, plant, or other material, or part, or an animal, plant or portion of other material any part of which was originally taken from the sea.~~

~~R. "Fish-smoking establishment" (plant) shall mean the premises, buildings, structures, and equipment employed or used in connection with the processing, storage, or handling of fish, fish products, or ingredients for smoking and/or the smoking and subsequent processing, storage, or handling of the smoked fish, fish product, or fish ingredients within the plant.~~

~~S. "Smoked fish or fish products" shall mean a fish or fish product which, for the prime purpose of taking on the flavor and/or color of smoke, has been (1) subjected to the direct action of smoke or smoke flavor from the burning of wood, wood sawdust, or similar burning material; (2) immersed in or sprayed with a smoke-flavored solution.~~

~~T. "Transportation" shall mean the physical movement, or the acceptance for physical movement, of seafood products by a carrier.~~

~~U. A "day boat" shall mean any fishing boat or vessel that leaves and returns to port on the same day.~~

~~R23-1-SF3~~ ~~ADULTERATION~~

~~A. Only wholesome and accepted seafood products and ingredients shall be used by the processor. "Wholesome" shall mean in sound condition, clean, free from adulteration, and otherwise suitable for use as human food.~~

~~B. "Adulterated" shall mean the condition of fish, fish products or ingredients, (a) if they bear or contain any poisonous or deleterious substance in a quantity which may render them injurious to health; (b) if they bear or contain any added poisonous or deleterious substance for which no safe tolerance has been established by regulation, or in excess of such tolerance if one has been established; (c) if they consist in whole or in part of any filthy, putrid, or decomposed substance, or if they died by other than the conventional and approved method of killing, or are otherwise unfit for human consumption; (d) if they have been processed, prepared, packaged, or held under~~

~~unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; (e) if they are in whole or in part the product of a diseased fish; or (f) if their container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.~~

~~C. Products shall be deemed to be misbranded if they are so labeled as to deceive. All seafood products offered for sale shall be clearly identified by specie or generic name.~~

~~D. Seafood may be sampled or examined while in the possession of any person catching, handling, packaging, preserving, transporting or storing seafood products intended for sale and consumption as human food. Laboratory examination may be made as often as may be necessary to ascertain the wholesomeness of the product and to detect adulteration and/or misbranding. No seafood intended for human consumption shall be sold or offered for sale that is unsafe or in any way likely to injure the public health. Seafood may be condemned or destroyed or otherwise disposed of at the discretion of the Director of the Department of Health for cause. (Sec. 21-31-6 and Sec. 21-31-7).~~

~~E. No person shall sell, or represent for the purpose of sale, or imply as fresh, seafood which has been frozen at any time.~~

~~F. No seafood shall be stored in a frozen state for more than twelve (12) successive months except by permission of the Director. Immediately upon being frozen, seafood 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.~~

~~G. No person shall sell, or represent for the purpose of sale, seafood as being "fresh" unless it is as defined.~~

~~R23-1-SF4~~ ~~PLANT CONSTRUCTION, EQUIPMENT AND LOCATION~~

~~A. Plant Arrangement:~~

~~Plants in which fish are filleted and packed, or lobsters, crabs, and whelks are picked, handled and packed shall, if feasible, be so located that said establishment shall not be subjected to flooding by high tides. If plant floors become flooded, processing shall be discontinued until after waters have receded and the building cleaned and properly sanitized.~~

~~1. 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.~~

~~2. Packing rooms shall be large enough to permit sanitary handling of seafood and for the proper arrangement and thorough cleaning of equipment.~~

~~3. A separate room or rooms, or lockers which have adequate capacity for storing employees' street clothing, aprons, gloves and personal articles shall be provided.~~

~~B. Dry Storage:~~

~~Fish, cooked lobsters, crabs or whelks in dry storage shall be protected from contamination.~~

~~Floor wastes from a seafood storage area shall be discharged through a separate drainage system, or if discharged into a general drainage system carrying sanitary wastes, an air gap shall be provided which shall be located between the sewage system and drain(s).~~

1. ~~The storage area floor shall be constructed of impervious material, shall be free from cracks and uneven surfaces, and shall be graded to assure complete and rapid drainage of water (no less than 1/4 inch per foot).~~

2. ~~Walls of storage rooms shall be smooth and of material which will not deteriorate under repeated washing.~~

3. ~~Storage areas shall be so constructed that they will not receive drainage water from other portions of the plant. All the seafood shall be stored on racks and/or pallets no less than 6" off the floor. Storage areas should not serve as an entry way to other areas of the establishment. Storage areas shall be protected against sewage backflow by the installation of an air gap in the waste line or by provision of a separate drain system. In no event shall racks, pallets or shelving prevent proper cleaning and sanitizing of floor areas.~~

4. ~~Conveyances or devices used in the transport of seafood shall be so constructed that they may be easily cleaned. (Use of impervious material is recommended wherever possible).~~

~~C. Floors:~~

~~Floors shall be constructed of concrete or other impervious material and shall be graded to drain quickly, shall be free from cracks and uneven surfaces, and shall be maintained in good condition and kept clean.~~

1. ~~The floors of all rooms in which seafood is processed or packed or in which utensils are washed shall be constructed of concrete of good quality or of equally impervious tile laid closely with impervious joint material, or of metal surfacing with impervious joints, or of any other material which is equivalent to good quality concrete; the floors shall be maintained in good repair.~~

2. ~~The floor surface shall be smooth and graded to drain; the junctions between floors and walls, impervious to water.~~

~~D. Walls and Ceilings:~~

~~Walls and ceilings shall be smooth, washable and kept clean. If painted, it shall be kept covered with a light colored paint or otherwise with suitable impervious material.~~

~~E. Fly Control Measures:~~

~~All outer openings to toilet and wash rooms, filleting, picking and packing rooms, utensil cleaning and storage rooms, and locker rooms shall be effectively screened using a 16" mesh screening during the seasons when flies are present, unless other effective means approved by the department are provided for preventing the entrance of flies and other insects. Effective and safe in-plant fly-control measures shall be used to destroy or capture flies which may enter the plant despite the screening. Storage rooms shall be screened as necessary to prevent the entrance of flies into the other portions of the plant. All interior doors or other openings into the packing~~

~~rooms should be screened whenever necessary to keep the packing room free of flies.~~
~~1. Screen doors shall open outwardly and be self-closing.~~

~~F. Lighting:~~

~~Ample natural and/or artificial light, of at least 50 foot-candle power, shall be provided in all working and storage rooms.~~

~~G. Heating and Ventilation:~~

~~Working rooms shall be properly ventilated, and, shall be heated when necessary.~~

~~1. Proper ventilation reduces condensation and aids in retarding the growth of mold.~~

~~H. Water Supply:~~

~~The water supply shall be under pressure, easily accessible, adequate, and of a safe and sanitary quality and shall be approved by the Department of Health.~~

~~1. All seafood storage rooms, filleting, picking and packing rooms, and utensil washrooms shall be provided with water outlets properly located.~~

~~2. An automatically regulated hot-water system shall be provided with sufficient capacity to furnish water at a constant temperature of at least 170°F during all hours of plant operation and plant clean-up if this water is to be used for the sanitization of equipment and utensils.~~

~~3. Sufficient water shall be available for all plant needs when operating at maximum capacity. (Non-pressure supplies will not constitute compliance).~~

~~4. Hot and cold water outlets shall be provided at each sink compartment.~~

~~I. Plumbing and Related Facilities:~~

~~Plumbing shall be installed in compliance with local plumbing ordinances, or in the absence of such ordinances, shall be substantially equivalent to the recommendations contained in the AMERICAN STANDARD NATIONAL PLUMBING CODE ASA A40.0-1955. Lavatory facilities shall have running hot and cold (or warm) water and shall be so located that said facility can be readily observed and used by plant personnel. Signs shall be posted in toilet rooms and near lavatories, directing employees to wash their hands before starting work and after each interruption. Conveniently located, separate toilets shall be provided for each sex.~~

~~1. There shall be no cross-connections between the approved pressure water supply and water from a non-approved source; nor shall there be any fixtures or connections through which the approved pressure supply might be contaminated by back-siphonage.~~

~~2. There shall be at least one lavatory for every 20 employees among the first 100 employees, and at least one lavatory for each 25 employees in excess of the first 100. (Twenty-four lineal inches of wash sink or eighteen inches of a circular basin when provided with water outlets for such space will be considered equivalent to one lavatory).~~

3. ~~The lavatories shall be provided with hot water (at least 100°F either from a controlled-temperature source with a maximum temperature of 115°F or from a hot-and-cold mixing or combination valve. (Steam water mixing or steam-water combination valves are not acceptable).~~

4. ~~Supplies of soap and single-service hand towels must be available near the lavatory. (Other sanitary drying devices, if approved by the Department of Health, are also acceptable).~~

5. ~~The toilet-room doors shall be tight fitting and self-closing, and vestibules shall be provided unless specifically exempted by the Director.~~

   ~~Where facilities have been approved without a vestibule, mechanical means of ventilation to the outside shall be provided.~~

6. ~~The toilet rooms shall be kept clean and in good repair.~~

7. ~~A supply of toilet paper shall be available in the toilet rooms at all times.~~

8. ~~At least 5-foot-candle illumination (natural or artificial) shall be provided in toilet rooms.~~

9. ~~Toilet rooms shall be ventilated by a direct opening to the outer air, or by an approved mechanical ventilating system. (Exhaust fans, if used, should have a minimum capacity 2 cubic feet a minute per square foot of floor area). Air vents should be screened or have self-closing louvers.~~

10. ~~Conveniently located, separate toilets shall be provided for each sex. The number of water closets provided must comply with applicable state laws. In the absence of such laws, the following number of water closets should be provided:~~

~~**Number of Employees**~~	~~**Number of Water Closets (1)**~~	
	~~**Male**~~	~~**Female**~~
~~1 to 9~~	~~1~~	~~1~~
~~10 to 24~~	~~2~~	~~2~~
~~25 to 49~~	~~3~~	~~3~~
~~50 to 74~~	~~4~~	~~4~~
~~75 to 100~~	~~5 (2)~~	~~5 (2)~~

~~(1) Wherever urinals are provided, one water closet less than number specified may be provided for each urinal installed, except that the number of water closets in such care should not be reduced to less than two-thirds of the minimum specified.~~

~~(2) A 24-inch trough will be considered equivalent to one urinal. One additional fixture for every 30 employees over the first 100.~~

~~11. No unprotected drainpipes or wastepipes shall be located over food processing or storage areas, or over areas in which containers or utensils are stored or washed. (Drip troughs (shields) draining to the floor is an approved method of preventing contamination from drainpipes).~~

~~J. Sewage Disposal:~~

~~Sewage shall be discharged into public sewers wherever possible. Where private sewage disposal systems must be utilized, they shall be constructed according to the state requirements as provided in Health Department Regulation R23-1-SD which established the minimum standards relating to location, design, construction, and maintenance of individual sewage disposal systems.~~

~~K. Rodent Control:~~

~~Seafood processing plants shall be free from rodents.~~

~~1. The plant shall be constructed so as to prevent the entrance of rodents.~~

~~2. Rodenticides which are highly toxic to humans shall not be stored in seafood processing plants, and shall not be used except under the supervision of a licensed pest control operator or other qualified specialist with the approval of the Health Department. (Rodenticides which have a low toxicity for humans should be identified, stored, and may be used, after the approval of the Health Department, in such a manner as to prevent contamination of the product, ingredients, and equipment, and to cause no health hazards to employees.~~

~~3. All openings accessible to rodents shall be rodent-proofed by using a 1/4" hardware mesh (screen).~~

~~L. Construction of Breaking, picking or Filleting Benches and Tables:~~

~~The tops of processing benches and tables, and contiguous walls to a height of at least two feet above the bench top, shall be of smooth concrete, corrosion-resistant metal, or other durable, non-absorbent material, free from cracks, and so constructed that drainage is complete, rapid and is directed away from the stored meats. Filleting or picking blocks shall be easily cleanable. Wooden blocks, if used, shall be of solid, one-piece construction, and shall be easily removable. Blocks of lead or other toxic materials are prohibited. Stands or stalls, if any, shall be of painted, finished material.~~

~~Stools used by pickers shall have no attached padding, and shall be so constructed as to be easily cleaned.~~

~~Plants shall not have processing benches or other equipment attached to wall areas.~~

~~R23-1-SF5 CLEANING AND SANITIZING~~

~~A. Construction and Cleaning of Utensils and Equipment:~~

~~Food contact surfaces of utensils and equipment used for ice handling, shall be smooth, corrosion-resistant, impervious, and non-toxic material which will not readily disintegrate or crack and shall be so constructed as to be easily cleaned, and shall be kept in good repair.~~

1. ~~Knives, cleavers and other tools or implements shall be maintained in a sanitary condition.~~

2. ~~The use of enameled, tinned, or galvanized material in any food contact equipment other than single-service shipping containers is not permitted.~~

3. ~~There shall be no exposed screw, bolt, or rivetheads in the parts touching or draining to the food, and all joints shall be welded or soldered flush and have a smooth surface. (The use of welded joints which have been ground smooth is recommended because soldered joints have been proven to be generally unsatisfactory for equipment used in the Seafood Industry).~~

4. ~~Containers shall be clean, fabricated of non-toxic metal, waxed paper, glass, or other impervious material and be so designed and fabricated that the contents will be protected from contamination during shipping and storage. Covers of returnable containers shall be so designed as to protect the pouring lip of the container and shall be sealed so that tampering can be detected.~~

5. ~~Tanks, tubs, and picked-meat storage containers shall be so located that their top rim is at least two feet above the floor.~~

6. ~~All utensils and equipment shall be in good repair.~~

7. ~~Containers used to convey lobsters, crabs and whelks into picking rooms shall not be placed on tables or benches therein. Uncovered containers holding cooked lobsters, crabs, whelks, or the meat therefrom shall not be stacked.~~

8. ~~Cooking vessels and wire baskets used to contain the cooked lobsters, crabs, or whelks shall be of stainless steel.~~

~~B. General Cleanliness:~~

~~Premises shall be kept clean and free of litter and rubbish. Miscellaneous and unused equipment and articles which are not necessary to plant operations shall not be stored in rooms used for fish or seafood picked-meat storage, fish filleting, picking, packing, or repacking. No domestic animal or fowl shall be permitted in a processing plant. The seafood picked-meat or fish storage, filleting, breaking or picking and packing portions of the plant, when in operation, shall be restricted to the handling of fish, lobsters, crabs, or whelks. Unauthorized persons shall be excluded from the plant.~~

1. ~~Filleters or pickers shall not go into or through the packing room for any purpose. (An exception may be made in small operations, where an employee may work in both the packing room and the picking or filleting room. In such cases, the employee should be required to change aprons and wash his hands thoroughly before entering the packing room).~~

2. ~~Employees in processing rooms shall wear clean outer garments, and all persons entering such rooms shall wear a cap or hair net confining the hair.~~

3. ~~Smoking or other use of tobacco is prohibited.~~

4. ~~Use of jewelry and finger nail polish is prohibited.~~

5. ~~Breast pockets should not contain pens, pencils, or other articles that may drop onto the product.~~

~~C. Cleaning of Buildings and Equipment:~~

~~Benches, stools, floors and walls of the storage rooms and packing and filleting or picking rooms shall be cleaned within two hours after the day's operations have ceased. Windows and skylights shall be kept clean. Refrigerators shall be kept clean. All equipment, utensils, work surfaces, and knives, cleavers, picks, forks and other tools or implements shall be cleaned by scrubbing with water and detergent and rinsed with potable water within two hours after the day's operations, and shall be maintained in a sanitary condition.~~

1. ~~Scales, filleting or meat-picking tables, packing tables, benches, and all other equipment of similar nature shall be made of non-corrodible material or kept painted. Cutting boards shall be removable and should be kept in a reasonably smooth condition; badly split boards are prohibited. Approved rubber base composition boards should be used when possible. Conveyors and all other equipment shall be of a design that permits easy and thorough cleaning.~~

2. ~~Wash sinks, detergents and brushes, including special brushes needed for cleaning equipment, must be available and used according to the requirements of the Department.~~

~~SINK WASHING~~

~~Wash sinks should be made of impervious, non-toxic material. Sink compartments should be large enough to permit the complete immersion of the largest utensil to be sink washed. A second compartment should be provided in the sink for clean water rinsing, unless some other acceptable method, such as a spray rinse, is provided. In the case of bactericidal treatment by immersion in hot water, both the bactericidal treatment and rinse may be accomplished simultaneously in the second compartment. If bactericidal treatment by means of immersion in chemical solutions is selected, a separate or third compartment should be provided for this operation.~~

~~IN PLACE WASHING~~

~~Utensils and equipment which have to be washed "in place" will require pre-rinse, wash, rinse, and bactericidal treatment. A watertight container is best washed by preparing a solution of the detergent in the container itself and using this to scrub all parts of the unit. Rinsing, preferably would be accomplished either by complete filling or by thorough spray rinse. The bactericidal treatment methods are described in Item 4.~~

a. ~~Cleaned benches, blocks, and stalls should be flushed or sprayed as often as necessary, and at least once each week with a solution containing not less than 100 parts per million of available chlorine or other disinfecting agents in effective concentrations as approved by the Department of Health.~~

b. ~~All shelves, tables and other equipment in the filleting or meat-picking and packing rooms shall be clean.~~

c. ~~Periodic clean-water flushing of filleting or breaking/picking benches, utensils, table~~

~~surfaces and other equipment during working periods is recommended.~~

~~d. Periodic in-plant chlorinated (break-point) water for flushing of filleting benches, etc., is recommended.~~

~~D. Bactericidal Treatment of Utensils and Equipment~~

~~All utensils and equipment in the processing and packing rooms which come into contact with filleted fish or picked meats shall be subjected to an effective bactericidal treatment at the end of each day's operation. Containers which have been subjected to bactericidal treatment should have a residual bacterial plate count of not more than 1 per milliliter of capacity, and equipment not over 100 colonies per 8 square inches (i.e. 2 per sq. cm.) of food contact surface, in three out of four samples (Reference, Standard Methods — American Public Health Association, for information on apparatus and procedure for making rinse and swab counts).~~

~~Large equipment which might be recontaminated before use shall be cleaned at the end of each day's operation and shall be subjected to effective bactericidal treatment immediately before use.~~

~~Returnable shipping containers, if used, shall be subjected to an effective bactericidal treatment the day they are to be used and shall be protected against contamination until filled.~~

~~Approved Methods of Bactericidal Treatment:~~

~~1. All utensils and other equipment shall be treated by one or more of the following methods:~~

~~a. Immersion in hot water of at least 170°F for at least one-half minute. (An accurate indicating thermometer must be provided and used). A booster heater or other devices may be necessary for water to be maintained at 170°F.~~

~~b. Chemical Sanitization:~~

~~Immersion for at least one minute in or exposure for at least one minute to a flow of a solution containing not less than 50 parts per million of free chlorine at the end of the run. All product-contact surfaces must be thoroughly treated by prolonged wetting by the bactericidal solution, and piping, if so treated, must be filled and have the acceptable residual concentration at the end of the piping system. Bactericidal sprays containing not less than 100 parts per million of free chlorine may be used for large equipment. If atomized into said equipment, it shall be done in such a manner as to assure complete coverage of the internal surfaces with a 200 ppm chlorine residual. Bactericidal treatment with chemicals is not effective unless the surface has been thoroughly cleaned.~~

~~c. Exposure for at least 15 minutes at a temperature of at least 170°F, or for at least five minutes at a temperature of at least 200°F, in a steam cabinet equipped with an indicating thermometer located in the coldest zone. (Absence of a thermometer violates this item). A vent or valve must be installed at the bottom of large steam cabinets to permit the discharge of cold air when steam is admitted.~~

~~BACTERICIDES OTHER THAN CHLORINE WILL NOT BE ACCEPTED UNTIL OFFICIAL TESTS ARE MADE OR APPROVED BY THE HEALTH DEPARTMENT.~~

~~E. Storage of Equipment:~~

~~Equipment and utensils which have been cleaned and given bactericidal treatment shall be stored so that they are thoroughly drained and protected against any environmental contamination. The utensils can be stored in a steam chest; in a special cabinet; or otherwise in the packing room on clean shelves, stands, tables, or racks. Storage racks should be at least three feet above the floor.~~

~~F. Handling of Single-Service Containers:~~

~~All single-service containers shall be stored and handled in a sanitary manner, and, if necessary, shall be given bactericidal treatment immediately prior to filling.~~

~~1. Single-service containers in the packing room shall be kept on stands or tables at least two feet above the floor and shall be protected against contamination from splash.~~

~~R23-1-SF6 SEAFOOD~~

~~A. Packing of Seafood:~~

~~Filleted fish or picked meats shall be packed without exposing them to contamination. Seafood 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. Each individual package of fresh or frozen fish, lobster, crab or whelk meat shall have permanently recorded on the package or label so as to be easily visible the name and address, certificate number and State of the packer, repacker or distributor. Packages of frozen fish shall show the date or code of packing. The explanation of any code shall be available to the consumer upon request.~~

~~1. Wording, such as "Packed for" or "Distributed by" shall be used wherever necessary to clarify the name on the label. Packing into containers with other plant certification numbers will not be permitted. Recording identification information on containers by use of a rubber stamp will not be acceptable. Returnable shipping containers may be identified with tags of at least 2 5/8 x 5 1/4 inches in size and made of substantial waterproof stock.~~

~~2. The packing code should be made available at the request of the Department of Health. Code dating of non-frozen products is also recommended.~~

~~B. Candling of Fish Fillets:~~

~~Fish fillets shall be placed over a light of suitable intensity for the detection of any parasites, cysts, etc. These foreign items shall be removed from the fillets before packaging.~~

~~C. Handling of Gurry:~~

~~Barrels or any other receptacles for waste or gurry shall be water-tight, kept covered and shall be thoroughly cleaned and sanitized after each emptying. All gurry shall be removed from the premises at least once a day.~~

~~D. Open Air Processing:~~

~~Fish shall be processed only within the enclosure of an approved establishment maintained as provided in these regulations.~~

~~E. Shell Disposal:~~

~~Shells from which meats have been removed shall be removed promptly from the picking room and disposed of in an approved manner.~~

~~F. Use of Containers:~~

~~Containers used to take lobsters, crabs into picking rooms shall not be placed on tables or benches therein. Uncovered containers of cooked lobsters, crabs, whelks, or the meat therefrom, shall not be stacked.~~

~~Cooking vessels and wire baskets used to contain the cooked lobsters, crabs, or whelks, during processing and plant handling thereafter shall be of stainless steel.~~

~~G. Picking of Lobsters, Crabs and Whelks:~~

~~Meat from lobsters, crabs, or whelks shall be picked into containers or onto surfaces which have been properly sanitized with a chlorine solution of not less than 50 parts per million of free chlorine.~~

~~H. Retail Seafood Display:~~

~~All unwrapped or unenclosed seafood on display shall be protected by glass or otherwise from public handling or other contamination and kept at below 45°F at all times.~~

~~R23-1-SF7~~ ~~REFRIGERATION~~

~~A. Refrigeration of Filleted Fish:~~

~~Filleted fish shall be cooled to an internal temperature of 45°F or less with two hours after packing and stored and shipped under similar temperature conditions. Further cooling to a temperature not exceeding 40°F is recommended.~~

~~Seafood which will not be packed within one hour after delivery to the packing room shall be cooled to an internal temperature of 45°F or less within two hours.~~

~~B. Refrigeration of Lobsters, Crabs and Whelk Meats:~~

~~Meat from lobsters, crabs, whelks, or parts thereof not immediately removed from the shells after cooking shall not be sold, given away, or used for food purposes unless such lobsters, crabs, whelks, or parts thereof have been kept in sanitary containers and refrigerated at less than 45°F.~~

~~Shucked lobster, crab, or whelk meat shall be cooled to a temperature of 45°F or less within two hours after picking. Containers of such products shall be packed in cracked ice or otherwise suitably refrigerated at a temperature of 40°F or below until sold.~~

~~A temperature of 0°F shall be maintained in the frozen-storage rooms.~~

1. ~~Picked lobster, crab, or whelk meat shall be cooled to an internal temperature of 45°F or less within two hours after packing and stored and shipped under similar temperature conditions. (Five pound containers will ordinarily have to be stored in crushed or flaked ice immediately after packing, to attain this degree of cooling. For containers holding more than five pounds, shucked meats will ordinarily require cooling prior to placement in containers).~~

2. ~~Packaged fish, lobster, crab, or whelk meat to be frozen shall be properly stacked to insure rapid freezing, and frozen at an ambient air temperature of 0°F or less, with packages frozen solid within 12 hours after the start of freezing, and frozen meats shall be handled in such a manner as to remain frozen solid and held at 0°F or less until sold to the final consumer, if sold as a frozen product.~~

~~C. Ice:~~

~~Ice shall be obtained from sources approved by the Department of Health and shall be stored and handled in a clean manner.~~

~~D. Fresh Fish Shipments:~~

~~Fresh fish shipments should be packed in ice for delivery and should be well iced when received. Finely crushed ice should be used in preference to large pieces to avoid bruising the fish. Fish should be handled carefully to avoid bruises and punctures of the flesh which cause quality breakdown.~~

~~E. Thawing Frozen Seafood:~~

~~Frozen seafood shall be thawed at refrigerator temperatures of 45°F or below or under cool, potable running water (70°F or below), of quick thawed as part of the cooking process, or by any other method satisfactory to the Director.~~

~~R23-1-SF8~~ ~~FISHING VESSELS~~

~~A. Holds:~~

~~The holds of all fishing boats and vessels used for the taking of transportation of fish for food purposes shall at all times be maintained in a sanitary condition. Pen boards shall be thoroughly washed with chlorinated water containing at least twenty parts per million, or a "detergent-sanitizer" having equivalent sanitizing capabilities, and shall be scrubbed immediately after coming out of the hold. Pen boards which are cracked, splintered, or otherwise punctured, so as to be unsanitary, shall not be used. Holds shall be thoroughly washed and scrubbed with chlorinated water or water containing a suitable "detergent-sanitizer."~~

~~Holds and pen boards of all vessels, excepting those engaged in lobster dragging operations, shall be thoroughly cleaned, dried, and painted at least once a year or more often, if necessary, with a lead-free paint.~~

~~B. Handling and Storage:~~

~~All fish of the following species shall be eviscerated as they are caught and before being packed:~~

~~Haddock, Cod, Pollock, or any other fish which may be so designated.~~

1. ~~The gutting of fish at sea shall be thorough and complete with the removal of all the internal matter from the body cavity. Fish shall be thoroughly washed before being iced. Ice shall be used, so that all fish are kept apart in the center of the pens. Ice must be in actual and continuous contact with the fish. It shall effectively separate all fish from bulkheads, sheathing, shelves, and pen boards, and must be in quantity to last for the duration of the storage period and assure the preservation of said seafood.~~

2. ~~Gills must be removed on all fish mentioned above from April 1st to November 1st on all boats other than "Day" Boats.~~

3. ~~Forks shall not be used for the transferring of fish from one receptacle to another or from the holds of vessels into unloading receptacles. If picks are used, only the head area of the fish shall be penetrated.~~

~~C. Toilets and Lavatories:~~

~~Ship's personnel must use the facilities provided aboard vessels for personal cleanliness; signs requiring employees to wash their hands before returning to work after any absence shall be conspicuously posted in such facilities.~~

~~(Item B3 of this section will take effect three (3) months after the acceptance of these regulations.)~~

~~R23-1-SF9 SMOKED FISH PROCESSING~~

~~A. Brining of Fish:~~

~~Only clean refined salt, or filtered brine of a temperature not exceeding 50°F shall be used in the brining of fish.~~

~~Where necessary to prevent contamination of fish, covers shall be provided for tanks, and containers, including brining and thawing tanks.~~

~~B. Fuel:~~

~~Fuel used for smoking (wood, excelsior, etc.) shall be clean and shall be stored away from fish, fish products or ingredients.~~

~~C. Use of Preservatives for Fish:~~

~~Only salt, sugar, wood smoke, vinegar, pure spices, spice flavorings, and sodium benzoate may be used as fish preservatives. The quantity of sodium benzoate shall not exceed one-tenth of one percent by weight of product and must be designated on the label.~~

~~The use of the salts of nitrate and the salts of nitrite in fish for any purpose is prohibited.~~

~~D. Use of Coloring Matter on Fish:~~

~~The use of any matter which imparts color to fish is prohibited.~~

~~E. Drip Pans:~~

~~In an establishment engaged in preparing, preserving, or smoking fish, metal drip pans shall be provided and placed under racks of smoked fish in order to catch the drippings. The pans shall be kept clean and in good repair.~~

~~R23-1-SF10 CLAM JUICE~~

~~A. Construction and Cleaning of Utensils and Equipment:~~

~~The parts of utensils and equipment which come in contact with the juice being processed or which may drain into equipment containing juice, including equipment used for pasteurization, shall be made of smooth, corrosion-resistant, impervious, non-toxic material which will not readily disintegrate or crack and shall be so constructed as to be easily disassembled and cleaned and shall be kept in good repair.~~

~~1. The use of enameled, tinned, or galvanized material in any juice contact equipment other than approved single-service shipping containers is not acceptable.~~

~~2. There shall be no exposed screw, bolt, or rivet heads in the parts touching or draining to the juice and all joints shall be welded or soldered with lead free solder, flush and have a smooth surface. (The use of welded joints which have been ground smooth is recommended; soldered joints are not recommended and have been proven to be generally unsatisfactory).~~

~~3. Containers shall be clean, fabricated of non-toxic metal, or be of waxed paper composition, glass or other impervious material, and so designed and fabricated that the contents will be protected from contamination during shipping and storage. Covers of returnable containers shall be so designed as to protect the pouring lip of the container and shall be sealed so that tampering can be detected.~~

~~B. Pasteurization of Clam Juice:~~

~~No clam juice intended for human consumption shall be sold or offered for sale without first being pasteurized in equipment approved by the Department.~~

~~Clam juice is to be heated for at least 30 minutes at no less than 143°F to insure proper pasteurization. A proper timer and thermometer, approved by the Department, shall be used to insure that the time and temperature is achieved.~~

~~C. Refrigeration:~~

~~Clam juice shall be cooled to a temperature of 45°F or less within two hours after processing. The containers of juice shall be packed in cracked ice or otherwise suitably refrigerated at a temperature of 40°F or less until sold.~~

~~Frozen clam juice shall be handled in such a manner as to remain frozen solid and held at 0°F or less until sold to the final consumer if sold as a frozen product.~~

~~R23-1-SF11 TRANSPORTATION~~

~~A. Transit and Storage of Seafood:~~

~~All fish and fishery products whether inside or outside any establishment or in transit shall at all times be kept iced or otherwise properly cooled and kept in containers or display cases which are sanitary and protected from the direct rays of the sun and other elements conducive to spoilage or contamination. To prevent spillage trucks, boxes, containers, receptacles and mechanical conveyors, shall not be overloaded. During processing, storage and/or transportation, fish or fish products shall not be allowed to come in direct contact with the floors of the plant and/or transportation facility.~~

~~1. Seafood while being transported shall be in an enclosed conveyance with doors closed securely or such products must be in covered containers or otherwise wrapped or packaged to insure protection from contamination. Potentially hazardous foods shall be kept at safe temperature during all periods of transportation and delivery.~~

~~2. Insulated containers may be used for transportation of frozen seafood, provided that the internal temperature of the frozen seafood at no time exceeds zero degrees Fahrenheit except during brief periods of loading and unloading when temperatures shall not exceed 10°F.~~

~~B. Vehicles used for transporting seafood shall not be used for any purpose other than that for which it was intended.~~

~~C. Vehicles of transportation shall be equipped as follows:~~

~~1. Insulation and a mechanical refrigeration system or other refrigeration method or facilities capable of maintaining an air and product temperature of 0°F or lower while loaded with any frozen food; and no higher than 45°F for refrigerated seafood products.~~

~~2. With a thermometer or other appropriate means of temperature measurement indicating air temperature inside the vehicle. The dial or reading element of the thermometer shall be mounted on the outside of the vehicle.~~

~~3. Vehicles used for route delivery shall comply with all equipment provisions herein specified for vehicles of transportation and shall be equipped with curtains or flaps in the doorway area or with port doors to maintain refrigeration during stops.~~

~~D. Handling Practices for Over-the-Road Transportation:~~

~~1. Vehicles for frozen products transportation shall be precooled to an air temperature of 20°F or lower before loading.~~

~~2. Frozen food shipments shall not be accepted for transportation when the internal product temperature exceeds 0°F.~~

~~3. Frozen food shall be loaded within a vehicle of transportation to provide for free circulation of refrigerated air at the front, rear, top, bottom, and both sides of the load except for vehicles of envelope-type construction wherein refrigerated air circulates within walls of said vehicles.~~

~~4. The mechanical refrigerating unit of vehicles shall be turned on and doors of vehicles shall be~~

~~kept closed during any time interval when loading or unloading operations cease.~~

5. ~~The average product temperature of any shipment of frozen food shall be determined during loading and unloading by adequate temperature readings.~~

E. ~~Handling Practices for Route Delivery:~~

1. ~~In addition to all provisions specified in Section FF6.2 of R23-1-FF, entitled Frozen Food Products, the following provisions shall be met:~~

   a. ~~Each lot for individual consignment shall be refrigerated by maintaining an air and product temperature of 0°F or lower;~~

   b. ~~Insulated containers shall be precooled to a temperature of 20°F or lower before being loaded with frozen food;~~

   c. ~~Doors of vehicles shall be kept closed during any time interval that loading or unloading operations cease.~~

F. ~~Sanitary Provisions:~~

1. ~~All interior surfaces of vehicles and devices used for transporting frozen food shall be clean and free of objectionable odors before being loaded with frozen food.~~

2. ~~Frozen food shall be securely packaged or wrapped in a sanitary manner before they are accepted for transportation.~~

~~R23-1-SF12 MISCELLANEOUS~~

A. ~~Records:~~

~~Complete and accurate records shall be kept by every fish dealer of all business transactions.~~

B. ~~Health of Personnel:~~

~~Any person known to be infected with any disease in a communicable form, to be a carrier of any disease which can be transmitted through the handling of fish, or who has an infected wound or open lesion on any exposed portion of his body shall be excluded from the filleting or packing plant. Any owner or manager who has reason to suspect that any employee has contracted a communicable disease shall immediately notify the proper health officials. Pending appropriate action by the health officials, said employee shall be excluded from the plant.~~

C. ~~Supervision:~~

~~The management shall designate a reliable individual to be accountable for compliance with the items of these regulations having to do with plant and personnel cleanliness.~~

D. ~~Cleanliness of Employees:~~

~~Employees shall wash their hands with a liquid or powdered dispensed soap and water before~~

~~beginning work and again after each interruption and before returning to work.~~

1. ~~When manual handling of filleted fish or picked seafood meats becomes necessary, sanitized rubber gloves shall be worn, or the hands shall be washed and disinfected immediately before such manual handling.~~

2. ~~Finger cots, gloves, and/or shields if worn by filleters or pickers shall be sanitized as often as necessary and at least twice daily. (Use of waterproof finger cots or shields is recommended as preferable to those made of an absorbent material). Any person who handles seafood shall wear a clean apron or coat. Rubber aprons shall be washed daily and hung so as to dry easily when not in use.~~