

Chapter 12: The Seafood HACCP Regulation

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Objective:

In this module, you will learn:

- What are the requirements of the seafood HACCP regulation.
- How to reference the specific requirements.

In December 1997, the FDA initiated a seafood regulation based on the seven principles of HACCP called “Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.” This regulation has become known as “the seafood HACCP regulation.” It will be referred to in this chapter as “the regulation.” A copy of the regulation is provided in Appendix I.

• ***Regulation Format***

The regulation is part of Title 21 of the Code of Federal Regulations (CFR), Part 123, and is subdivided into three subparts and 13 sections.

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Regulation Format

Subpart A — General provisions

- 123.3 Definitions
- 123.5 Current GMPs
- 123.6 HACCP plan
- 123.7 Corrective actions
- 123.8 Verification
- 123.9 Records
- 123.10 Training
- 123.11 Sanitation control procedures
- 123.12 Special requirements for imported products

Subpart B — Smoked and smoke-flavored fishery products

- 123.15 General
- 123.16 Process controls

Subpart C — Raw molluscan shellfish

- 123.20 General
- 123.28 Source controls

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Explanatory Note:

The terms "fish" and "fishery product" together define the products that are subject to this regulation.

• Definitions 123.3

Twenty important terms are used throughout the regulation. They are:

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Definitions 123.3

- certification number
- critical control point
- critical limit
- fish
- fishery product
- hazard
- importer
- molluscan shellfish
- preventive measure
- process-monitoring instrument
- processing
- processor
- scombroid toxin-forming species
- shall
- shellfish-control authority
- shellstock
- should
- shucked shellfish
- smoked or smoke-flavored fishery products
- tag

Of the terms listed above, a few definitions need to be emphasized.

Fish means freshwater or saltwater finfish, crustaceans, aquatic animal life (including alligators, frogs, aquatic turtles, jellyfish, sea cucumbers, sea urchins and roe) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

Fishery product means any human food product where fish is a characterizing ingredient. [Note: This definition exempts products from the mandatory HACCP requirements that contain inconsequential amounts of fish. For example, Worcestershire sauce contains some anchovy paste but is not characterized by that ingredient.]

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Who must comply?

Importer
Processor — domestic and foreign

Importer means either the U.S. owner/consignee or the U.S. agent/representative of the foreign owner/consignee at the time of the product's entry into the United States. This person is responsible for ensuring that goods being offered for entry are in compliance with all laws affecting the importation. Ordinarily, the importer is not the custom-house broker, freight forwarder, carrier or steamship representative. [Note: The ownership of an imported product can change many times in a short period of time after entry into the United States. However, the person who is the owner or consignee at the time that the product is offered for entry is identified as the importer because: 1) that person has the ability to decide whether to offer the product for entry, and 2) that person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this to FDA.]

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 means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding fish or fishery products. [Note: Eviscerating done by an aquaculture grower before delivery to a processing plant would make it necessary for the grower to comply with the requirements of this regulation. Fishing vessels and carriers may be affected by this regulation indirectly through the controls that processors may impose on them to meet HACCP obligations. However, vessels are not directly affected by the regulation, except for factory trawlers and similar vessels. Retail establishments must follow state and local government regulations. The Food Code (FDA's model food ordinance that many state and local regulatory authorities use in developing their food laws and regulations) requires that raw materials for retail establishments come from approved sources.]

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This regulation does not apply to:

- The harvest or transport of fish or fishery products.
- Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.
- The operation of a retail establishment.

Shall is used to state mandatory requirements.

Should is used to state recommended or advisory procedures or to identify recommended equipment.

Explanatory Note:

The terms importer, processor and processing together define who is subject to this regulation.

Explanatory Note:

Products that do not move in interstate commerce are not subject to the regulation. However, products are considered to have entered into interstate commerce if raw materials, ingredients, packaging, etc. have originated outside the state.

Explanatory Note:

The use of the term "should" in the FDA regulation may differ from its use in Chapters 5 through 11 of this manual. Chapters 5 through 11 are designed to teach the principles of HACCP, including certain activities that need to be carried out to properly implement HACCP plans. Identifying these activities as those that "should" be enacted means they are important for the HACCP program to be effective. Many of these activities may be mandatory elements of the regulation.

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- *Current Good Manufacturing Practices (CGMPs) 123.5*

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Current Good Manufacturing Practices 123.5

- Regulations found in Title 21, Part 110 of the Code of Federal Regulations
- Proper practices for the safe and sanitary handling of all foods

The Food Drug and Cosmetic Act deems food to be adulterated if processed under insanitary conditions. The Current Good Manufacturing Practices describe the conditions and practices that must be followed to avoid producing adulterated food product. Part 110 applies to the processing of all FDA-regulated food products including fish and fishery products because it is the basis for determining whether the facilities, methods, practices and controls used to process these products are safe and whether the products have been processed under sanitary conditions. The purpose of the seafood HACCP regulation is to set out requirements specific to the processing of fish and fishery products.

- *Hazard Analysis 123.6(a)*

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Hazard Analysis 123.6(a)

Every processor shall conduct or have conducted a hazard analysis.

The regulation requires that every processor perform a hazard analysis. It outlines two major steps in a hazard analysis:

- Determine whether there are hazards that are reasonably likely to occur.
- Identify preventive measures to control the identified hazards.

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Hazards that are "reasonably likely to occur:"

Those "for which a prudent processor would establish controls"

This means a prudent processor would establish controls because there is a reasonable possibility that a hazard will occur. To make this decision, examine:

- Experience,
- Illness data,
- Scientific reports and
- Other information
(e.g., FDA’s Fish and Fishery Products Hazards and Control Guide).

The criteria for including a food-safety hazard in a processor’s HACCP plan should be the likelihood that the hazard will occur or develop in that product without proper controls (e.g., based on the processing technique, the harvest location, the species).

An example of a hazard that is reasonably likely to occur is histamine in certain fish species. Histamine reaction is one of the most frequently reported illnesses from seafood. The relationship between time and temperature abuse after harvest and the formation of the toxin is well-established.

It is the end product of the hazard analysis — the HACCP plan and its implementation — that will be judged by the regulator and not the hazard analysis itself. For this reason, the regulation does not require that the hazard analysis be performed in any particular way or that it be documented in writing for regulatory review. However, a written hazard analysis will help the processor remember the thought process used to identify the hazards and develop the HACCP plan. This will be useful when periodic plan reassessments are conducted and when the plan is reviewed by regulators.

• **HACCP Plan 123.6(b)**

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HACCP Plan 123.6(b)

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur.

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A HACCP plan shall be specific to:

- Each processing location.
- Each species of fish and type of fishery product.

When HACCP plan components are similar, some fish and fishery products may be grouped under a single HACCP plan.

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- *HACCP Plan Contents 123.6(c)*

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The HACCP plan shall:

- List the food-safety hazards that are reasonably likely to occur.
- List the CCPs.
- List the critical limits.
- List the monitoring procedures.
- List predetermined corrective-action plans.*
- List the verification measures.
- Provide for a system of monitoring records.

* Processors are not required to predetermine corrective actions.

Food-safety hazards can include: natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition that is related to safety (e.g., scombroid toxin-forming species), parasites that are related to safety (e.g., fish used for raw consumption), unapproved food and color additives, and physical hazards. They can be hazards that are introduced inside the processing plant or hazards that occur before, during or after harvest.

The frequencies of the monitoring and verification procedures must be included in the HACCP plan. Monitoring records must provide the actual values or observations noted during monitoring.

- *Signing and Dating the HACCP Plan 123.6(d)*

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The HACCP plan shall be signed and dated by:

The most responsible individual at the processing facility
or a higher level official of the processor.

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

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The HACCP plan shall be signed and dated:

- Upon initial acceptance.
- Upon any modification.*
- At least annually.*

* This is a verification requirement.

• *Low Acid Canned Foods and Acidified Foods 123.6(e)*

Processors who must comply with the requirements of part 113 or 114 (acidified and low-acid canned foods) of the CFR do not need to address the hazard of *Clostridium botulinum* in their HACCP plans. Their HACCP plans do not need to include controls to prevent that hazard, but they must continue to comply with 113 or 114. Other hazards may be reasonably likely to occur in an acidified or low-acid canned fishery product (e.g., histamine in canned tuna), and these must be addressed in the HACCP plan as appropriate.

• *Sanitation Controls and the HACCP Plan 123.6(f)*

FDA recognizes that sanitation controls may be troublesome to manage in a HACCP plan. It is often difficult to determine appropriate critical limits and corrective actions for sanitation controls, particularly those relating to personnel hygiene (e.g., hand washing). For this reason, the regulation does not require that sanitation controls be included in the HACCP plan. However, sanitation controls that are not in the plan must be monitored according to the sanitation provisions of the regulation. Sanitation is discussed in section 123.11.

• *Legal Basis 123.6(g)*

FDA's application of HACCP is primarily based on the Federal Food Drug and Cosmetic Act. This section of the act makes it unlawful to process food under conditions that may render it injurious to health. Any fish or fishery products processed or imported in violation of this regulation can be considered adulterated and subject to regulatory action.

Notes:

Explanatory Note:

HACCP plans will not be preapproved by FDA before they are implemented by the processor. They should not be submitted to the agency for review. FDA reached this decision because:

- HACCP plans should be evaluated on-site, a process best accomplished during inspections of processing facilities.
- FDA does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of HACCP implementation by processors.

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- *Corrective Action 123.7*

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Corrective Action 123.7

Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

The regulation requires that a corrective action take place whenever a critical limit is not met at a CCP.

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Corrective Actions — Two Choices

- Predetermined
- Alternate Procedure
 - Segregate and hold product.
 - Determine product acceptability.
 - Apply corrective action to product and process.
 - Reassess the HACCP plan.

Processors have a choice of developing a predetermined corrective-action plan in advance as part of their HACCP plans or of following the alternate procedure for corrective actions provided in the regulation. When a processor develops a plan in advance, he/she follows the plan that is appropriate when the deviation occurs. These corrective-action plans become part of their HACCP plans as previously described in section 123.6(c).

A predetermined corrective-action plan provides a processor with benefits such as faster action when a deviation occurs and less need to justify to management the appropriateness of the corrective action after it has been taken. But unusual situations may arise that may not be addressed in predetermined corrective-action plans. Processors may choose not to predetermine their corrective actions. In these cases, the alternate corrective-action procedure must be followed.

A proper corrective-action plan describes the steps that are to be taken and assigns responsibility for taking those steps. It is designed to ensure that:

- No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.
- The cause of the deviation is corrected.

The alternate corrective-action procedure involves:

- Segregating and holding the affected product until the next two requirements are met.
- Determining whether the product is safe for distribution. This decision must be made by someone who has suitable training or experience. This training or experience must be in the field(s) of science that is necessary for the person to understand the public health consequences of the critical-limit deviation.
- Take corrective action, as necessary, to ensure no unsafe product enters commerce.
- Take corrective action, as necessary, to fix the problem that caused the deviation.
- Determine whether the HACCP plan needs to be modified to reduce the risk that the deviation will happen again and modify the HACCP plan as necessary. This decision must be made by someone who has met the training requirements covered in section 123.10.

All corrective actions must be fully documented in records.

- **Verification 123.8**

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Every processor shall verify:

- That the HACCP plan is adequate to control the food-safety hazards that are reasonably likely to occur.
- That the HACCP plan is implemented effectively.

Every processor must 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 must include, at a minimum, reassessment of the HACCP plan, ongoing verification activities, and record reviews.

The HACCP plan must be reassessed at least once per year and whenever any changes occur that could affect the hazard analysis or the HACCP plan in any way. This could include changes in:

- Raw materials or source of raw materials.
- Product formulation.
- Processing methods or systems.
- Finished product distribution systems.
- The intended use or consumers of the finished product.

The purpose of the reassessment is to ensure that the HACCP plan is adequate to control the food-safety hazards which are reasonably likely to occur. It must be performed by an individual who meets the training requirements described in section 123.10. If a processor has no HACCP plan because no significant hazards were identified, then the hazard analysis must be reassessed whenever any changes occur that could affect the hazard analysis.

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The regulation requires ongoing verification activities in addition to periodic reassessment. These ongoing activities are in keeping with the HACCP principle that verification must ensure that the HACCP plan is being implemented on a day-to-day basis. These ongoing verification procedures must be listed in the HACCP plan.

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Ongoing verification:

- Consumer complaint review.
- Calibration of process-monitoring instruments.
- Periodic end-product and in-process testing (processor's option).

Records must be kept of the calibration procedures and end-product or in-process testing that is performed as part of a processor's HACCP activities.

Consumer complaints must be reviewed by the processor to determine whether they relate to problems at a CCP. The regulation does not give regulators access to consumer complaints but does give them access to corrective action records that relate to problems identified by consumer complaints.

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Review of records:

- CCP monitoring records.
- Corrective-action records.
- Calibration records.
- In-process and end-product testing records.

Explanatory Note:

Importer and sanitation records are not required to be reviewed.

The regulation requires that processors review certain records as part of verification. The purpose of these reviews is to ensure that the records are complete and that the activities occurred in accordance with the processor's written procedures. The records must be reviewed by someone who meets the training requirements described in section 123.10.

Monitoring and corrective-action records must be reviewed within one week of when the record was made. Calibration and in-process or end-product testing records must be reviewed in a timely manner.

Sometimes the review of a consumer complaint or the performance of verification procedure will indicate a potential public-health problem. When this happens, the processor must follow the corrective-action procedures described in section 123.7.

- *Records 123.9*

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Records required by the regulation:

- Monitoring records.
- Corrective-action records.
- Verification records.
- Sanitation-control records.
- Importer-verification records.

The records required by the regulation must:

- Contain certain information.
- Be completed at the time of the activity.
- Be signed or initialed by the operator or observer.
- Be retained for specified periods of time.
- Be available for review and copying by regulatory authorities.

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Required information on each record:

- Name and location of the processor or importer.
- Date and time of the activity being recorded.
- Signature or initials of the person making the record.
- Identity of the product and the production code where appropriate.

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Record retention:

- One year for refrigerated products.
- Two years for frozen or preserved products.

If permanent storage at the processing facility is not practical (e.g., a remote processing site or a processing vessel), the records may be transferred to some other facility at the end of the season. But the records must be able to be promptly returned when requested by a regulatory agency.

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A key feature of the HACCP verification process is access by government inspectors to the the HACCP plan, monitoring records and corrective-action records. Examination of HACCP records enables an inspector to see how the processing facility operates over time rather than just on the day of the inspection. Additionally, it enables the inspector to review the adequacy of the processor's preventive-control system.

FDA has concluded that records and plans should be protected to the extent possible to promote the implementation of HACCP across the seafood industry. The regulation generally states that HACCP plans and records which come into FDA's possession will be treated as either trade secrets or commercial confidential materials.

• *Training 123.10*

The regulation requires that certain activities and functions be performed by an individual trained in HACCP.

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The HACCP-trained individual shall:

- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- Review HACCP records.

Processors can use a trained employee or a trained third party to perform these functions. The jobs may be done by one person or by several as long as they have been properly trained. The regulation defines a "HACCP-trained individual" as one "who has successfully completed training in the application of HACCP principles to fish and fishery product processing that is at least equivalent to that received under a 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 if it has provided knowledge at least equivalent to that provided through the standardized curriculum." This course material, developed by the National Seafood HACCP Alliance, is the standardized curriculum that has been recognized by FDA.

• *Sanitation Control Procedures (SCP) 123.11*

Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. In writing the seafood HACCP regulation, FDA concluded that the GMP regulations (21 CFR 110) had not proven fully effective in encouraging seafood processors to take full responsibility for ensuring that sanitation in their plants consistently met minimum standards. For these reasons, the regulation requires that processors take certain actions to control sanitation conditions and practices.

These actions must be taken even if a processor determines there is no need for a HACCP plan. The sanitation requirements of the regulation may be made part of the processor's HACCP plan or may be managed separately. Some processors may choose to use a combination of these approaches.

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General Requirement

- Current GMP regulations are the standard for proper sanitation conditions and practices.
- Eight key sanitation conditions and practices.
- Mandatory sanitation monitoring with record keeping.
- Mandatory corrections with record keeping.
- Recommended SSOP.

The SCP regulation encourages, but does not require, that each processor develops a Sanitation Standard Operating Procedures (SSOP). The SSOP should describe how the processor will ensure that certain key sanitation conditions and practices will be met. It should also describe how the plant operations will be monitored to ensure that the conditions and practices will be met.

Whether or not a processor chooses to write an SSOP, the key sanitation conditions and practices that are relevant to the plant must be monitored.

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Eight key sanitation conditions and practices:

- Safety of water.
- Condition and cleanliness of food-contact surfaces.
- Prevention of cross-contamination.
- Maintenance of hand-washing, hand-sanitizing and toilet facilities.
- Protection from adulterants.
- Labeling, storage and use of toxic compounds.
- Employee health conditions.
- Exclusion of pests.

The purpose of the monitoring is to ensure that the requirements of the current GMP regulations are met. Monitoring frequencies are not specified but must be sufficient to ensure that the current GMP requirements are met.

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When the conditions and practices contained in the current GMP regulations are not met, they must be corrected in a timely manner. Records must be kept of the monitoring and the corrections. These records are subject to the same requirements as the HACCP records, except plant-verification review.

• *Imported Products 123.12*

It has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. FDA's surveillance system for imports has traditionally consisted of: reviews of customs entry forms for fish and fishery products being offered for entry into the United States, sensory analyses (wharf examinations) and sample collections for laboratory analysis of products awaiting entry, and automatic detention of products with a history of problems. As with traditional processing-plant inspections, this method is a "snapshot" approach that is not preventive.

Under the seafood HACCP regulation, HACCP controls are required for imported fish and fishery products as well as for domestic products. The definition of processor explicitly includes those who process seafood in foreign countries. Additionally, the regulation requires that importers take certain steps to verify that their foreign suppliers meet the requirements of the regulation.

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Importer Verification:

- Import from countries with a memorandum of understanding (MOU) or
- Implement verification procedures.

Importers may meet their obligation in one of two ways. They may import fish and fishery products that are covered by memorandums of understanding between the United States and a foreign country. In this case, they do not need to take any other action to meet the requirements of the regulation.

Otherwise, the importer must have and implement written verification procedures for ensuring that the fish and fishery products offered for import into the United States were processed in accordance with the requirements of the regulation.

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Importer Verification Procedures:

- Product specifications and
- Affirmative steps.

Product specifications should cover those characteristics of the product that would be useful in providing assurance that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act. This section relates to contaminants that may render the food injurious to health and to insanitary processing conditions. It may be appropriate for a specification for frozen tuna steaks to include a maximum limit for histamine of 50 ppm.

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Importer Verification Procedures

Affirmative steps may include any of the following:

- Obtain foreign processor's HACCP and sanitation monitoring records for the lot being entered.
- Obtain continuing or lot-by-lot certificate from competent third party.
- Regularly inspect foreign processor.
- Obtain foreign processor's HACCP plan and written guarantee that regulation is being met.
- Test the product and obtain written guarantee that regulation is being met.
- Perform other verification procedures that provide equivalent level of assurance.

An importer may hire a competent third party to perform verification activities. However, the importer remains responsible for demonstrating to FDA that the requirements have been met.

The importer must keep records in English that document that the affirmative steps have been performed. The records must describe the results of the steps. These records are subject to the records requirements described in section 123.9. Importers that also process fish or fishery products must also meet the HACCP and sanitation requirements of the regulation for their processing operations.

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- *Smoked and Smoke-Flavored Fishery Products 123.15 and 123.16*

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Smoked and Smoke-Flavored Fishery Products

- HACCP plan must include controls for *Clostridium botulinum* toxin formation for the shelf life of the product under normal and moderate abuse conditions.
- Where product is subject to 21 CFR 113 or 114, the HACCP plan need not include such controls.

Smoked fish has been linked to a few cases of botulism. *Clostridium botulinum*, the bacteria that causes botulism, is prevented from growing in properly smoked fish by a combination of barriers, including salt, smoke, nitrite and, in the case of hot-smoked fish, heat. Careful control of these parameters is necessary to ensure the safety of the finished product. Such controls must be included in the HACCP plans of these products, unless the product is preserved by the addition of acid or heat under the controls required by the acidified or low-acid canned food regulations (21 CFR 113 and 114).

It is important to note that if there are other significant hazards, they must be included in the HACCP plan.

- *Raw Molluscan Shellfish 123.20 and 123.28 and Control of Communicable Diseases 1240.60*

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Raw Molluscan Shellfish 123.20

- HACCP plans must include a means for controlling the origin of the raw molluscan shellfish.
- Where processing includes a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern, the HACCP plan need not include controls on sources of origin.

The largest number of reported illnesses from consumption of seafood is caused by raw molluscan shellfish (oysters, clams and mussels). These hazards are primarily introduced before the molluscan shellfish are harvested. The risk of occurrence of these hazards is reduced by ensuring that the molluscan shellfish come from sanitary growing waters. In most cases, the sanitary quality of molluscan-shellfish growing waters is determined by a state or national agency called a shellfish-control authority.

The regulation provides very specific requirements for controlling the source of origin for raw molluscan shellfish. It is important to note, however, that other hazards may also be reasonably likely to occur in these products, and they must be identified in the HACCP plan.

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Raw Molluscan Shellfish 123.28

Processors shall only process molluscan shellfish from:

- Growing waters approved by a shellfish-control authority.
- Federal growing waters not closed by an agency of the federal government.

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Raw Molluscan Shellfish 123.28

Shellstock Receiving

- If source is a harvester, harvester must be in compliance with any license requirement.
- If source is another processor, processor must be certified by a shellfish-control authority.
- Containers of shellstock must be properly tagged.

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Raw Molluscan Shellfish 1240.60

Required information on tag:

- Date and place shellfish were harvested (state and site).
- Type and quantity of shellfish.
- Harvester identification number, name of harvester or name or registration number of harvester's vessel.

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Raw Molluscan Shellfish 123.28

Records for shellstock receiving must document:

- Date of harvest.
- Location of harvest by state and site.
- Quantity and type of shellfish.
- Date of receipt by the processor.
- Name of harvester, name or registration number of the harvester's vessel or harvester's identification number.

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Raw Molluscan Shellfish 123.28

Shucked molluscan shellfish containers must bear a label that contains:

- Name of packer or repacker.
- Address of packer or repacker.
- Certification number of packer or repacker.

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Raw Molluscan Shellfish 123.28

Records for shucked product must document:

- Date of receipt.
- Quantity and type of shellfish.
- Name and certification number of the packer or repacker.