HACCP

SGR 137

Hazard Analysis and Critical Control Point
Training Curriculum

6th Edition – June 2020

Developed by the **National Seafood HACCP Alliance** for Training and Education

National Seafood HACCP Training Program

Seafood HACCP Alliance

The National Seafood HACCP Alliance (SHA) based in the Association of Food & Drug Officials (AFDO) develops and maintains training courses in basic HACCP and sanitation control programs that are recognized by the U.S. Food and Drug Administration as 'companion training programs' to complement its *Fish and Fishery Products Hazards and Controls Guidance*, assisting compliance with Code of Federal Regulations Title 21 Part 123.1o, the seafood HACCP regulation. The SHA/AFDO courses and training materials are available in classroom and internet formats. These courses are used in SHA/AFDO's Train-the-Trainer courses. For the most current information on all courses and training materials, please consult the AFDO website at http://afdo.org/seafoodhaccp.

SHA History

The SHA program began as an idea during the April 1993 National Sea Grant Forum on Seafood Safety and Quality. The board of directors of the Association of Food and Drug Officials of the Southern States (AFDOSS) then passed a resolution to advance a seafood HACCP training program, and the Council of Sea Grant Directors followed with financial support for the first meeting of the National Seafood HACCP Alliance in December 1993.

Since this modest beginning, the SHA program has received continuing support through grants from the U.S. Food and Drug Administration, the U.S. Department of Agriculture National Institute of Food and Agriculture (formerly the Cooperative State Research, Education, and Extension Program) and the National Sea Grant College Program. Although there are many HACCP training programs and consultants, the SHA training program remains distinct in that it is the primary and proven training program recognized by seafood regulatory authorities in the United States. It is the foundation training program for most regulatory agencies monitoring seafood commerce in the United States.

Numerous experts and related programs have been involved in production and progressive revisions of training materials and the SHA/AFDO Training Protocol. The industry training program was initiated in 1994 with a cadre of seafood specialists from various Sea Grant and Cooperative Extension Service programs, and eventually expanded to include academic talent from every state in the nation. These initial efforts were complemented with regulatory talent from every pertinent Federal and State food safety authority in the United States, as well as various international authorities. Commercial expertise from wholesale and retail seafood sectors has also been contributed by representatives of prominent seafood trade associations.

Since the creation of the SHA, seafood committees have involved participation from an ever-growing list of professionals who all voluntarily share their experience and service in an effort to make a difference for the nation's seafood product safety. A complete list of all SHA participants since 1993 is maintained on the AFDO/Seafood HACCP Alliance website, http://www.afdo.org/seafoodhaccp..

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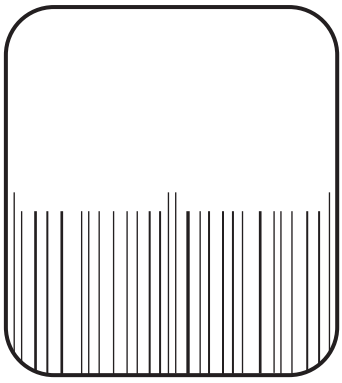
For your convenience, the National Seafood HACCP Alliance has incorporated updates included in the August 2019 revisions to the FDA Fish and Fishery Products Hazards and Controls Guidance 4th edition.



Current SHA Leadership

The content of SHA training program and materials is maintained by a voluntary group of experts. AFDO staff (afdo.org) may be contacted for information regarding the official Training Protocol, course certifications, approved courses and recognized trainers.

A complete list of active participants on the Seafood HACCP Alliance Steering Committee, Executive Steering Committee and working committees is listed on the AFDO website, http://www.afdo.org/seafoodhaccp.

These individuals lead the production of the current 2020 editions of the SHA training manuals, and the accompanying training slides sets and seafood HACCP model plans. These required training materials may be obtained from the Florida Sea Grant College Program at https://www.flseagrant.org/seafood/haccp/.

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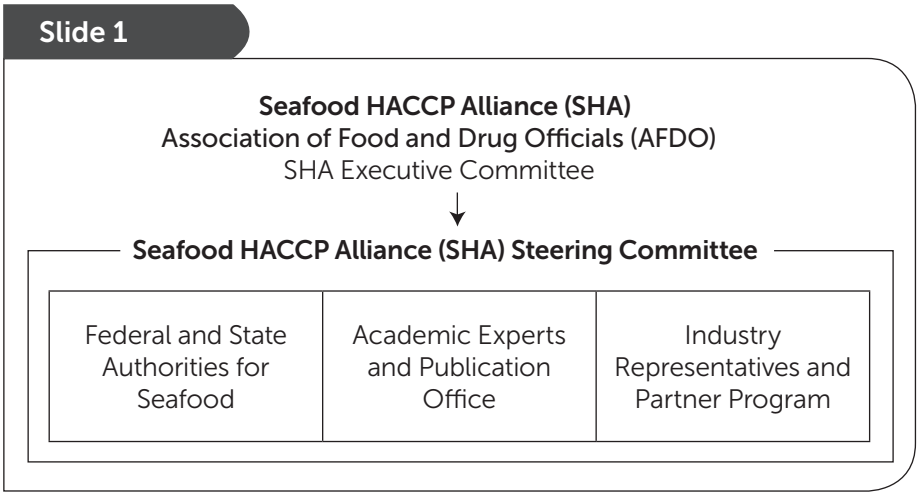
National Seafood HACCP Alliance for Training and Education

The National Seafood HACCP Alliance (SHA) provides a current, convenient and cost-effective education and training program to assist commercial and regulatory compliance with the prevailing requirements for product safety during processing and import of any seafood in the United States. The structure for the SHA program is based on collaboration among federal and state food inspection officials, academic food safety researchers and educators, and various representatives from the seafood and aquaculture industry with commerce in the U.S. (Slide 1). The program is maintained by the Association of Food and Drug Officials (AFDO) through a standing Executive Committee and a voluntary SHA Steering Committee. The SHA Steering Committee directs development of all training materials and courses, and the accompanying SHA Protocol. Any individual, company, agency or nation can participate in the SHA program through communications with AFDO headquarters in York, PA (http://www.afdo.org/seafoodhaccp; email contact afdo@afdo.org).

Slide 1



SHA Training Protocol and Materials

The SHA Training Protocol is intended to maintain a uniform and standard training format based on qualified trainers, current training materials, approved courses, and course audits for both domestic and international audiences (Slide 2). AFDO records and issues all certificates for participants that complete an approved SHA course. Certificates are issued for SHA courses in 'HACCP: Hazard Analysis and Critical Control Point Training' and 'Sanitation Control Procedures for Processing Fish and Fishery Products.' The HACCP course is offered in both a formal classroom setting and through a self-guided Internet

version that participants can complete online. To obtain an AFDO certificate of course completion, the Internet participants must later attend a one-day "Segment Two" session in person.

The SHA training materials include the standard SHA training manuals, model HACCP plans, and the *FDA Fish and Fishery Products Hazards and Controls Guidance*. The HACCP models are for reference as example plans for processing and importation of various seafood products (Slide 3). Some of these materials have been translated for international audiences.

Slide 2

SHA Protocols for Domestic and International Courses:
- Qualified Trainers
- Approved Training Materials and Courses
- Course Audits
- Certificates for Course Completions

SHA Courses
- HACCP: Hazard Analysis and Critical Control Point
- SCP: Sanitation Control Procedures for Processing Fish and Fishery Products
- Train-the-Trainer (TTT) Courses

Web Link

SHA HACCP Model Plans
http://afdo.org
http://flseagrant.org

Slide 3

Seafood HACCP Alliance Training Materials:
- HACCP: *Hazard Analysis and Critical Control Point Training Curriculum*
- *Sanitation Control Procedures for Processing Fish and Fishery Products*
- HACCP Models
- *FDA Fish and Fishery Products Hazards and Controls Guidance*

Seafood HACCP Training Requirements

The SHA program and training materials are designed to meet the HACCP training requirements established under Title 21 Code of Federal Regulations (CFR) Part 123.10 of the U.S. Food and Drug Administration's mandatory seafood HACCP inspection program. The mandates in 21 CFR Part 123.10 require that certain HACCP activities must be completed by a "HACCP-trained individual." The National Seafood HACCP Alliance course is the standardized curriculum by which FDA will evaluate other training courses (Slide 4). A HACCP-trained individual is one who has successfully completed FDA-recognized training in

the application of HACCP to fishery products (at least equivalent to that received under a "standardized curriculum" recognized by FDA) or has acquired the knowledge through job experience. Attending an SHA course is not mandatory, but it does provide assurances that the resulting knowledge will be consistent with regulatory expectations.

Slide 4

National Seafood HACCP Alliance for Training and Education program offers current, standardized courses to assist compliance with U.S. FDA's requirements for "HACCP-trained individuals" consistent with federal regulation 21 CFR Part 123.10

Maintaining Course Integrity

All training agenda are outlined in accordance with the prevailing "HACCP and SCP Training Protocol (see "Seafood HACCP Protocol" under Seafood HACCP Training on the Association of Food and Drug Officials (AFDO) website.)

Basic HACCP Training Course Agenda

(16 Contact Hours with SHA HACCP Training Manual and FDA Hazards Guide)

The standard agenda provides guidelines for time per topic. The standard agenda must be a minimum 16 contact hours. Supervisory Trainers must submit a course agenda with their Domestic or International Course Registration Form. When submitting the agenda with the course application, provide actual proposed times and show that the course is a minimum of 16 contact hours. It is recommended but not required that the course be taught over a 3-day period. The times allotted to each section are to allow for sufficient learning opportunities. However, there is flexibility in the design based on the nature of the audience (i.e. homogeneous audience by species or processing methods or very small class size). Regardless of the format of the course, allow 3-4 contact hours from the 16 hours, for the practical exercise. One useful alternative approach to stimulate participation is to arrange the work sessions following the respective instruction, e.g., work session on hazard analysis to follow the lecture on Determining Critical Control Points, and the work session on developing the HACCP Plan following the lecture on Record-Keeping. If using this format, instructors should indicate these changes in the agenda submitted with the course application. Instructors may also elect to supplement information in Chapter 3 (Seafood Safety Hazards) with additional seafood-specific hazards unique to the audience, product types or region. Instructors should assure they are familiar with course requirements as outlined by the HACCP and SCAP Training Protocol.

Internet "Segment Two" HACCP Course Agenda

(6.5 Contact Hours minimum with the use of FDA Hazards Guide)

The Seafood HACCP Alliance offers an alternative training format that includes an Internet HACCP course (Segment One) followed by a one-day course called Segment Two conducted by a SHA/AFDO qualified Trainer. The two segments of this alternative training format are described below.

Segment One (Internet Course) – The initial Internet based training course is designed to teach students the curriculum presented in the first two days of the SHA/AFDO Basic HACCP Course. Students must register for the Segment One Internet course at http://seafoodhaccp.cornell.edu. The Internet course consists of 12 modules, each of which corresponds to the chapters in the Hazard Analysis and Critical Control Point Training Curriculum. It is recommended that students use the SHA/AFDO Training Manual and the FDA Hazards Guide as tools to assist the learning process. Each student's progress through the Internet course will be tracked by the Username and Password that they create after registering for the course. Upon course completion, an email letter of "Course Completion" for Segment One from Cornell University will be sent to the student. This notification will serve as the student's "ticket" to attend an SHA/AFDO Segment Two training course. All 12 Internet course modules must be completed within 6 months of the processing of the initial Internet course registration.

Segment Two ("Face-to-Face" training course taught by a SHA/AFDO 'qualified' Trainers) – To receive an AFDO "Certificate of Course Completion" equivalent to the one provided upon completion of the traditional classroom course, students who have completed the Segment One Internet course must then complete their training by attending a "face-to-face" (classroom format) training course called Segment Two. The course must be taught by a SHA/AFDO qualified Trainer. Segment Two course schedules are posted at http://www.afdo.org/seafoodhaccp. This Website can also be used to locate a qualified trainer in a specific state or the nation. SHA/AFDO recommends the Segment Two course be completed within six months – and no longer than two years from the date of completion of the Segment One Internet course. The Supervisory Trainer conducting the SHA/AFDO approved course is responsible for making final determinations regarding this deadline mindful of experience and related factors for each participant. Segment Two HACCP training courses must be a minimum of 6.5 contact hours following the approved agenda which includes at least 2 hours for conducting practical exercises with hazard analysis and development of HACCP plans. All students must have access to the FDA's *Fish and Fishery Products Hazards and Control Guidance*.

Sanitation Control Procedures Course Agenda

(6.5 Contact Hours with SHA SCP Training Manual)

The SCP course is intended to explain how to maintain the required sanitation control records that are required to accompany a seafood HACCP plan. The SCP course is not a basic sanitation course, but rather a 'how to' monitor course featuring the 8 key sanitation areas or conditions specified in the FDA Seafood HACCP Regulation. The SCP course references the current good manufacturing practices, GMP 21 CFR 117, including advice regarding required training and training records for employees and addressing 'cross-contact' to prevent potential food allergen problems. The course can vary in length depending on the nature of the audience and intended use. The required contact time is 6.5 hours to assure sufficient instruction for how to maintain required records for the 8 key sanitation conditions. Each sanitation condition is discussed in individual chapters with three basic parts:

- Sanitation monitoring, corrections and records;
- Background information on sanitation; and
- Sanitation Control Guides (examples)

Chapter 1

Introduction to the Alliance Course and HACCP

In Chapter 1 we will describe the objective and format of the Seafood HACCP Alliance training course. We will also review expectations for those who participate in this training followed by background information on the HACCP concept (Slide 1).

Slide 1

In this chapter, you will learn the:
- Objective of the course
- Format of the course
- Expectations of the participants
- Meaning and importance of HACCP

Course Objective

This course provides training for the seafood industry and regulators consistent with regulatory requirements of the December 1995 United States Food and Drug Administration (FDA) Seafood Hazard Analysis and Critical Control Point (HACCP) regulation (see Chapter 12 and Appendix 1). The regulation became effective in December 1997 to ensure the safe processing and importing of seafood products in the United States. This regulation specifies that training is required for persons responsible for developing and modifying the HACCP plan and for reviewing records. This course contains the information necessary for you or other members of your team to meet the HACCP training requirements outlined in the FDA's regulation (Slide 2). Numerous state authorities and nations have adopted various versions of HACCP for seafood safety.

Slide 2

Course Objective
- The FDA HACCP regulation has a training requirement for individuals who develop or modify a HACCP plan or review records
- The Alliance training course can be used to demonstrate that you meet this requirement

Course Format

This seafood HACCP course is divided into three distinct parts (Slide 3):

- HACCP fundamentals using the FDA *Fish and Fishery Products Hazards and Control Guidance* (FDA Hazards Guide),
- Explanation of HACCP and FDA's regulation and guidance materials to help develop a HACCP plan, and
- Class exercises to provide practice and instruction in the development of seafood HACCP plans.

Slide 3

Course Format:
- HACCP fundamentals using the FDA Hazards Guide
- The FDA seafood HACCP regulation and guidance for developing HACCP Plans
- Practical group exercise to develop a model HACCP Plan

The first part of the course describes pre-requisite programs, seafood safety hazards and the preliminary steps that must be completed before applying HACCP principles. The seven principles of HACCP are then described to give a better understanding of the fundamentals on which HACCP is based. You will also learn how to use the FDA Hazards Guide to find the information needed to complete each HACCP principle. The class will progressively develop a HACCP plan for a common fresh fish, mahi-mahi, produced in fillet form by the fictional model "XYZ Seafood Company." This example will help you understand HACCP principles and how to use the FDA Hazards Guide to find the information you will need to apply these principles to a simple seafood processing example.

The second part of the course explains the seafood HACCP regulation and how it is related to each of the seven HACCP principles.

The third part is a practical exercise that demonstrates how to develop a seafood HACCP plan for a specific type of operation or product using the FDA Hazards Guide. During this part of the course, the class will be divided into teams to write HACCP plans for different seafood products.

What is Expected of the Participant

HACCP is an important safety-management system and can be integrated into any operation. However, HACCP can seem complicated and demanding until the basic concepts are understood. Therefore, you are encouraged to ask questions and to contribute first-hand experiences during the discussions (Slide 4).

Slide 4

Participants are encouraged to:
- Ask questions and participate in discussions
- Actively participate in the practical group exercise to develop a HACCP Plan
- Attend all parts of the course

This manual includes exercises that require class participation throughout the training. Keep in mind that the more you contribute to these exercises, the less complicated the HACCP system will seem and the easier it will be to develop and implement a HACCP plan.

To comply with the protocol for this training, your instructor is also required to monitor and assure that you have attended all parts of the course to be eligible for a certificate of course completion from the Association of Food and Drug Officials.

Training Manuals

There are two training manuals that you will use throughout this training course. We will describe each of them and the type of information that they contain (Slide 5).

Seafood HACCP Training Manual (Blue Book)

The first training manual is the Seafood HACCP Alliance Training manual (blue book). This manual contains all of the information that will be covered in this course. This manual is yours. Become familiar with it. Learn where the definitions are, where the forms are that will help you develop a HACCP plan, and where to find other basic information. Make as many notes and marks in the text as needed to assist in creating and understanding a HACCP plan. Use the manual as a reference. Make as many copies of the enclosed forms as necessary, or copy the whole manual to share with others in your company.

FDA Hazards Guide (Gold Book)

The other training manual for this course is the FDA *Fish and Fishery Products Hazards and Controls Guidance*. You will learn how to use this manual to apply each of the seven principles of HACCP.

The Hazards Guide is intended to assist seafood processors in the development of their HACCP Plans. The Hazards Guide contains information that will help processors identify hazards that are associated with their products and help them formulate control strategies. The Hazards Guide is also intended to serve as a tool to be used by federal and state regulatory officials in the evaluation of HACCP Plans for seafood products.

Slide 5

The Seafood HACCP Training Manual (blue book) provides:
- Written content that describes each presentation in the course
- Reference information and forms to help you develop a HACCP Plan

The FDA Hazards Guide provides:
- Guidance for the seafood industry to help them identify hazards for their products and develop effective control strategies
- A tool for regulatory officials to help them evaluate HACCP Plans for seafood products

Key Definitions and Concepts Used in the FDA Regulation and FDA Hazards Guide

There are a number of definitions for HACCP terms and key concepts used in the FDA Seafood HACCP regulation and in the Hazards Guide that seafood processors should understand (Slide 6). We will review each of these definitions as the corresponding HACCP principle is introduced in each Chapter of the Alliance Training manual. We will also introduce key concepts or terms from the FDA Hazards Guide when they are needed to understand hazards or appropriate control strategies for them. A complete set of definitions for HACCP terms and other key concepts can be found in Appendix 4 of this training manual. You can refer to them at any time during or after this course.

Slide 6

Key Definitions and Terms used in the FDA Seafood HACCP regulation and Hazards Guide are provided for reference in Appendix 4

Meaning and Importance of HACCP

HACCP is an acronym that stands for Hazard Analysis and Critical Control Point (Slide 7). It is a systematic approach to the identification, evaluation and control of food-safety hazards. The concepts behind this term are important.

HACCP is a preventive system of food safety hazard controls rather than a reactive one. Food processors can use it as a management tool to ensure safer food products for consumers. The HACCP system is designed to identify

Slide 7

HACCP stands for **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oints

the unique food safety hazards associated with specific types of products or processing operations and then to develop a HACCP Plan to prevent, eliminate or minimize those hazards.

HACCP is not a zero-risk system, but it is designed to minimize the risk of food-safety hazards to acceptable levels (Slide 8). It is a proven approach to help assure food safety. In 1973, FDA required HACCP-type controls for processing low-acid canned foods to protect against *Clostridium botulinum*, the bacteria that can produce the toxin which causes botulism.

Slide 8

A HACCP system is:
- Preventive, not reactive
- A management tool use to protect the food supply
- Designed to minimize the risk of food safety hazards, but is not zero risk

Brief History of HACCP

The HACCP concept was first applied to food production during efforts to supply safe food for the United States space program in the early 1960s. It was decided that existing quality control techniques did not provide adequate assurance against contamination during food production. The end-product testing necessary to provide assurance that the food would be safe would be so extensive that little food would be available for space flights (Slide 9). Currently, HACCP has been adopted by many food processors to assure the safety of their food products.

Slide 9

Origins of HACCP:
- Pioneered in the 1960s
- First used when foods were developed for the space program
- Adopted by many food processors

In 1985 the National Academy of Sciences (NAS) recommended that the HACCP approach be adopted by all regulatory agencies and that it should be mandatory for food processors (Slide 10). This recommendation led to the formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Slide 10

National Academy of Sciences Recommendation:
The HACCP approach should be adopted by all regulatory agencies and it should be mandatory for food processors.

This committee standardized the HACCP principles used by industry and regulatory authorities.

HACCP is endorsed worldwide by many countries and organizations, and although the regulatory approaches may differ from one nation to another, the HACCP concepts are the same.

Seven Principles of HACCP

FDA's Seafood HACCP regulation and other domestic and international HACCP control systems are based on seven basic principles or steps (Slide 11). These principles will be explained in more detail in this course. Likewise, a Glossary of HACCP and regulatory definitions are included in Appendix 4.

Slide 11

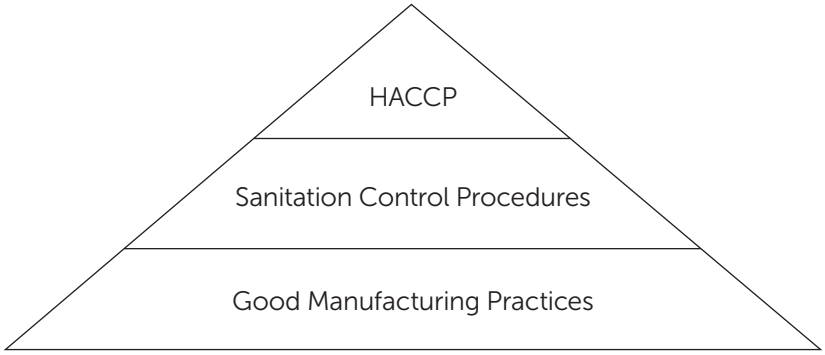
Seven principles of HACCP:
1) Conduct a hazard analysis
2) Determine the critical control points (CCPs) in the process
3) Establish the critical limits
4) Establish monitoring procedures
5) Establish corrective actions
6) Establish verification procedures
7) Establish record-keeping procedures

HACCP Is Part of a Complete Food Safety System

HACCP is a preventive system for ensuring food safety, but it is not a stand-alone system. To be effective, HACCP must be built upon current food safety programs such as Good Manufacturing Practices (GMPs) and Sanitation Control Procedures (SCPs). These programs are known as "prerequisites" that provide a foundation for the HACCP program (Slide 12).

Slide 12

HACCP is not a stand-alone system.
HACCP is built on a foundation of Good Manufacturing Practices.



Chapter 2

Prerequisite Programs and Sanitation Control Procedures

Prerequisite Programs

HACCP is not a stand-alone program, but part of a larger system of control procedures to ensure food safety. For HACCP to function effectively, it needs to be accompanied by what are called "prerequisite programs" (Slide 1).

Slide 1

In this chapter, you will learn:
- The importance of prerequisite programs for HACCP
- Good Manufacturing Practices (GMPs)
- Sanitation Control Procedures (SCPs)
- Examples of SCP monitoring

Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome food. Some of these programs are required by regulations such as Good Manufacturing Practices (GMPs) and Sanitation Control Procedures (SCP) and others are recommended (Slide 2).

Slide 2

Definition:
Prerequisite programs are procedures, including Good Manufacturing Practices (GMPs), that address environmental and operational conditions which provide the foundation for the HACCP system.

Web Link

An Internet training course on the basic requirements of the FDA Good Manufacturing Practices regulation is available at https://instituteforfoodsafety.cornell.edu/gmptraining

There are a number of federal requirements that may also be considered prerequisite programs about which processors must be aware. While this course cannot discuss all prerequisite programs in detail, is it important for seafood processors to know that depending on the product being processed or the nature of your operation, there will be additional federal compliance requirements that apply to the foods being processed.

There are also specific state or local code requirements for food processing establishments in your area that specify where your operation should be located and how it is constructed and maintained. You may also need to obtain specific permits or licenses from state or local authorities. There may be product-specific requirements for nutritional and allergen labeling. If the product is being imported into the United States, in addition to meeting the Seafood HACCP requirements for importers, it is necessary to meet the Prior Notice requirements of the 2002 Bioterrorism Act, known formally as the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

There may be other requirements and recommendations that apply to you depending upon the nature, size and location of your business (Slides 3 and 4). These include:

- Requirements from federal, state local authorities , including:
  - Food Defense and Biosecurity Requirements
  - Food Safety Modernization Act (FSMA) Requirements
  - Labeling Requirements
    - Food Allergen Labeling and Consumer Protection Act (FALCPA)
    - Country of Origin Labeling (COOL)
    - Nutritional Labeling and Education Act (NLEA)
- Recommendations for facility/operating programs, including:
  - Environmental Monitoring
  - Shipping Controls
  - Recall and Traceability Programs
  - Supplier controls
  - Preventive maintenance

Slide 3

Federal, State or Local Requirements

- Food Defense and Biosecurity Requirements
- Food Safety Modernization Act (FSMA) Requirements
- Labeling Requirements
  - Food Allergen Labeling and Consumer Protection Act (FALCPA)
  - Country of Origin Labeling (COOL)
  - Nutritional Labeling and Education Act (NLEA)
- State and Local Licenses and Permits

Slide 4

Recommended programs
- Environmental Monitoring
- Shipping Controls
- Recall and Traceability Programs
- Supplier controls
- Preventive maintenance

The remainder of the chapter will focus on those prerequisite program requirements that support your compliance with the Seafood HACCP Regulation.

Required Prerequisite Programs for Seafood HACCP

In 2011, the U.S. Congress passed a comprehensive bill called the Food Safety Modernization Act (FSMA). As a result of this new law, the U.S. Food and Drug Administration (FDA) issued several new food safety-related regulations, only some of which apply to seafood processors. One new regulation -- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food [PC for Human Food (21 CFR Part 117)] -- has parts that are applicable to seafood processors. This new regulation established additional requirements for employee training, record keeping, and revised existing Current Good Manufacturing Practice regulations.

Based on the existing Seafood HACCP Regulation and the new additions from FSMA, the following are prerequisite programs that a processor is required to have in place in order to support the Seafood HACCP program (Slide 5).

- **Employee training and training records** (21 CFR 117 Subparts A and F)
- **Current Good Manufacturing Practice (GMPs)** (21 CFR 117 Subpart B)
- **Seafood HACCP Regulation-Sanitation Control Procedures** (21 CFR 123.11)

Slide 5

Required Prerequisite Programs for Seafood HACCP
- Employee training and training records
- Current Good Manufacturing Practice (GMPs)
- Seafood HACCP Regulation-Sanitation Control Procedures

Employee Training and Training Records

21 CFR Parts 117 A and F address requirements for food employee qualifications, training and keeping records on training.

Employee Qualifications

Employees who supervise or who manufacture, process, pack or hold food must be **qualified** to perform their assigned duties and are required to have the

Note

Two online course options that may be helpful to processors are:

(1) **Seafood HACCP Alliance (SHA)** offers a 12-module online Seafood HACCP Course that covers **food safety** training requirements. It is available at http://seafoodhaccp.cornell.edu/Intro/index.html.

(2) **Institute for Food Safety at Cornell University** offers an online GMP course that covers **food hygiene, employee health and personal hygiene** at https://instituteforfoodsafety.cornell.edu/gmptraining.

There may be other course options that also satisfy the requirements.

It is important to note that completion of any specific course and training records are not the full measure for compliance. Actual employee performance is the primary measure for compliance.

education, training and/or experience necessary to manufacture, process, pack or hold clean and safe food.

Employee Training

To meet the **training requirements** employees must receive training in the principles of food hygiene and food safety which must include information on the importance of employee health and personal hygiene. The appropriate scope of the training depends on the employee's assigned duties.

Firms may decide whether a single training would be appropriate for all individuals, or separate job-specific trainings would be more appropriate. This may be dependent upon the complexity of the operations and where preventive measures may need to be applied.

The training may be provided by facility personnel, a third-party source, or a combination of both. Training may be provided by any reasonable means, for example, on the job, in a classroom setting, or online (Slide 6).

Slide 6

Training Requirements - Preventive Controls for Human Food (21 CFR 117)

- Employees must be qualified to perform assigned jobs
- Training in food hygiene and food safety
- Supervisors assure compliance
- Training records maintained

There is no frequency interval specified in the regulation for training; however, it is expected that appropriate training occurs prior to employees independently performing their duties. It is also anticipated that refresher training will be provided when needed.

Training Documentation and Record-Keeping Requirements

Facilities are required to keep records that document the training on the principles of food hygiene and food safety for those who supervise or perform manufacturing, processing, packing, or holding activities for food. Processors must maintain records of this training **for 2 years.**

Slide 7 provides two examples of training records. The first documents various training events for an individual employee. The second is a simple sign-in sheet documenting employee attendance.

Slide 7

Example of Training Records

Employee Training Record			
Employee: *Anybody Jones*		**Position/Duty:** Processing belt for shrimp cooker	
COURSES	**LOCATION**	**DATE COMPLETED**	**SIGNED**
Basic Sanitation Course (Seafood HACCP Alliance)	Headquarters	Nov 01, 2015	*Ben Smith*
GMP's 117	Plant Unit 3	Jan 15, 2017	*BS*
SCP Monitoring	Plant Unit 3	Jan 15, 2017	*BS*
Basic Sanitation Review	Headquarters	Feb 01, 2017	*S Otwell*

Group Employee Training Record	
Course: Personnel Hygiene and Food Safety Level 1	**Location:** *Headquarters*
DATE COMPLETED: April 15, 2017	**SIGNED** *Ben Smith, Supv. No. 1*
EMPLOYEES	
Nancy Dolittle – Packing and Labeling	
Anyone Jones – Shrimp cooker belt	
Wei Not – Recv Dock	
Bettie Done – Thawing	

Good Manufacturing Practices (GMPs) (21 CFR 117 Subpart B)

Good Manufacturing Practices (GMPs) is a federal regulation (see Appendix 3) that applies to all food manufacturers and is the basis for determining whether the facility, processing methods, practices and controls used to process food products are suitable to allow for the production of safe and wholesome food and whether the products have been processed under sanitary conditions.

GMPs outline the minimum standards that a food processing facility needs to meet including (but not limited to): personnel, buildings and facilities, equipment, production and process controls, raw materials, and manufacturing operations (Slide 8).

Slide 8

Good manufacturing practices (GMPs) are the basis for determining if process methods produce safe foods and whether products have been processed under sanitary conditions.

GMPs were recently updated. One major change is that prevention of allergen cross-contact is explicitly addressed. "Cross-contact" differs from "cross-contamination". Allergen cross-contact is the unintentional incorporation of undeclared food allergens into food while cross-contamination is the contamination of food with bacterial, chemical or physical hazards (Slide 9).

Note

A complete version of the current GMPs Part 117 is in Appendix 3.

Slide 9

Good Manufacturing Practices (21 CFR Part 117 Subpart B)

- Describes requirements for food processors to ensure safe and sanitary production of foods.
- First released in 1969 (21 CFR Part 110), GMPs for food manufacturing were revised in 1986 and again in 2015 (21 CFR Part 117).
- The updated GMPs include prevention of allergen cross-contact.

HACCP systems must be built upon a firm foundation of compliance with the GMPs. Implementation of effective sanitation procedures is an important part of complying with GMPs. FDA recognized that seafood processors needed to pay stricter attention to certain GMP requirements that pertained to sanitation and incorporated specific sanitation control procedures in the Seafood HACCP regulation (Slide 10).

Note

Appendix 1: FDA's Seafood HACCP Regulation

Slide 10

Seafood HACCP programs must be based on a solid foundation in compliance with the GMPs and SCPs.

Sanitation Control Procedures (SCPs)

The Seafood HACCP Regulation (21 CFR Part 123) contains specific provisions that outline monitoring, corrections and record requirements associated with **Sanitation Control Procedures** (SCPs). The SCPs are explained in 21 CFR Part 123.11.

SCPs are the necessary procedures to meet specified GMPs requirements which, in the absence of control, could impact food safety. When SCPs are in place, HACCP plans can more effectively focus on the hazards associated with the product or process and rather than the processing plant environment or employee practices (Slide 11).

Slide 11

Sanitation control procedures (SCPs) are used by food processing firms to meet requirements in the GMPs.

SCPs are an effective means to control potential food safety hazards that might be associated with the processing environments and employee practices.

By properly implementing SCPs, a processor is able to control potential food safety hazards caused by unsanitary conditions associated with the plant environment and employee practices.

Seafood HACCP Sanitation Control Procedures (21 CFR 123.11)

The provisions associated with Part 123.11 of the Seafood HACCP Regulation include one recommendation and three requirements (Slide 12).

Slide 12

Sanitation Control Procedures
Recommended:
- Written Sanitation Standard Operating Procedures (SSOPs)

Required:
- Monitoring
- Corrections
- Recordkeeping

The regulation recommends that processors create a written **sanitation standard operating procedure (or SSOP)** in order to effectively carry out their **Sanitation Control Procedures (SCP).**

Written SSOPs are recommended, as they would outline the goals, methods and activities that are needed to be performed in order to meet the SCP requirements.

Well-designed, **written** SSOPs that are properly implemented are an effective means to prevent insanitary conditions associated with the processing environment and employee practices that may contribute to food safety hazards. For example (Slide 13), SSOPs can be designed to help control some

Web Link

The training manual for *Sanitation Control Procedures for Processing Fish and Fishery Products* (SGR 119) is available through the University of Florida IFAS Extension Bookstore, http://www.ifasbooks.com (follow the HACCP link)

Slide 13

Examples of Sanitation Control Procedures

Control of bacterial cross contamination hazards
- Maintain product flow
- Location of hand washing stations
- Equipment cleaning and sanitizing

Control of chemical cross contamination and/or allergen cross-contact hazards
- Proper chemical storage
- Proper chemical labeling
- Correct use of chemicals
- Production scheduling to prevent allergen cross-contact.

bacterial hazards by specifying procedures to prevent cross contamination and cross-contact by:

- Maintaining proper product flow and limiting certain employee tasks and movement.
- Locating hand washing and sanitizing stations in the processing area to better facilitate proper hand washing.
- Using proper cleaning and sanitizing procedures for equipment.

Likewise, SSOPs can be used to help control some chemical contamination hazards or cross-contact of allergens by specifying procedures for:

- Storing chemicals in an appropriate place.
- Labeling all chemicals.
- Using chemicals per label directions.
- Scheduling production to prevent allergen cross-contact.

Table 2 on pages 30-36 provides an example of a written SSOP.

The regulation requires that processors **monitor** the conditions and practices in their facility related to eight (8) key areas of sanitation. This monitoring must occur with sufficient frequency to show compliance with current GMP requirements. **The regulation also requires** that processors **correct problems** that are identified during monitoring, and **keep records** of their monitoring results and the corrections that were made.

Eight Key Sanitation Areas

The Sanitation Control Procedures focus on eight key areas of sanitation that have been derived from the GMPs (Slide 14). To understand what each area encompasses and to successfully comply with the Seafood HACCP regulation Part 123.11 requirements, it is highly recommended to review the GMP citations associated with each of the Eight Key Sanitation Areas. Table 1 (see pages 21-22) demonstrates this relationship between the Eight Key Sanitation Areas and Good Manufacturing Practices.

Slide 14

Eight key areas of sanitation:

1) Safety of water
2) Condition and cleanliness of food contact surfaces
3) Prevention of cross contamination
4) Maintenance of hand washing, hand sanitizing and toilet facilities
5) Protection from adulterants
6) Labeling, storage and use of toxic compounds
7) Employee health
8) Exclusion of pests

A general description of each of the eight key areas of sanitation is provided below.

1) Safety of water: Water (and ice) that contacts food or food-contact surfaces shall be of safe and of sanitary quality (Slide 15)

- Source of water and the plumbing system that conveys water to and throughout the building must provide a safe supply. For companies using a municipal water source for processing and making ice, the water treatment authority is responsible for safety of source and conveyance to the building. Documents must include annual water quality tests from the water authority. Companies using private water systems (e.g. wells), are directly responsible for adequate monitoring and documentation of the safety of the water source. Municipalities can provide guidance.
- Protection of water used for food and food manufacturing must prevent contamination from potential cross-connections and backflow. To ensure water is safe, cross-connections must be prevented. There must be no cross connection or backflow potential between the water supply and piping for wastewater or sewage.

Slide 15

1) Safety of water:

- Source and treatment of water that comes in contact with food or food contact surfaces
- Water used in the manufacture of ice
- Cross-connections between potable and non-potable water supplies

2) Condition and cleanliness of food contact surfaces: Food contact surfaces shall be of a proper design and maintained in a clean and sanitary manner to prevent food contamination (Slide 16).

- Food contact surfaces must be designed, fabricated, maintained, and installed so that they are easy to clean and able to withstand the environment in which they are used. Equipment must have smoothly bonded seams and be made of impervious materials that can be easily cleaned and sanitized. Food contact surfaces must also be maintained in suitable condition to prevent cross-contamination and allergen cross-contact. For example, poorly bonded joints, corroded parts, exposed bolts, screw heads, or even pitted surfaces that could trap water or soils should not be used.
- Adequate cleaning and sanitizing procedures and frequencies must be established for all food contact surfaces, including equipment, utensils, food containers, gloves, and outer garments. Suggested frequencies for cleaning and sanitizing include: before use, after processing interruptions, and as necessary. Cleaning is accomplished using detergent and water at a suitable temperature. Sanitizing is accomplished using approved sanitizing agents such as chlorine, quaternary ammonium or iodine-based compounds.

Slide 16

2) Condition and cleanliness of food contact surfaces:
- Design, workmanship, maintenance, and materials used for food contact surfaces
- Routine scheduled cleaning and sanitizing of food contact surfaces including gloves and outer garments

3) Prevention of cross contamination: Employee hygiene, personnel practices and the design of the facility must prevent cross-contamination and allergen cross-contact (Slide 17).

- Employees shall maintain adequate personal cleanliness and conform to adequate hygienic practices to prevent product cross–contamination and allergen cross-contact. Workers must wear clean and appropriate attire and must wash and sanitize their hands at appropriate intervals. Gloves must be used appropriately and are not a substitute for hand washing and sanitizing.
- Employees must understand that their actions can contribute to product contamination. Employees' hands or gloves, along with equipment and utensils must be washed and sanitized (when necessary) after being contaminated. For example, employees working in the raw product area should not work with the finished product without washing and sanitizing their hands, gloves, equipment, or utensils to avoid cross-contamination.
- Plant design must prevent cross-contamination and allergen cross-contact, including contamination of food, food contact surfaces, and packaging material. Operations must be adequately separated where cross-contamination and/or allergen cross-contact is likely to occur. Raw product and unpackaged cooked ready-to-eat product must be separated to avoid contamination. Food contact surfaces must be cleaned and sanitized when

contaminated. Packaging materials must be stored and handled properly so they do not become a source of contamination.

Slide 17

3) Prevention of cross-contamination:
- Employee hygiene practices
- Employee food handling practices
- Plant design and layout
- Physical separation of raw and ready-to-eat products

4) Maintenance of hand washing, hand sanitizing and toilet facilities: Sanitary facilities must be accessible, properly maintained, and adequately supplied. An adequate sewage disposal system must be in place (Slide 18).

- Hand washing and, where appropriate, hand sanitizing facilities should be at each location where good sanitary practice requires their use. Effective hand washing and sanitizing supplies must be available. Water at suitable temperature and sanitary towel service or suitable drying devices must be available and designed to prevent recontamination.
- An adequate sewage disposal system is required. Adequate and readily accessible toilet facilities with self-closing doors to protect food from airborne contamination must be maintained in sanitary condition. All toilet facilities must be adequate, in good repair (e.g. not leaking), and properly supplied with paper towels, soap, etc.

Slide 18

4) Maintenance of hand washing, hand sanitizing, and toilet facilities:
- Maintenance and location of hand washing, hand sanitizing, and toilet facilities
- Maintenance of adequate sewage disposal system

5) Protection from adulterants: Food, food contact surfaces, and food packaging material must be protected from microbiological, chemical and physical contaminants and allergen cross-contact (Slide 19).

- Precautions must be taken to prevent cross-contamination and allergen cross-contact.
- Potential sources could include: water splashing from the floor, condensate from air conditioners, refrigerator condensers, pipes, light fixtures and ceilings, toxic substances (e.g., pesticides, fuel, cleaning compounds, and sanitizing agents), filth, and physical contaminants (e.g., glass, metal fragments, dirt or corrosion from fans and other fixtures), and airborne allergen dust.

Slide 19

5) Protection from adulterants:
- Protect food, food contact surfaces, and food packaging material from contaminants.

6) Labeling, storage and use of toxic compounds: Prevent contamination from toxic compounds. Toxic cleaning compounds, sanitizing agents and pesticides must be properly labeled, used and stored in a manner that protects food, food contact surfaces and packaging material from contamination (Slide 20). Toxic compounds must be stored in a secured area with limited access separated from food processing and areas where food and packaging materials are stored.

Slide 20

6) Labeling, storage and use of toxic compounds

7) Employee health: Food handlers with an apparent illness, wound, or open lesions could be a source of microbiological contamination (Slide 21). Policies must be in place that exclude or restrict employees who exhibit or are diagnosed with symptoms of an illness, wounds or other afflictions that could be a source of microbial contamination of food, food contact surfaces, and food packaging material.

Slide 21

7) Employee health conditions:
- Controls are necessary to ensure that employee health conditions do not cause food contamination.

8) Exclusion of pests: Pests, such as rodents, birds, domestic animals and insects are not allowed in any area of a food processing and/or storage facility (Slide 22). Even if pest control is contracted to an outside company, the processor is responsible to assure there are no pests in the facility.

Slide 22

8) Exclusion of pests:
- Pests must not be present in the food processing facility.

Table 1

Seafood HACCP Regulation Sanitation Requirements (21 CFR 123.11(b)) and their relation to the Good Manufacturing Practice Regulation. (The previous GMPs 21 CFR 110 have been replaced by 21 CFR 117.)

	Part 123.11(b) Monitoring Equipment	21 CFR Part 117 Subpart B – Current Good Manufacturing Practices
1	Safety of Water	**Water Supply** .37(a) Water supply must be derived from adequate source and adequate for operations. **Plumbing** .37(b)(3) Prevention of contamination from plumbing .37(b)(5) Backflow prevention and cross-connections **Processes and Controls** .80(a)(1) Water used for washing, rinsing, or conveying food .80(c)(16) Ice
2	Condition and cleanliness of food contact surfaces	**Sanitation of Food Contact Surfaces** .35(d)(2) Wet processing conditions must be cleaned and sanitized as necessary to preclude allergen cross-contact and cross contamination. **Food contact surfaces, equipment and/or utensils:** .40(a)(1) Designed and made from materials that are adequately cleanable and maintained to preclude cross-contact and cross contamination. .40(a)(2) Designed, constructed and used to avoid adulteration of food from all contaminants. .40(a)(3) Installed to facilitate cleaning and maintenance .40(a)(4) Corrosion resistant .40(a)(5) Made of nontoxic materials and able to withstand environment of use, action of food, and cleaning conditions .40(a)(6) Maintained to protect from cross-contact and cross contamination. .40 (b) Smoothly bonded seams **Processes and Controls** .80(c)(1) Equipment taken apart for thorough cleaning when necessary
3	Prevention of cross-contamination	**Personnel** .10(b) Employee cleanliness .10(b)(1) Outer garments .10(b)(2) Personal cleanliness .10(b)(3) Handwashing and sanitizing .10(b)(4) Unsecured jewelry and other objects that cannot be sanitized .10(b)(7) Clothing and personal belonging storage .10(b)(8) Eating, drinking, gum, tobacco use .10(b)(9) Other precautions to preclude cross-contact and cross contamination **Plant Construction and Design** .20(b) Space sufficient for sanitary operations and food safety including prevention of allergen cross-contact .35(f) Storage & handling of cleaned portable equipment & utensils
4	Maintenance of hand washing, hand sanitizing, and toilet facilities	**Plumbing** .37(b)(2) Plumbing properly convey sewage and liquid waste .37(b)(3) Plumbing must not constitute a source of contamination .37(b)(5) Plumbing must protect against backflow or cross connections with waste water systems .37(c) **Sewage disposal** .37(d) **Toilet facilities** .37(e) **Hand-washing facilities**

Table 1 (cont.)

	Part 123.11(b) Monitoring Equipment	21 CFR Part 117 Subpart B – Current Good Manufacturing Practices
5	Protection from adulterants	**Personnel Cleanliness** .10(b)(5) Maintaining gloves in clean and sanitary condition **Plant Construction and Design** .20(b)(2) Adequate space, design, separation, and practices to reduce potential for allergen cross-contact and cross contamination. .20(b)(4) Drip & condensate: adequate space in aisles/work spaces to prevent contamination by clothing or personal contact .20(b)(5) Shatter resistant glass bulbs, fixtures, etc. in areas over exposed food .20(b)(6) Adequate ventilation to minimize **allergen** cross-contact or contamination of food, food packaging, or contact surfaces **Sanitation of Food Contact Surfaces** .35(d)(3) Storage, use, and disposal of single use articles to protect against **allergen** cross-contact **Equipment and Utensils** .40 (a)(1) Maintained to protect against allergen cross-contact .40(a)(6) Protect from allergen cross-contact .40(g) Compressed air or other gases introduced into food or used in cleaning **Processes and Controls – Prevention of Allergen Cross-Contact and Cross Contamination** .80(a)(4) Precautions to prevent **allergen** cross-contact and contamination from any source .80(b)(5) Raw materials & ingredients protected against **allergen** cross-contact and against contamination .80(c)(2) Conditions and controls to minimize **allergen** cross-contact or contamination .80(c)(5) Work-in-process and rework to protect against **allergen** cross-contact and contamination .80(c)(6) Finished food protection .80(c)(7) Equipment, containers, and utensils constructed, handled and maintained to protect against **allergen** cross-contact and cross contamination .80(c)(12) Batters, breading, sauces, similar preparations – **allergen** cross-contact .80(c)(13) Filling, assembling, packaging, etc.- cross contamination, **allergen** cross-contact
6	Proper labeling, storage and use of toxic compounds	.35(b) (2) Identification and storage of toxic chemicals. .35(c) Use of pesticides
7	Control of employee health conditions	.10(a) Disease control
8	Exclusion of pests	.35(c) Pest control

Meeting the Sanitation Requirements of the Seafood HACCP Regulation

This section will cover how processors can meet the three requirements outlined in **Part 123.11-Sanitation Control Procedures** for **(1) sanitation monitoring, (2) sanitation corrections** and **(3) sanitation controls records.**

Sanitation Monitoring Requirements [123.11 (b)]

Processors are required to monitor and document conformance with specified GMP provisions that are applicable to their plant, the food being processed and organized into the focused eight key areas of sanitation previously discussed (Slide 14). FDA requires that these eight key areas of sanitation be monitored at a frequency sufficient to ensure conformance. In addition to simply monitoring the results be must be recorded and corrections made for any deficiencies.

The frequency or time for monitoring will vary according to various types of products and the schedule of operations. For example, in certain processing plants using municipal water, the safety of the processing water may be checked annually. However, plants using private water sources such as well water will likely require more frequent monitoring checks. Examples of monitoring frequencies are illustrated in Slide 23.

Sanitation Corrections Requirements [123.11 (b)]

Processors are required to correct in a timely manner those conditions and practices that are not met.

For example, if during a pre-operational check of the plant the processor monitored the conditions of food contact surfaces and determined that a processing line was not adequately cleaned during the clean-up shift, then the processor would be obligated to make a sanitation correction and could do so by ensuring that the equipment was adequately cleaned and sanitized prior to use. See Slide 23 for examples of corrections.

Sanitation Control Records Requirements [123.11 (c)]

Processors are required to maintain sanitation control records that document sanitation monitoring and corrections. As with other records required by the Seafood HACCP Regulation, the SCP monitoring forms or records are subject to recordkeeping requirements outlined in the FDA's seafood HACCP regulation and must include the name and location of the processor, the date and time the monitoring was performed, and corrections made.

Slide 23

Examples of monitoring frequency and corrections

Sanitation Condition/Practice	Frequency of Monitoring	Corrections
Safety of water	Municipal source: Annually Private well: Semi-annually Cross connections: Semi-annually (unless changes are made) for hard plumbing between potable and non-potable lines Cross connections: daily, if hose bibs not protected	Example: If report of water shows high coliform counts, stop processing. Resample water and/or ice to determine required corrections before restarting.
Condition and cleanliness of food contact surfaces	Condition of processing equipment: Monthly or more often if equipment is repaired or replaced to assure it meets the construction standards. Cleaning and sanitizing of equipment, utensils, gloves, and outer garments that come in contact with food: Daily, every time the equipment is cleaned and sanitized. Raw seafood, once a day at start. Ready-To-Eat (RTE) seafoods, start and every 4 hours Record sanitizer concentrations.	Example: If sanitizer concentration is too low, stop. Make new sanitizing agent and clean and sanitize again.
Prevention of cross contamination	Plant design: Monthly or more often if modifications are made to the facility. Employee practices: Daily, at start of production and at least every four hours during production. More often if necessary to ensure that employees hands, gloves, equipment and utensils are washed and sanitized (as necessary) after being contaminated. Separation of raw and cooked products performed daily. Coolers and processing area every four hours during operations and at the end of processing to ensure that unpackaged cooked product is separated from raw product.	Example: If raw product touches or otherwise contaminates cooked product, the cooked product will not be distributed and source of problem will be corrected.

Slide 23 (cont.)

Sanitation Condition/Practice	Frequency of Monitoring	Corrections
Maintenance of hand washing, hand sanitizing and toilet facilities	Hand washing and hand sanitizing facilities: Daily, during pre-op inspection to make sure soap, warm water and paper towels are available and toilet facilities are in good repair. The concentration of hand sanitizing solutions should be monitored at pre-op and every four hours during processing for RTE products.	Example: If toilet seal is leaking, it must be fixed.
Protection from adulterants	Protection from adulterants: Daily at start-up and every four hours to make sure food is protected from contaminants like condensate, floor splash, and glass.	Example: Condensation falling from the ceiling, pipes and cooling coils above food handling areas can drip onto food, packaging materials or food contact surfaces. Affected product must be segregated and evaluated, fix insulation of pipes and increase air circulation in the room.
Labeling, storage and proper use of toxic compounds	Labeling, storage and proper use of toxic compounds: Daily, during pre-op inspection to make sure toxic compounds are properly labeled and stored.	Example: If a bottle is unlabeled, remove the bottle from processing area, identify its content and label appropriately or destroy.
Employee health conditions	Employee health conditions (illness, wounds, etc.): Daily, before production starts.	Example: Employee who has an infected wound in the hand could be assigned to an area away from food processing.
Exclusion of pests	Exclusion of pests: Monthly for outside monitoring. Daily monitoring, during pre-op inspection for processing and storage areas. Grounds around a plant may require monthly checks to discourage attraction of pests: checking the inside of the processing facility for pest activity would be daily.	If rodent excrement found, remove and clean area before start. If daily problem, call pest control company and look for source of entry.

Required elements of SCP monitoring records are listed in Slide 24. Examples of typical SCP monitoring forms are provided in Forms 1-3 (see pages 37-40). Form 1 includes a daily monitoring frequency for both raw and ready-to-eat food. Form 2 illustrates less frequent or periodic monitoring for conditions or situations that are not expected to be frequent problems. Form 3 is an example for a process operation such as a warehouse that has only certain key sanitary concerns.

Slide 24

Required Elements of SCP Monitoring Records
- Name and address of the firm
- Date and time of the recorded activity
- Include all of the eight key sanitary concerns pertinent to the operation
- Monitoring procedure and appropriate frequency
- Monitoring results
- Corrections taken
- Signature or initials of person conducting the monitoring

Examples of Conditions when Sanitation Areas may not be Applicable to a Processor

The regulation indicates that it is possible that certain of these sanitation areas may not always be applicable or relevant to all types of processing facilities. For example, a processor such as a warehouse that receives, stores and ships pallets of frozen fish blocks (a box-in, box-out operation) may not need to address Area 2 of the Eight Key Sanitation Areas -- **condition and cleanliness of food contact surfaces** -- as the processor, in this example, does not have food contact surfaces. This is important to note that monitoring would not be required for those key areas that are not relevant. The eight key areas were designed to include those aspects of the GMPs that are most likely to have an impact on food safety.

The follow are additional examples of questions that can be asked to determine if the Eight Key Sanitation Areas and their related GMP provisions would or would not apply for a particular processing operation (Slide 25). For these examples the facility processes only chilled Atlantic Salmon and Pacific Cod fish fillets.

Slide 25

A facility processes only chilled Atlantic Salmon and Pacific Cod fillets.
- Does SCP concerning safety of water apply? How?
- Does SCP concerning protection from adulterants apply? How?

Example 1: Key Sanitation Area 1: Safety of Water.

(1) Does this area apply to a processor of Atlantic Salmon and Pacific Cod fillets?

Answer: Yes. A processor processing salmon fillets will use water in the facility for a wide array of processing and sanitation activities. This provision applies.

(2) How could the processor monitor the safety of the water supply and how often (frequency) should this be monitored to satisfy the SCP monitoring requirements of the Seafood HACCP Regulation?

Answer: Because this firm's water is supplied by a municipal water regulatory authority, this provision can be satisfied by **obtaining the water quality information** (how) **annually** (frequency) from the water authority, often provided in the invoice for water fees.

Example 2: Key Sanitation Area 5: Protection from Adulteration and the provisions that pertain to equipment and utensils.

(1) Does this area apply to this processor of Atlantic Salmon and Pacific Cod fillets?

Answer: Yes and no. The sanitation controls apply to the prevention of cross-contamination and allergen cross-contact. As a food processor, the provisions associated with cross-contamination will apply. However, because this facility only processes Atlantic Salmon and Pacific Cod fish fillets, allergen cross-contact would not apply.

FDA currently does not expect seafood processors to implement allergen cross-contact controls when processing multiple finfish species within a facility nor does the agency expect the implementation of allergen cross-contact controls when processing multiple crustacean species within a facility. FDA does expect controls for cross-contact to be in place between finfish and crustaceans within a facility.

(2) How could the processor monitor the applicable provision (cross-contamination) and how often should this be monitored to satisfy the SCP monitoring requirements of the Seafood HACCP Regulation?

Answer: Because equipment and utensils are used each day processing occurs, the processor would need to establish a frequency interval at least **once per day** or more frequently as needed.

Summary

Section 123.11 of the Seafood HACCP Regulation addresses Sanitation Control Procedures. In this section, there is one recommendation, three requirements. It is **recommended** that processors create a written SSOP that describes how sanitation procedures will be performed. It is **required** that processors (1) monitor the facility sanitation conditions and provisions related to eight key sanitation areas, (2) correct deficiencies noted during monitoring and (3) maintain sanitation control records which document sanitation monitoring and corrections. Finally, sanitation monitoring, corrections and sanitation controls recordkeeping may be performed as part of a firm's HACCP Plan controls, or separately (Slide 26).

Slide 26

Sanitation in the Seafood HACCP Regulations:
- SCPs are required and written SSOPs are recommended,
- Monitoring for the eight key areas of sanitation is required,
- Recording monitoring results is required,
- Making corrections and documenting them is required.

HACCP versus SCPs

The SCP provisions of the regulation (Part 123.11) provide flexibility regarding how a processor will meet the monitoring, corrections and record-keeping requirements. Processors may create sanitation controls as part of an expanded HACCP plan, or can create sanitation controls as a cross-cutting system that establishes the prerequisite foundation for species/finished product and process-focused HACCP Plans.

This course recommends that processors document control of sanitation hazards separately from the control of species and process-related hazards controlled by their HACCP Plans.

Sanitation controls are not typically included in the HACCP plan. Sanitation controls address the overall processing plant environment and employee practices. If sanitation controls are established as a prerequisite program, HACCP controls can then focus on the control of species related and process-related hazards for a given finished product.

For example, hand washing is an overarching employee practice and not specifically limited to a given product or processing step. Likewise, routine cleaning of food contact surfaces is not specifically related to a single product or a particular processing step. Examples of hazards that are controlled by a HACCP plan and those addressed with Sanitation Control Procedure are shown in Slide 27.

Slide 27

Hazard	Control	Type of Control	Control Program
Histamine	Time and temperature controls for fish	Product specific	HACCP
Pathogen survival	Time and temperature controls for smoking fish	Processing step	HACCP
Contamination with pathogens	Wash hands before touching product	Employee	Sanitation or SCP
Contamination with pathogens	Limit employee movement between raw and cooked areas	Employee	Sanitation or SCP
Contamination with pathogens	Clean and sanitize food contact surfaces	Plant environment	Sanitation or SCP
Chemical contamination	Use only food-grade grease	Plant environment	Sanitation or SCP

Example of Written Sanitation Standard Operating Procedures and Records (SSOPs)

It is recommended that companies create and implement written Sanitation Standard Operating Procedures (SSOP) to facilitate meeting the Sanitation Control Procedures (SCP) requirements. A SSOP is a set of procedures a firm will follow that addresses the environment conditions of the facility.

Table 2

The following is an example of a written SSOP for a fictitious company producing raw and cooked RTE seafood products:

Table 2. Model Sanitation Standard Operating Procedure

1) Safety of water (FDA Key Sanitation Condition No. 1)

Controls and Monitoring:

a) All water used in the plant is from a reliable municipal water system. Municipal water bills indicate that the water source is safe. **Monitoring Frequency: Annually**.
b) The water system in the plant was designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. Copies of building inspection reports indicate that the plumbing system is properly constructed. **Monitoring Frequency: When plumbing is installed or modified.**
c) All water faucets and fixtures inside and outside the plant have antisiphoning controls. Water faucets and fixtures are inspected for the presence of antisiphoning controls. **Monitoring Frequency: Daily before processing**.

Corrections:

a) In the event of municipal water treatment failure, the plant will stop production, determine when the failure occurred, and hold products produced during the failure until product safety can be assured. Production will resume only when water meets state and federal water quality standards.
b) Corrections will be made to the plumbing system, if necessary, to correct problems. Production will resume only when water meets state and federal water quality standards.
c) Water faucets and fixtures without antisiphoning controls will not be used until antisiphoning controls have been implemented.

Records:

a) Municipal water bill and monthly sanitation control record.
b) Building plumbing inspection report and periodic sanitation record.
c) Daily Sanitation Control Record.

2) Condition and cleanliness of food contact surfaces (FDA Key Sanitation Condition No. 2)

Controls and Monitoring:

a) Food contact surfaces are readily cleanable (do not have cracks, cavities, crevices, overlapping joints, mineral scale, etc. that are not possible to adequately clean and sanitize). The sanitation supervisor inspects food contact surfaces to determine if they are readily cleanable. **Monitoring Frequency: Daily**.

Table 2 (cont.)

b) Food contact surfaces are cleaned and sanitized:

1) Before operations begin, food contact surfaces are rinsed with cold water and sanitized with a 100 ppm sodium hypochlorite sanitizer. The sanitation supervisor inspects food contact surfaces to determine if they are clean and have been wetted with sanitizer. **Monitoring Frequency: Daily before operations begin**.
2) During breaks (every 4 hours), major solids are physically removed from floors, equipment, and food contact surfaces. All surfaces are rinsed with cold water. Food contact surfaces are scrubbed, using brushes with a chlorinated alkaline detergent in warm (≥120°F) water. All other surfaces and floors are rinsed with cold water. Food contact surfaces are sanitized with a 100-150 ppm chlorine as sodium hypochlorite sanitizer solution. Floors are sanitized with a 400-600 ppm quaternary ammonium chloride sanitizer. Utensils are cleaned in a deep sink with a warm chlorinated alkaline detergent, rinsed in warm water (≥120°F), and dipped in a 100 ppm chlorine as sodium hypochlorite sanitizer prior to use. The sanitation supervisor checks sanitizers before use and inspects food contact surfaces to determine if they are clean and have been sanitized. **Monitoring Frequency: At the 4- and 8-hour breaks**.
3) When changing over from a finfish to a crustacean, food contact surfaces must be cleaned to prevent allergen cross-contact. **Monitoring Frequency: Upon changeover.**
4) At the end of daily operations, major solids are physically removed from floors, equipment, and food contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. Food contact surfaces are scrubbed using brushes with a chlorinated alkaline detergent in warm (≥120°F) water. Floors and walls (splash zone) are washed with warm chlorinated alkaline detergent, using push brooms on floors. All surfaces are thoroughly rinsed with clear water before applying sanitizer. Food contact surfaces are sprayed with 100-150 ppm chlorine as sodium hypochlorite sanitizer solution. Floors and walls are sprayed with a 400-600 ppm quaternary ammonium chloride sanitizer solution. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner in warm (≥120°F) water, dipped in a 100-150 ppm chlorine as sodium hypochlorite sanitizer and air dried. The sanitation supervisor inspects food contact surfaces to determine if they are clean and have been sanitized. **Monitoring Frequency: Daily at the end of operations**.

c) Workers wear clean gloves and outer garments.

1) Workers working with raw and cooked product wear clean gloves, clean outer garments, and waterproof aprons. Waterproof aprons are cleaned and sanitized twice each day, at the midday break and at the end of the shift.
2) Administrative personnel wear smocks when in processing areas. Smocks are laundered in-house as needed.
3) Maintenance workers wear gray uniforms. Uniforms are laundered in house as needed.
4) Production supervisors monitor the use of gloves and the cleanliness of workers' outer garments. **Monitoring Frequency: Daily before operations and after each break**.

Table 2 (cont.)

Corrections:

a) Food contact surfaces that are not readily cleanable are repaired or replaced.
b) Adjust sanitizer concentration. Food contact surfaces that are not clean are cleaned and sanitized.
c) Gloves that become a potential source of contamination are cleaned and sanitized or replaced. Outer garments that become a potential source of contamination are cleaned and sanitized or replaced.

Records:

a-c) Daily Sanitation Control Record

3) Prevention of cross contamination (FDA Key Sanitation Condition No. 3)

Controls and Monitoring:

a) Production supervisors have received basic food sanitation training, including prevention of allergen cross-contact. Plant manager schedules basic food sanitation courses for new production supervisors. **Monitoring Frequency: When production supervisors are hired**.
b) Employee practices do not result in food contamination or allergen cross-contact (hair restraints, glove use, hand washing, personal belongings storage, eating and drinking, boot sanitizing).

1) Workers wear hairnets, headbands, caps, beard covers, or other effective hair restraints and do not wear jewelry or other objects that might fall into the product, equipment, or containers.
2) Workers wear disposable gloves and replace them as needed.
3) Workers wash their hands and gloves thoroughly and sanitize them before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated.
4) Clothing and personal belongings are not stored in production areas.
5) Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas.
6) Workers wear color-coded aprons (blue in raw product areas and white in cooked product areas) and are not allowed to enter or pass through other processing areas.
7) Workers sanitize their boots in footbaths containing 400 ppm quaternary ammonium chloride sanitizer solution before entering processing areas.
8) Production supervisors monitor employee practices. **Monitoring Frequency: Daily before operations and every 4 hours during production**.

c) Boot sanitizing solutions are checked every 4 hours during production. Sanitation supervisor checks boot sanitizing solutions. **Monitoring Frequency: Daily before operations and every 4 hours during production**.
d) Plant grounds are in a condition that protects against contamination of food. Sanitation supervisor inspects plant grounds. **Monitoring Frequency: Daily before operations**.
e) Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste. **Monitoring Frequency: Every 4 hours**.

Table 2 (cont.)

f) Floors are sloped to facilitate drainage. Processing area floors are inspected for adequate drainage. **Monitoring Frequency: Daily before operations**.
g) Plant buildings are maintained in good repair. Raw-product processing and cooked-product processing areas are separated. Coolers, including the evaporators, are cleaned annually, or more often if needed. Non-food contact surfaces in processing and packaging areas are cleaned daily at the end of the shift. Raw and cooked products are physically separated in coolers. Allergenic ingredients are properly labeled and segregated. Packaging materials are protected from contamination during storage. Sanitation supervisor inspects plant. **Monitoring Frequency: Daily before operations**.
h) Cleaning and sanitizing equipment is color-coded for specific plant areas: blue for raw-product processing areas, white for cooked-product processing areas, and yellow for toilet facilities and general plant cleaning. Sanitation supervisor observes that proper equipment is used. **Monitoring Frequency: At each cleanup period**.
i) Production is scheduled to prevent allergen cross-contact. **Monitoring Frequency: Before operations, per production schedule.**
j) Allergenic ingredients are clearly labeled during storage and production. **Monitoring Frequency: Prior to use and every 4 hours**.

Corrections:

a) New production supervisors receive basic sanitation instruction.
b) Workers correct deficiencies in hair restraint use, jewelry use, glove use, hand washing, personal belonging storage, eating and drinking in processing areas, and boot sanitizing before working with raw or cooked products.
c) Boot sanitizing solution is changed.
d) Sanitation supervisor initiates correction of potentially contaminating condition.
e) Waste is removed.
f) Floors with standing water will have the drains unplugged, or, if necessary, consultations will be held with plumbing or general contractors and corrections will be made to correct floor drainage problems.
g) Sanitation supervisor initiates correction of potentially contaminating condition, including assessment of product quality.
h) Sanitation equipment that is being used in the wrong plant area is cleaned and sanitized and exchanged for correct equipment. Sanitation supervisor initiates correction of potentially contaminating condition.
i) Adjust order of production to have products with allergens produced last.
j) Improperly labeled ingredients removed from production area until correctly labeled.

Records:

a) Periodic Sanitation Control Record or training record.
b-j) Daily Sanitation Control Record.

Table 2 (cont.)

4) Maintenance of hand washing, hand sanitizing and toilet facilities (FDA Key Sanitation Condition No. 4)

Controls and Monitoring:

a) Toilet facilities are provided near the workers' dressing room, physically separated from processing areas. Toilet facilities have self-closing doors, are maintained in good repair, and are cleaned and sanitized daily at the end of operations. Toilet facilities are supplied with toilet paper and other supplies as needed. Sanitation supervisor inspects the toilet facilities and hand washing facilities. **Monitoring Frequency: Daily before operations and every 4 hours during operations**.
b) Handwashing/sanitizing facilities are provided in raw and cooked processing areas and in the toilet facility. Hand washing facilities have: hot and cold running water with foot-activated valves; liquid hand soap; hand sanitizer solutions that are changed every 4 hours during production; sanitary towel service; signs directing workers to wash their hands and gloves thoroughly. Sanitation supervisor inspects the hand washing facilities and checks hand sanitizer strength. **Monitoring Frequency: Daily before operations and every 4 hours during operations**. Note: handwashing procedures are covered under FDA key sanitation condition No. 3, prevention of cross contamination.

Corrections:

a) Sanitation supervisor initiates repairs of toilet or hand washing facilities as needed.
b) Sanitation supervisor restocks facilities or adjusts sanitizers.

Records:

a-b) Daily Sanitation Control Record.

5) Protection from adulterants (FDA Key Sanitation Condition No. 5)

Controls and Monitoring:

a) Cleaning compounds, sanitizers, and lubricants used in processing and packaging areas are approved for use in food plants. Receiving manager checks invoices at receiving before food-grade chemicals are stored. **Monitoring Frequency: When cleaning compounds, sanitizers, and lubricants are received**.
b) Food-grade and non-food-grade chemicals and lubricants are stored separately outside processing and packaging areas. Sanitation supervisor inspects chemical storage areas. **Monitoring Frequency: Daily before operations**.
c) Food, food contact surfaces, and food packaging materials are protected from adulteration from biological, chemical and physical contaminants and allergen cross-contact. Safety-type light fixtures are used in processing and packaging areas. Sanitation supervisor inspects processing and packaging areas. **Monitoring Frequency: Daily before operations and every 4 hours**.
d) Equipment is in good repair with no loose or missing metal parts. Sanitation supervisor inspects processing and packaging equipment. **Monitoring Frequency: Daily before operations**.
e) Drip or condensate does not contaminate food or packaging materials. **Monitoring Frequency: Daily before operations and at 4- and 8-hour breaks**.

Table 2 (cont.)

Corrections:

a) Unapproved chemicals are returned or used in non-processing areas.
b) Improperly stored chemicals are moved to the correct storage area.
c) Evaluate the safety of the product and determine disposition of the contaminated ingredients/product.
d) Repairs are made as needed to defective equipment.
e) Sanitation supervisor corrects any condensation problems.

Records:

a) Periodic Sanitation Control Record.
b-e) Daily Sanitation Control Record.

6) Labeling, storage and use of toxic compounds (FDA Key Sanitation Condition No. 6)

Controls and Monitoring:

a) All toxic compounds used in the plant are labeled with the manufacturer's name, use instructions, and the appropriate EPA approval, or have documentation with the necessary information. Receiving manager verifies that this information is present before toxic compounds are stored. **Monitoring Frequency: When toxic compounds are received**.
b) Cleaning compounds, sanitizing agents, lubricants, pesticide chemicals, and other toxic compounds are properly labeled and stored in a closed and locked cage in dry storage outside processing and packaging areas and separately from food-grade chemical, food-grade lubricant, and packaging material storage. Only authorized personnel have access to the cage. Sanitation supervisor checks cage for cleanliness and container leakage. **Monitoring Frequency: Daily before operations**.
c) All manufacturers' instructions and recommendations are followed. Only authorized personnel fill small working containers, such as containers of hand sanitizing compounds. These containers are properly marked with the common name of the chemical and are not stored in any way that may cause the chemical to fall or drip onto food or food-packaging materials. Sanitation supervisor verifies proper procedures and labeling. **Monitoring Frequency: Daily before operations**.

Corrections:

a) Toxic compounds without proper information are placed on hold until information is obtained. Toxic compounds without documentation are returned to the supplier.
b) Improperly stored chemicals are moved to the correct storage area. Leaking containers are resealed or replaced as necessary. Storage cage will be cleaned by the next working day.
c) Misuse of toxic compounds results in disciplinary action or retraining. Potentially contaminated food is discarded or destroyed. Improper labeling of working containers is corrected.

Records:

a) Periodic Sanitation Control Record.
b-c) Daily Sanitation Control Record.

Table 2 (cont.)

7) Employee health (FDA Key Sanitation Condition No. 7)

Controls and Monitoring:

a) Workers report to their immediate supervisor any health condition that might result in food contamination. Supervisors report suspected health problems to the plant manager. The plant manager decides if a potential food contamination situation exists. **Monitoring Frequency: Daily before operations**.
b) Supervisors check for infected lesions that might contaminate food. **Monitoring Frequency: Daily before operations**.

Corrections:

a) Workers who represent a potential risk are sent home or reassigned to non-food contact jobs.
b) Cover lesion with impermeable bandage, reassign, or send worker home.

Records:

a-b) Daily Sanitation Control Record.

8) Exclusion of pests (FDA Key Sanitation Condition No. 8)

Controls and Monitoring:

a) A pest management firm treats the outside of the building. They also inspect the interior of the building and treat as necessary with appropriate chemicals. **Monitoring Frequency: Every other month**.
b) Plant grounds and interior areas are kept free of litter, waste, and other conditions that might attract pests. Outer plant doors are kept closed, processing areas are screened with plastic curtains, and electric bug-killing devices are located outside entrances to processing areas. No pets are allowed in the plant. Supervisors report any pest problems to the plant manager. The sanitation supervisor inspects for the presence of pests. **Monitoring Frequency: Daily before operations**.

Corrections:

a) Conditions that may cause pest problems are corrected.
b) The pest management firm is notified of any pest problem and treats the problem. Pest treatments are more frequent if problems are identified.

Records:

a) Periodic Sanitation Control Record.
b) Daily Sanitation Control Record.

Form 1

Daily Sanitation Control Record with all 8 Key Sanitation Areas

Daily Sanitation Control Record						
Report Date:			**Firm Name:**			
Line 1: Raw seafood (not ready-to-eat) **Line 2: Ready-to-eat**			**Firm Address:**			
Sanitation Area and Goal	**Pre-Op Time**	**Start Time**	**4 Hour Time**	**8 Hour Time**	**Post-Op Time**	**Comments and Corrections**
1) Safety of water (See Monthly Sanitation Control Record) • Back Siphonage – Hose (S/U)*						
2) Condition and cleanliness of food contact surfaces (See Monthly Sanitation Control Record) • Equipment cleaned and sanitized						
Line 1: (S/U)						
Line 2: (S/U)						
• Sanitizer Strength Sanitizer Type _____ Strength _____ ppm _____						
Line 1: (ppm)						
Line 2: (ppm)						
• Allergen cross-contact controls performed during each production changeover (S/U)						
• Gloves and aprons clean and in good repair						
Line 1: (S/U)						
Line 2: (S/U)						
*S = Satisfactory / U = Unsatisfactory						

Form 1 (cont.)

Sanitation Area and Goal	Pre-Op Time	Start Time	4 Hour Time	8 Hour Time	Post-Op Time	Comments and Corrections
3) Prevention of cross-contamination (See Monthly Sanitation Control Record)						
• Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)						
• Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)						
• Unpackaged cooked products separated from raw products (S/U)						
• Allergenic ingredients are clearly labeled during storage and production (S/U)						
• Production is scheduled to prevent allergen cross-contact						
4) Maintenance of hand washing, hand sanitizing, and toilet facilities						
• Hand washing and hand sanitizing stations adequate						
Line 1: (S/U)						
Line 2: (S/U)						
• Hand sanitizing station Sanitizer Type _____						
Strength _____ ppm _____						
Line 2: (ppm)						
• Toilets clean, properly functioning, and adequately supplied (S/U)						
5) Protection from adulterants and 6) Labeling, storage, and use of toxic compounds						
• Product protected from contamination and allergen cross-contact (S/U)						
• Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)						
7) Employee health • Employees do not show signs of medical problems (S/U)						
8) Exclusion of pests • Pests excluded from processing area (S/U)						
S = Satisfactory / U = Unsatisfactory						
Signature or initials _____ Date _____						

Form 2

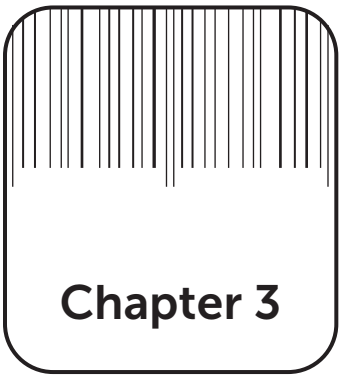
Monthly Sanitation Control Record

Monthly Sanitation Control Record		
Firm Name: _____ **Firm Address:** _____	**Date:** _____	
Sanitation Area	**Decision**	**Comments/Corrections**
1) Safety of water		
• Safe and sanitary source (S/U) (Annual)		
• No cross-connections in hard plumbing (S/U)		
2) Condition and cleanliness of food contact surfaces		
• Processing equipment and utensils in suitable condition (S/U)		
3) Prevention of cross-contamination		
• Physical conditions of plant and layout equipment (S/U)		
S = Satisfactory / U = Unsatisfactory Additional Comments: Signature or initials: _____		

Form 3

Periodic Sanitation Control Record with 5 of the 8 Key Sanitation Areas

Periodic Sanitation Control Record			
Firm Name: _____ **Firm Address:** _____			**Date:** _____
Condition	**S**	**U**	**Comments/Corrections**
1) Safety of water:			
a) Municipal water bill (annually).			
b) Building plumbing inspection report (when plumbing is modified)			
3) Prevention of cross-contamination:			Name(s)
a) Production supervisors have received basic food sanitation training (when hired).			
5) Protection from adulteration:			
a) Invoices for food-grade chemicals checked at receiving before chemicals are stored.			
6) Labeling, storage and use of toxic compounds:			
a) Labels or documents for toxic compounds checked at receiving before compounds are stored.			
8) Exclusion of pests:			
a) Pest management firm's report is satisfactory (every other month).			
S = Satisfactory / U = Unsatisfactory			
Comments and Corrections: Report by: _____			



Chapter 3

Seafood Safety Hazards

It is important in developing a HACCP plan or modifying an existing plan to be aware of the potential seafood safety hazards that are associated with the products and processes. The rationale for implementing a seafood HACCP program is to prevent the potential seafood safety hazards that are "reasonably likely to occur" and could cause disease or injury if not adequately controlled (Slide 1). Awareness of the potential hazards must also include some knowledge about the most appropriate and effective controls. This chapter provides a brief introduction to some of the most common hazards of concern. The FDA's *Fish and Fishery Products Hazards and Controls Guidance* (Hazards Guide), provides step-by-step directions to assist in determining the specific hazards and their respective controls. Controls can differ by product types and processes. Use of the Hazards Guide will be explained in Chapter 5-Hazard Analysis.

Slide 1

In this chapter you will learn about:

- Food Safety Hazards that have been associated with seafood and are considered "reasonably likely to occur" if not subject to appropriate controls.

In developing a HACCP plan, it is important to understand that seafood hazards only refer to the conditions or contaminants in food that can cause illness or injury to people (Slide 2). Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. Processors should have prerequisite programs in place to properly address all of these conditions (refer to Chapter 2 for prerequisite programs).

Slide 2

Hazards: a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of appropriate controls.

Undesirable conditions may not impose a particular food safety hazard, but they are subject to other regulatory controls and pre-requisite requirements (i.e., GMPs and Sanitation Control Procedures (SCPs). Examples include:

- Insects
- Hair
- Filth
- Spoilage
- Economic fraud
- Violations of regulatory food standards not directly related to safety

However, since these conditions are often not directly related to the safety of the product, it is recommended that they should not be included within a HACCP plan.

Categories for Seafood Safety Hazards

The FDA Hazards Guide describes two different categories of potential seafood safety hazards that all seafood processors must consider and evaluate. (Slide 3)

Slide 3

Potential seafood safety hazards can be grouped into two categories:

- Species-related hazards
- Process-related hazards

Species-related hazards are unique hazards that are associated with specific types or species of finfish and shellfish. Finfish are classified as vertebrates because they have a backbone and shellfish are classified as invertebrates because they do not have a backbone. Each species or type of finfish and shellfish may have unique potential seafood safety hazards associated with the water that they live in, their feeding habits, whether they are wild-harvested or farm-raised, or other unique characteristics.

Process-related hazards are potential food safety hazards that may be associated with specific types of finished fishery products as a result of the finished product form, the package type, the method of distribution and storage, or the processing methods that are used. These potential hazards must be evaluated for specific product types or processing methods regardless of the species of finfish or shellfish used in the product.

Note

It is not within the scope of this course to go into detail on the seafood hazards. This topic is too large and would be covered better in separate microbiology, toxicology and food-processing courses. The purpose of this chapter is to help participants develop an awareness of the kinds of hazards that may occur in seafood and to learn some of the general controls to prevent these hazards. Food processors may find it necessary to work with technical experts with more knowledge and experience with potential seafood safety hazards for various products and processes.

Types of Food Safety Hazards

A list of all species-related and process-related hazards is provided in Slide 4. We will discuss each of these hazards in the rest of this chapter.

General information about each hazard and the type of seafood products that could be affected will be provided followed by a brief explanation of possible control strategies. Additional background information and potential control strategies for each of these food safety hazards can be found in the FDA Hazards Guide.

Slide 4

Species-Related Hazards

- Pathogens from the Harvest Area (molluscan shellfish only)
- Parasites (finfish and shellfish)
- Natural Toxins (finfish and shellfish)
- Scombrotoxin or Histamine (certain species of finfish only)
- Environmental Chemical Contaminants (wild and farm raised finfish and shellfish)
- Aquaculture Drugs (farm raised finfish and shellfish only)

Process-Related Hazards

- Pathogenic bacteria growth (includes general pathogens, *C. botulinum* and *S. aureus*)
- Pathogen survival through cooking or pasteurization
- Pathogen survival through processes that do not use heat
- Pathogen contamination after cooking or pasteurization processes
- Food allergens
- Food intolerance substances
- Metal and glass inclusion

Pathogens in Seafood

The first group of potential food safety hazards that we will review is related to bacterial and viral pathogens. This hazard can be a species-related hazard for some seafood products, and also encompasses a number of process-related hazards for various finished seafood products, packaging types or processing methods. We will provide general background information on microorganisms in food, define pathogens, and then summarize general control strategies for pathogens. We will then describe specific pathogens that may require unique control strategies. Additional background information that can help you understand this potential seafood safety hazard can be found in the FDA Hazards Guide.

All foods can contain living organisms too small to be seen with the naked eye. They are called by the generic term "microorganisms." Microorganisms are classified into various groups including: yeasts, molds, bacteria, and viruses.

Microorganisms are found everywhere: air, dirt, fresh and salt water, skin, hair, animals and plants. People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and parasites daily without ill effect. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to control them if necessary. It is important to understand the different types of microorganisms in order to distinguish the types that cause foodborne illnesses.

Many microorganisms are beneficial. Certain kinds of yeast, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Certain kinds of yeast are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health. The term "probiotics" is being used for live microorganisms placed in food to provide a health benefit to the consumer.

Although thousands of different microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms are called pathogens. Pathogens that are transmitted by food are called foodborne pathogens. Among the five groups of microorganisms described earlier, only bacteria, viruses and parasites are typically included among those that can make seafood unsafe (Slide 5). Generally, yeast and molds do not pose a hazard in seafood.

Slide 5

Microorganisms that can be pathogenic and cause seafoodborne illnesses:
- Bacteria
- Viruses

How Bacterial Pathogens Cause Illnesses

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication (Slide 6). Foodborne infections are caused by consuming live pathogens that grow within the body, usually in the intestinal tract. Foodborne infections can be visualized much the same as an infection on your skin, except that it is an infection on the surface of the intestinal tract. Foodborne infections are caused by organisms such as *Salmonella* spp., *Shigella* spp., and *Listeria monocytogenes* to mention a few. If certain types and amounts of these particular bacteria are simply present in the seafood when consumed, they can grow and infect the consumer.

The other kind of bacterial hazard is foodborne intoxication, which is a condition caused by swallowing preformed toxins (i.e., toxins produced by microorganisms in the food before it is eaten). The onset of symptoms from a foodborne intoxication is often more rapid than symptoms from a foodborne infection that requires more time for the bacteria to grow after consumption.

Slide 6

Bacterial Hazards:
- Foodborne infection
- Foodborne intoxication

Evidence of an illness due to seafood-borne intoxications can occur within minutes to hours after consumption, whereas most foodborne infections are not evident until hours or days after consumption. Foodborne intoxications can be caused by certain types of bacteria such as *Staphylococcus aureus* or *Clostridium botulinum* that can produce staph enterotoxins or *botulinum* neurotoxins, respectively. If certain types of these bacteria are allowed to grow in the seafood prior to consumption, they can produce toxins to levels that could cause intoxication of the consumer.

Control Strategies for Bacterial Pathogens

Slide 7 describes three general control strategies to prevent, eliminate or reduce the potential hazards associated with bacterial pathogens to an acceptable level. One or both of these strategies may be necessary for certain types of food to ensure that consumers who eat the product do not get sick.

Slide 7

Control strategies for pathogens in seafood:
- **Source controls** for high risk products like raw molluscan shellfish require that they only be harvested from waters that do not have elevated levels of pathogens
- **Prevent or reduce pathogen growth** to an acceptable level by: freezing, refrigeration, minimizing exposure to temperatures above 40°F, drying, or salting
- **Eliminate or kill pathogens** by cooking, pasteurizing, or using other non-heat lethal treatments

Certain bacteria can be a potential hazard simply due to their presence in or on the seafood in any amount when consumed, whereas other types may require growth to a level or amount that is more hazardous. Knowledge regarding bacterial hazards due to presence or growth is important relative to selection of appropriate controls. Based on the nature of seafood harvests and aquaculture farming, it is reasonable to assume that some potentially hazardous bacteria will be present on live and raw products.

Source Controls – Live clams, oysters and mussels feed by pumping water through their system and filtering out algae and other microorganisms. If pathogens are present at high levels in the water, the number of pathogens in the clam, oyster or mussel will also be high. Because these shellfish are commonly eaten raw, it is essential that they only be harvested from waters that do not contain high levels of pathogens to minimize risk. National and state

shellfish regulatory authorities monitor water quality and close areas that are known or likely to have high pathogen levels to shellfish harvesting.

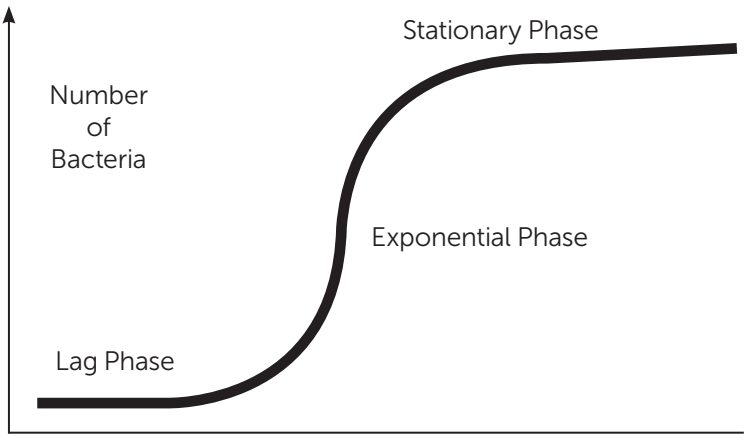
Eliminate or Kill Bacterial Pathogens – An effective cooking procedure can significantly reduce or eliminate the pathogens. Improper cooking could allow the pathogens to survive in amounts that still pose a hazard. Selection of appropriate controls must always consider potential bacteria survival.

Most seafood products that are purchased in retail stores or restaurants is cooked before it is consumed and most pathogens are killed during normal cooking. However, if a seafood processor will be producing a cooked or pasteurized product, it is necessary to scientifically demonstrate that their cooking process is sufficient to kill any pathogens that may be present and to prevent the cooked products from being re-contaminated after the cooking process. These same principles apply to other processes that do not use heat to eliminate pathogens.

Prevent Bacterial Pathogen Growth – In some cases, seafood is eaten raw or as ready-to-eat (RTE) products that do not require cooking just before consumption (Slide 7 above). These products would require additional controls to reduce or eliminate certain types and amounts of bacteria that may be present at harvest or introduced as contaminants during processing and handling.

Bacterial growth occurs in phases beginning with a slow or lag phase that provides time for adjustment to the growing conditions (Slide 8). Eventually under favorable conditions, the bacteria growth can rapidly accelerate with exponential growth or doubling as each bacterium grows large and divides. One bacterium divides into two, two into four, four into eight, eight into sixteen, and so on. Under ideal conditions, some bacteria double every 20 minutes. One bacterium can multiply to more than 30,000 bacteria in five hours and over 16 million in eight hours.

Slide 8



Effective controls remove or reduce the favorable growth conditions (Slide 9). Bacteria prefer favorable temperatures, moisture and certain atmospheric conditions (air or reduced-oxygen atmospheres) for growth. Hazard prevention usually involves controls and monitoring of these conditions to restrict and eliminate bacterial growth.

Slide 9

What bacteria need for favorable growth:
- Food (nutrients from the seafood)
- Water (moisture in the seafood)
- Proper temperature
- Air, minimal air or no air (reduced-oxygen)

Controls for Specific Types of Bacterial Pathogens

Some pathogens may grow under unique conditions or may be particularly resistant to environmental conditions. For example, some types of pathogens may form spores that are resistant to heat. Other pathogens may grow in conditions that would inhibit the growth of most other pathogens. For example, pathogens like *Listeria* may grow slowly at refrigeration temperatures, and other pathogens like *Staphylococcus aureus* can grow even at salt levels high enough to prohibit the growth of most other pathogens. We will now review these unique pathogens that may need specific control measures to eliminate them or prevent their growth.

Bacterial Sporeformers and Non-Sporeformers

Bacterial hazards can be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g., *Clostridium* spp. and *Bacillus* spp.) pass through a dormant stage in their life cycle called a spore. When a bacterium exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to non-sporeforming bacteria. Because they are dormant, spores are not hazardous as long as they stay spores. Unfortunately, if they survive a processing step designed to kill non-sporeforming bacteria, they may become a hazard in the food if they are allowed to germinate from the spore form and grow. When sporeformers are a concern, the process steps used to control them are often much more rigorous than necessary to control non-sporeformers (Slide 10).

The following list of potential foodborne bacterial pathogens includes those that are more "reasonably likely to occur" in seafood, but this listing is not fully inclusive. Additional, emerging pathogens may be added over time based on experience and discovery.

Slide 10

Pathogens of Concern for Seafood Products:
- Sporeforming bacteria
  - *Clostridium botulinum*
  - *Bacillus cereus*
  - *Clostridium perfringens*
- Non-Sporeforming bacteria
  - *Listeria monocytogenes*
  - *Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis*)
  - *Shigella* spp. (e.g., *S. dysenteriae*)
  - Pathogenic *Staphylococcus aureus*
  - *Vibrio* spp. (e.g., *V. cholerae, V. parahaemolyticus, V. vulnificus*)
  - Others (*Campylobacter jejuni, Yersina enterocolitica, Shigella* spp. and *Escherichia coli*)

Clostridium botulinum (Sporeformer)

Clostridium botulinum is found throughout the environment and has been isolated from soil, water, vegetables, meats, dairy products, ocean sediments, the intestinal tracts of fish, and the gills and viscera of crabs and other shellfish. *C. botulinum* is a sporeforming bacterium that grows in the absence of air. These characteristics allow it to survive normal cooking temperatures and to grow in a vacuum-packaged and modified-atmosphere environment. *C. botulinum* produces a powerful neurotoxin that causes botulism. Growth is necessary for *C. botulinum* to produce toxin. Symptoms include diarrhea, vomiting, abdominal pain, nausea and weakness. These are followed by double, blurred vision and dilated, fixed pupils. In severe cases, paralysis of the muscles responsible for breathing can cause death.

There are various types of *C. botulinum* (Type A, B, C, D, E, F and G) that are classified according to the type of neurotoxin they can produce. *C. botulinum* Type E is the most common type associated with fish and fishery products. It is a particular concern because it grows at temperatures as low as 38°F and can produce little noticeable evidence of spoilage. In contrast, *C. botulinum* Type A is the form of this bacteria that is most common in land-based products (i.e., vegetables). It is a common contaminant on processing equipment. It will grow at temperatures above 50°F and produces a putrid odor in products in which it grows. However, its spores are much more heat-resistant than the Type E form of the bacteria. Thus controls for Type E and Type A would differ.

Because *C. botulinum* produces heat-resistant spores and requires the absence of oxygen for growth, botulism has been most commonly associated with improperly canned food (usually home canned). Semi-preserved seafood, including smoked, salted and fermented fish, has also been identified as a cause of botulism. Packaging of raw, non-frozen fishery products in reduced-oxygen or with restricted-oxygen exposure (i.e., anaerobic packaging such as vacuum packs with oxygen impermeable film) is also considered favorable for potential growth of *C. botulinum* Type E if the packages are not properly refrigerated.

C. botulinum Type E can be controlled by inhibiting growth of the bacteria or by destroying it in the seafood (Slide 11). Proper thermal processes for canned seafood destroy the bacteria. Heavy salting or drying to reduce the water activity (aw) below 0.93 and fermentation or acidification to below pH 4.6 are effective means of preventing *C. botulinum* growth. Maintaining proper storage temperatures alone is not considered an adequate control measure for *C. botulinum* Type E because of its ability to grow at low temperatures and because of the severity of the illness. In many products, it is an important second barrier to growth. Additional controls are necessary for raw, non-frozen seafood packaged in anaerobic (limited oxygen) conditions that could allow spore germination.

Slide 11

Some controls for *Clostridium botulinum* in seafood:

- Destroy spores during processing (e.g., thermal processing [canning] or proper cooking to destroy the spores).
- Prevent potential growth by proper salting, drying, or pickling (acidification).
- Proper refrigeration, particularly for raw, non-frozen seafood packaged in anaerobic conditions (limited oxygen).
- Packaging refrigerated fishery products in permeable film that allows enough oxygen exposure to prevent anaerobic growth.

Bacillus cereus (Sporeformer)

Bacillus cereus spores can germinate and grow in the presence or absence of oxygen. If allowed to grow, it can produce heat stable *Bacillus* toxins that cannot be destroyed by routine cooking. They occur in soils and can be easily transmitted to many types of foods. They have been associated with illnesses involving cooked vegetables and meats, rice, and dairy products. They are not commonly associated with popular seafood products, but their occurrence in foodborne illnesses is considered somewhat underreported. Difficulty in detection and reporting is partially due to the variation in symptoms that can appear similar to other pathogenic bacteria, and the symptoms are relatively mild and of short duration. B. *cereus* can cause two types of illnesses. The more common is diarrhea and abdominal pains that can occur within 4 to 16 hours after consumption of contaminated food, followed by symptoms for up to 24 hours. The less frequent illnesses involve a more acute onset of nausea and vomiting within 1 to 5 hours which can persist for up to 24 hours after consumption.

Controls are necessary to prevent temperature abuse and prolonged storage or display of previously prepared foods without refrigeration (Slide 12). A primary concern is with precooked, chilled food products with expected long shelf lives. It is important to use rapid chilling methods to reduce the temperature of hot prepared foods like soups. It is best to cool hot foods below 40°F (5°C) within less than 4 hours after preparation, display or serving. Likewise, it is important to reheat cold prepared foods rapidly to above 165°F (74°C).

Slide 12

Some controls for *Bacillus cereus* in seafood:
- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper chilling rates for warm prepared food
- Proper refrigeration for prepared, ready-to-eat (RTE) food with extended shelf lives

Listeria monocytogenes (Non-sporeformer)

Listeria monocytogenes is widespread in nature and has been isolated from soil, vegetation, marine sediments and water. In the early 1900s, L. *monocytogenes* was recognized as a bacterium that caused illness in farm animals. More recently, it has been identified as the cause of listeriosis in humans. Most healthy individuals are either unaffected by L. *monocytogenes* or experience only mild flu-like symptoms. Victims of severe listeriosis are usually immunocompromised. Those at highest risk include cancer patients, individuals taking drugs that affect the body's immune system, alcoholics, pregnant women, persons with low stomach acidity, and individuals with AIDS. Severe listeriosis can cause meningitis, abortions, septicemia and a number of other maladies, some of which may lead to death.

The greatest threat of listeriosis is from ready-to-eat products that do not require further cooking before they are eaten (RTE). The L. *monocytogenes* in raw food that will be cooked before consumption is less of a concern to the food industry since the bacteria are killed during cooking. L *monocytogenes* has been isolated from raw fish, cooked crabs, raw and cooked shrimp, raw lobster, smoked fish and surimi (seafood analog). One of its most significant characteristics is its ability to grow at temperatures as low as 31°F.

L. monocytogenes can be controlled by thorough cooking of the seafood and by preventing cross contamination once the seafood is cooked (Slide 13). Since the infective dose of L. *monocytogenes* is thought to be small, time/temperature abuse of food products may not be necessary to cause illness. As an additional safeguard, temperature controls for ready-to-eat seafood is recommended to control potential growth.

Slide 13

Some controls for *Listeria monocytogenes* in seafood:
- Proper sanitation to prevent product contamination (product source, process facilities, and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

Salmonella spp. (Non-sporeformer)

Salmonella is naturally found in the intestinal tracts of mammals, birds, amphibians, and reptiles, but not in fish, crustaceans or mollusks. *Salmonella* is transferred to seafood through sewage pollution of the harvest environment or by contamination after harvest.

Salmonella food infection causes nausea, vomiting, abdominal cramps and fever. Outbreaks of *Salmonella* food infection have been associated with raw oysters, salmon, tuna salad, shrimp cocktail, stuffed sole, and gefilte fish.

Salmonella can be prevented by heating seafood sufficiently to kill the bacteria, holding chilled seafood below 40°F, preventing cross-contamination after cooking, and prohibiting people who are ill or are carriers of *Salmonella* from working in food operations (Slide 14). The infective dose of *Salmonella* is thought to be extremely variable, relatively high for healthy individuals and very low for at-risk individuals, such as the elderly or medically compromised. For this reason, illness could result even without time/temperature abuse, but temperature abuse has been a contributing factor in many outbreaks.

Slide 14

Some controls for *Salmonella* spp. in seafood:
- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

Staphylococcus aureus (Non-sporeformer)

Humans and animals are the primary reservoirs or source for *S. aureus*. Natural sources include the nose, throat and on the hair and skin of healthy individuals. However, the bacteria can also be found in air, dust, sewage and surfaces of food processing equipment. *S. aureus* can produce a toxin if allowed to grow in food. The toxin is not destroyed by cooking or other thermal process (i.e. canning processes). *S. aureus* has the ability to grow and produce toxins in food with very little available water (0.85 aw, 10 percent salt), which would prevent the growth of other pathogens.

Staphylococcus aureus food poisoning causes nausea, vomiting, abdominal cramping, watery or bloody diarrhea, and fever.

S. aureus can be controlled by minimizing time/temperature abuse of seafood, especially after cooking, and requiring that food handlers practice proper hygiene (Slide 15).

Slide 15

Some controls for *Staphylococcus aureus* in seafood:
- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

Vibrio cholerae (Non-sporeformer)

Vibrio cholerae is found in estuaries, bays, and brackish waters. It is naturally occurring and is not necessarily related to sewage contamination. V. *cholerae* tends to be more numerous in the environment during warmer months.

There are a number of types of V. *cholerae*, and these produce very different symptoms. One type, V. *cholerae* 01, initially causes abdominal discomfort and mild diarrhea. As the illness progresses, the symptoms may include watery diarrhea, abdominal cramps, vomiting and dehydration. Death can occur. Susceptibility to cholera is enhanced in people who have had gastric surgery, take antacids or have type O blood.

Another type of V. *cholerae*, non-01, causes diarrhea, abdominal cramps and fever. Nausea, vomiting and bloody diarrhea have also been reported. The severity of the symptoms is dependent, in part, upon the specific strain. In its most severe form, V. *cholerae* non-01 has resulted in septicemia (blood poisoning) in individuals with medical conditions that weaken their immune systems. The illness has been associated with consumption of raw oysters, but the bacterium has also been found in blue crabs.

V. *cholerae* can be prevented by cooking seafood thoroughly and by preventing cross-contamination once the seafood is cooked (Slide 16).

Slide 16

Some controls for *Vibrio cholerae, Vibrio parahaemolyticus* and *Vibrio vulnificus* in seafood:
- Product harvested from approved sources
- Proper refrigeration from harvest through processing
- Proper cooking
- Consumption advisories for more susceptible consumers

Vibrio parahaemolyticus (Non-sporeformer)

Vibrio parahaemolyticus is naturally occurring in estuaries and other coastal areas throughout most of the world. In most areas, *V. parahaemolyticus* is more numerous in the environment during the warmer months and, as a result, most outbreaks in the United States occur during the summer.

The most commonly experienced symptoms of *V. parahaemolyticus* illness include diarrhea, abdominal cramps, nausea, vomiting and headache. Fever and chills are less frequently reported. The illness has been associated with consuming contaminated crabs, oysters, shrimp, and lobster. Hazards from *V. parahaemolyticus* can be controlled by thoroughly cooking seafood and preventing cross-contamination after cooking. Control of time/ temperature abuse is also an important control measure (Slide 16).

Vibrio vulnificus (Non-sporeformer)

Vibrio vulnificus is a naturally occurring marine bacterium. *V. vulnificus* requires salt for survival and is commonly isolated at salinities of 7 parts per thousand (ppt) to 16 ppt. It is primarily found in the Gulf of Mexico, but it has also been isolated from the Atlantic and Pacific Oceans. The numbers of the bacterium in the environment are highest during the warmer months of April through October.

The most common symptoms include: skin lesions, septic shock, fever, chills and nausea. Abdominal pain, vomiting and diarrhea are less frequently reported. Death occurs in about 50 percent of the cases. A number of medical conditions make individuals more susceptible to the life-threatening effects of this bacterium, including liver disease, alcohol abuse, cancer, diabetes, chronic kidney disease, immunosuppressive drug or steroid usage, low stomach acidity, and AIDS. *V. vulnificus* sepsis has been associated with the consumption of certain molluscan shellfish.

Hazards from *V. vulnificus* can be controlled by thorough cooking of shellfish and by preventing cross-contamination once the seafood is cooked. The risk of *V. vulnificus* infection may also be reduced by refrigerating oysters soon after harvest during warm-weather months. Individuals in the "high risk" groups should not consume raw molluscan shellfish (Slide 16).

How Viral Pathogens Cause Illnesses

Like other microorganisms, viruses exist everywhere (Slide 17). They are very small particles that cannot be seen with a traditional microscope and cannot reproduce by themselves. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell. Viruses only grow once they enter a suitable host, and only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water, and frozen foods for months.

Viruses can be transmitted to infect consumers by contact with people, food or contaminated waters. They can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers). Transmission of viruses to foods is usually related to poor hygienic practices or harvest from non-approved, contaminated waters (e.g., illegal shellfish harvest). People who have viruses shed the particles

when they defecate. Food handlers with viruses can transmit them to food if they do not wash their hands properly. Poor hygienic practices can also result in contamination of food with bacterial hazards as well as viral hazards.

Slide 17

Hazards from viruses in foods
- Not truly "alive"
- Exist everywhere
- Do not grow in food
- Do not spoil food
- Transmitted by people, food and contaminated water
- Cause illness by infection

The following are examples of viral hazards that can be found in seafood (Slide 18).

Slide 18

Viruses:
- Hepatitis A virus causes fever and abdominal discomfort, followed by jaundice
- Norovirus group (formerly Norwalk Virus) causes nausea, vomiting, diarrhea, and abdominal pain (gastroenteritis); headache and low-grade fever may also occur

Hepatitis A Virus

Viruses survive better at low temperatures and are killed at high temperatures. As a result, most outbreaks of hepatitis occur during winter and early spring. Viruses can remain alive for long periods of time in seawater and have been shown to survive over one year in marine sediments.

Both raw and steamed clams, oysters, and mussels have been implicated in outbreaks of hepatitis A. Symptoms of hepatitis A include weakness, fever and abdominal pain. As the illness progresses, the individual usually becomes jaundiced. The severity of the illness ranges from very mild (young children often experience no symptoms) to severe, requiring hospitalization. The fatality rate is low, and deaths primarily occur among the elderly and individuals with underlying diseases.

Hazards from hepatitis A can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. However hepatitis A appears to be more resistant to heat than other viruses. A laboratory study showed that hepatitis A viruses in infected oysters were inactivated after heating at 140°F for 19 minutes. Therefore, mollusks steamed only until the shells open (a common cooking practice) are not exposed to heat long enough to inactivate hepatitis A viruses (Slide 19).

Slide 19

Some controls for viruses in seafood:
- Product from approved sources
- Thorough cooking

Norovirus

Norovirus is considered a major cause of nonbacterial intestinal illness (gastroenteritis). Illness from Norovirus has been associated with eating raw and steamed clams, oysters and cockles. Norovirus causes nausea, vomiting, diarrhea, abdominal cramps, and occasionally fever.

Hazards from Norovirus can be prevented by properly cooking seafood and by preventing cross-contamination of cooked seafood. Additionally, a recent outbreak has demonstrated that controlling overboard discharge of untreated sewage from shellfish harvesting vessels would reduce the incidence of illness attributable to Norovirus (Slide 19).

Parasites

Parasites are organisms that need a host to survive, by living on the host or within the host. Thousands of kinds of parasites exist worldwide; however only about 20 percent can be found in food or water, and less than 100 are known to infect people through consumption of contaminated food or water. There are two types of parasites that can infect people through food or water: parasitic worms and protozoa. Parasitic worms include roundworms (nematodes), tapeworms (cestodes) and flukes (trematodes). These worms vary in size from barely visible to several feet in length (Slide 20).

Slide 20

Parasites are organisms that need a host to survive.
- Thousands of kinds exist worldwide but less than 100 types are known to infect people through food consumption
- Types of concerns for seafood or water:
  - Parasitic worms (e.g., roundworms/nematodes, tapeworms/cestodes, and flukes/trematodes)

For most foodborne parasites, the food is part of their natural life cycle (e.g., nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to parasitic survival are a proper host (i.e., not all organisms can be infected by parasites) and a suitable environment (i.e., temperature, water, salinity, etc.).

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts (Slide 21). Consumer exposure to parasites depends on food selection, cultural habits and preparation methods.

Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food.

Slide 21

Methods of preventing transmission of parasites to foods by fecal contamination include:

- Good personal hygiene practices by food handlers
- Proper disposal of human feces
- Elimination of insufficiently treated sewage to fertilize crops
- Proper sewage treatment

The seafood parasite hazards have usually involved certain ready-to-eat products such as ceviche (pickled fish marinated with lime juice), lomi lomi (fish in a lemon base marinade), sashimi (raw fish), sushi (raw fish with rice), and cold smoked fish. The hazard concerns will vary according to different fish species, size and location of harvest. The following are examples of parasite hazards that have been associated with certain seafood (Slide 22).

Slide 22

Parasitic Worms:

- *Cryptosporidium parvum*
- Nematodes and roundworms (*Anasakis simplex, Pseudoterranova dicepiens, Eustrongylides* spp. and *Gnathostoma* spp.)
- Cestodes or tapeworms (*Diphyllobothrium latum*)
- Trematodes or flukes (*Chlonorchis sinensis, Heterophyes* spp., *Metagonimus* spp., and others)

Parasites in fish are considered a hazard only in fish that the processor knows or has reason to believe will be served raw or undercooked. In other products, parasites are considered filth but not hazardous. The FDA has established three freezing processes to kill parasites. Freezing and storing at -4°F (-20°C) or below for 7 days (total time), or freezing at -31°F (-35°C) or below for 15 hours, or freezing at -31°F (-35°C) or below until solid and storing at -4°F (-20°C) or below for 24 hours is sufficient to kill parasites. FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption. Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches) (Slide 23).

Slide 23

Some controls for *Anisakis simplex, P. decipiens* and *D. latum* parasites in seafood:
- Proper freezing
- Proper cooking

Flukes (Flatworms)

Flatworms is the common term used to refer to a large number of potential parasitic worms that appear as small, flat, and slender worms measuring about 20 mm long and 3-5 mm wide. They are also described according to the human organs they can infect, e.g., liver flukes, lung flukes, and intestinal flukes. Collectively, they cause the largest number of seafood-borne parasitic infections in the world, but occurrence is primarily within endemic areas of Asia including Korea, China, Taiwan, Vietnam and some Pacific Islands. These infections involve consumption of raw, fermented, undercooked or improperly pickled fish, crustaceans, and some mollusks usually taken from freshwater sources that involve the life-cycle of the parasite. Proper freezing, and heating or cooking as described above for other parasites can be effective controls to prevent infections.

Species-Related Hazards Associated with the Harvest or Growing Area

There are several different types of hazards that may be associated with the conditions found in the waters where these fish or shellfish are harvested. Natural toxins may be produced by naturally occurring algae that grow rapidly in some areas when conditions favor their growth. Some species of fish and shellfish may then accumulate these toxins at levels that can cause human illness. Likewise, environmental chemical contaminants or pollutants may be present in some waters where fish and shellfish live. If these species accumulate enough of these contaminants, consumers who eat them may suffer health consequences. These hazards may also be associated with farm-raised or aquaculture fish and shellfish if good practices are not followed. In addition, if drugs used to treat disease are not used properly they could also impact human health. We will review each of these species-related hazards next.

Slide 24

Species-Related Hazards Associated with the Harvest/Growing Area
- Natural Toxins
- Environmental Chemical Contaminants
- Aquaculture Drugs

Natural Toxins

Marine biotoxins (natural toxins) represent a significant threat to human health when humans consume fish and fishery products that contain certain small amounts of these toxins (Slide 25). The marine biotoxins comprise many distinct compounds, all produced by species of naturally occurring marine algae. Algae are at the base of the marine food chain. Consequently, the biotoxins produced by some algae are collected and concentrated through the food chain (e.g., mollusks, crustaceans and finfish) and ultimately are consumed by humans.

There are several recognized marine shellfish biotoxins; e.g. paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP), and amnesic shellfish poisoning (ASP). Molluscan shellfish waters are classified by state shellfish-control agencies to reduce the risk that these toxins will be carried by shellfish in commerce or from recreational harvest. Processors must assure production of molluscan shellfish only from those waters that have been approved for harvest. The geographic extent or existence of such shellfish toxins in waters outside the US would also be subject to evidence of careful monitoring for approved harvest.

FDA has established action levels for all of the marine biotoxins except CFP. None of these toxins can be fully destroyed by normal cooking, freezing, salting, acidification or smoking processes. However, there is some evidence that PSP levels, and perhaps levels of other shellfish toxins, can be reduced to safe levels through commercial canning processes.

Slide 25

Biotoxins – naturally occurring hazards:
- Shellfish Biotoxins
  - Amnesic Shellfish Poisoning (ASP; domoic acid)
  - Diarrhetic Shellfish Poisoning (DSP; okadaic acid)
  - Neurotoxic Shellfish Poisoning (NSP)
  - Paralytic Shellfish Poisoning (PSP; saxitoxins)
- Ciguatera Fish Poisoning (CFP)
- Tetrodotoxins (puffer fish poisoning)

Amnesic Shellfish Poisoning (ASP)

ASP is primarily caused by contaminated molluscan shellfish, primarily from cold water regions of North America. The shellfish become contaminated with domoic acid produced by dense growths of certain algae in the genus Pseudonitzschia. It should be assumed that all filter-feeding mollusks are capable of accumulating domoic acid. However, the only shellfish implicated in cases of ASP have been mussels. ASP has also been identified as a problem in the viscera of Dungeness, tanner, and red rock crabs, and anchovies along the western coast of the U.S. and Canada.

Controls for amnesic shellfish toxins in seafood largely depend on harvest of approved products from approved waters (Slide 26).

Slide 26

Control for shellfish biotoxins in seafood:
- Only harvest approved shellfish products from approved waters

Diarrhetic Shellfish Poisoning (DSP)

DSP is caused by contaminated molluscan shellfish. There has been no documented occurrence to date in the United States. However, instances have been documented in Japan, Southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada. Filter-feeding mollusks can accumulate toxins even at algae concentrations below that necessary to discolor the water. Mussels, oysters, hard clams and soft-shell clams have been implicated in cases of DSP. Contaminated scallops have caused cases of DSP in Japan, but the likelihood of scallops causing illness in this country is reduced because roe-on scallops are not typically consumed in the United States.

Controls for diarrhetic shellfish toxins in seafood largely depend on harvest of approved products from approved waters (Slide 26).

Neurotoxic Shellfish Poisoning (NSP)

Gymnodinium breve was first recognized as causing NSP in the mid 1960s. Blooms of this algae usually result in fish kills and can make shellfish toxic to humans. The blooms generally begin offshore and move inshore. G. breve produces three known toxins (brevetoxins).

NSP is caused by contaminated shellfish from the southeastern United States and New Zealand. Oysters and clams are the only shellfish associated with NSP illness. However, all filter-feeding mollusks are capable of accumulating neurotoxic shellfish toxins.

Controls for neurotoxic shellfish toxins in seafood largely depend on harvest of approved products from approved waters (Slide 26).

Paralytic Shellfish Poisoning (PSP)

There are many species of toxic algae that cause paralytic shellfish poisoning. These include algae in the genus Alexandrium, Pyrodinium and Gymnodinium. PSP can be caused by a combination of any of 18 toxins (saxitoxins), depending on the species of algae, geographic area and type of shellfish involved.

Controls for paralytic shellfish toxins in seafood largely depend on harvest of approved products from approved waters (Slide 26).

Ciguatera Fish Poisoning (CFP)

One additional natural toxin of significant concern in the U.S. and about the world is ciguatera fish poisoning (CFP). Although it originates in a form of natural algae, the food route to humans is by toxin accumulation in certain fish harvested from certain areas. By eating toxic algae, certain species of tropical

and subtropical fish can become toxic to humans. The algae species most often associated with CFP is *Gambierdiscus toxicus*, but others are occasionally involved. Toxic algae populations tend to fluctuate, influenced by the turbidity and nutrient content of the water. There are at least four known toxins that concentrate in the viscera, head or central nervous system of affected fish. Ciguatoxin is the principal toxin which can be in a variety of forms.

Currently, the principal test method is a mouse bioassay that is not suitable for commercial use. There is no validated method suitable for shipboard or dockside testing of large catches of fish. However, some tests are being evaluated and may soon be available. In the meantime, the fishing industry must rely on local knowledge of safe harvest areas and avoid harvest from any officially designated areas or species (Slide 27).

Slide 27

Control for ciguatera in seafood:
- Do not process certain fish harvested from waters that have been designated as potentially ciguatoxic

Other Marine Toxins

Tetrodotoxin (puffer fish)

Puffer fish, also called fugu or blowfish, contain the potent toxin, tetrodotoxin. It is unclear whether the fish itself produces the toxin, or like ciguatera, it is introduced to the fish by eating toxic algae. There are approximately 80 species of puffer fish that are known to contain tetrodotoxin in the Pacific, Atlantic and Indian Oceans. The domestic species of puffer, sometimes called sea squab, is much less poisonous than the Japanese species.

The primary control is avoidance of potential tetrodotoxic puffer fish (Slide 28). Puffer fish may not be imported into the United States except under strict certification requirements and specific authorization from FDA.

Slide 28

Control for tetrodotoxin in seafood:
- Do not process certain fish (puffer fish) that have been designated as potentially tetrodotoxic

Gempylotoxins

The gempylids, escolars or pelagic mackerels are a small group of fisheating oceanic fish. Important species in this group include: *Lepidocybium flavobrunneum* (escolar — California, Peru, Hawaiian Islands, Australia, South Africa, Cuba, Aru Islands, Madeira), and *Ruvettus pretiosus* (oilfish, castor oil fish, purgative fish — tropical Atlantic and Indo-Pacific Oceans).

Gempylids produce an oil that has a purgative effect. The diarrhea caused by eating the oil contained in the flesh and bones of gempylid fish develops rapidly and is pronounced but generally without pain or cramping. No other bad effects have been reported. There are not specific legal restrictions, but authorities advise caution that gempylid fish should not be imported or marketed in the United States (Slide 29).

Slide 29

Control for *gempyltoxin* in seafood:
- Do not process certain potentially gempylotoxic fish

Environmental Chemical Contaminants

Fish may be harvested from waters that are exposed to varying amounts of environmental contaminants. Industrial chemicals, pesticides, and many toxic elements may accumulate in fish at levels that can cause public health problems. Of greatest concern are fish harvested from freshwater, estuaries, and near shore waters rather than from the open ocean. Pesticides and herbicides used near aquaculture operations are also of concern. Because these hazards are unique to the fish and shellfish harvested from these areas, this is a hazard only associated with species that are grown and harvested in these areas.

Federal tolerances or action levels are established for some of the most toxic and persistent contaminants. States often use these limits for deciding whether to close waters for harvesting. Processors should be aware of these closures and should not purchase fish that have been harvested in closed areas. Pesticides and herbicides that may be used near aquaculture operations are also potential problems. Producer quality-assurance programs provide useful information for avoiding potential contaminants from a variety of sources, beginning with proper site selection. Controls are necessary to prevent potential hazardous chemical contaminations (Slide 30).

Slide 30

Controls for Environmental Chemical Contaminants (Pollutants)
- Do not harvest or sell fish or shellfish from waters that have been closed by federal, state, or local authorities due to environmental pollution
- Properly locate and monitor aquaculture farming operations to prevent pond contamination from runoff, and previous or new human activities

Aquaculture Drugs

Animal drugs may be used in the raising of aquatic species to: 1) treat or prevent disease, 2) control parasites, 3) affect reproduction, and 4) tranquilize. Illegal residues of drugs may occur in aquaculture species because of the use of unapproved drugs, use of drugs not in accordance with the approved labeling directions, failure to follow approved withdrawal times, or use of general purpose chemicals not labeled or approved for drug use. There are only a few approved drugs for aquatic species. However, FDA approval is required before any animal drug is used to ensure that unsafe drug residues will not occur in edible tissue when animals are treated following approved label directions. The withdrawal period is the period from the last time of drug treatment until the residuals are reduced or eliminated in the edible portions. The withdrawal time is usually within a number of days, depending on the drug, dosage, and growth of the seafood. Producer quality-assurance programs provide information and guidance for proper use of approved compounds and record-keeping practices that can be referenced in processor HACCP plans. Processors may consider conducting on-site audits of the animal-drug controls used by their producers. If rapid screening tests are considered for use by the processor or producer to detect or monitor drug residues in aquatic species, they must be validated for their intended use. These tests should only be used as a part of a complete risk reduction, quality-assurance program and not be used as the only monitoring tool. Presently, FDA has no data to indicate these tests will provide reliable, quantitative results for drug screening in farm-raised aquatic species (Slide 31).

Slide 31

Some controls for use of aquaculture drugs:

- When necessary, only use certain controlled drugs in the manner prescribed by a recognized veterinary expert
- Test for any excessive residuals in final products

Scombrotoxin (Histamine poisoning)

Another species-related hazard associated with certain types or species of finfish. Scombroid poisoning, also known as histamine poisoning, is caused by eating fish of certain species that have undergone some degree of spoilage by naturally occurring bacteria. These bacteria produce an enzyme that reacts with natural components (amino acids) of the fish flesh to produce histamine and biogenic amine compounds (putrescine and cadaverine). Certain species of fish are more likely to accumulate levels of these toxins that can cause human illness if they are not handled properly or are not kept cold enough from the time of harvest until they are consumed. Fish that have been involved in scrombroid poisonings include tuna, mahi-mahi, bluefish, sardines, amberjack and mackerel. The toxin is not eliminated or the amount present in the fish is not reduced by cooking or canning.

The histamine-forming bacteria usually grow rapidly only at high temperatures. At 90°F (32.2°C), unsafe levels of histamine may appear within six hours. At

70°F (21°C) the toxic conditions may appear within 24 hours. Because wide variations occur between individual fish even under the same conditions, it is necessary to consistently rapidly cool freshly harvested fish and maintain a low temperature until the fish are prepared for consumer use. Particularly for large fish, special precautions and equipment are required for the rapid removal of heat. Sensory analysis is a screening method that can help to reduce the risk of accepting histamine-containing fish. Periodic increases in product temperature during storage can result in more histamine being formed, but histamine may form during high temperature short time abuse without the usual odors of decomposition. Chemical analysis for histamine is also possible. A detailed knowledge of the temperature history of the product provides the best control measure (Slide 32).

Slide 32

Control for potential scombrotoxin in seafood:
- Temperature controls from the moment of harvest through processing, storage, and product distribution

Process-Related Hazards

Earlier in this chapter we discussed the process-related hazards that can be associated with the growth of microorganisms called pathogens and described specific controls for the pathogens of greatest public health concern. Pathogen growth or elimination is a process-related hazard because it is associated with the finished product form, the package type, the method of distribution and storage, or the processing methods that are used. We will now discuss the other process-related hazards (Slide 33).

Slide 33

Other Process-Related Food Safety Hazards
- Food Intolerance Substances (FIS)
- Food Allergens
- Metal and Glass Inclusion

Food Intolerance Substances (FIS)

Food intolerance substances, or FIS, include various compounds or ingredients that are approved or recognized for use with seafood products or processes, but they must be used in an appropriate or specified manner based on good manufacturing practices, regulatory limits and/or expert advice. Likewise, they should comply with established food grade standards or guidelines that assure safe composition and sources. Improper use or use of compounds from improper sources can result in hazards that cause intoxication, allergic-type

reactions or food intolerances. Some intentionally added chemicals used with seafood include food additives for preservation or processing aids, nutritional additives, and color additives (Slide 34).

Slide 34

Examples of Food and Color Additives
- Preservatives (e.g. nitrite, sulfites)
- Nutritional supplements (e.g. vitamins)
- Color Additives (FD&C Yellow No. 5)

Food and color additives are used in many fish and fishery products, including some usage by fishermen and aquaculture operations. Many additives are acceptable in such products when used in conformity with GMPs and established limits. Other additives are not permitted in fish or fishery products. Before using a food additive, the processor should become familiar with the applicable legal limitations for its use. The processor should be especially aware of food additives that are known to cause allergic-type reactions or are otherwise linked to adverse health consequences if not properly used. The use of color additives that are permitted should be carefully controlled to ensure they remain within established limits. Correct listing of food and color additives on the product label is a legal requirement.

Examples of such food and color additives that are used on fish and fishery products include sulfites and FD&C Yellow #5. Sulfites are mostly used during on-board handling of shrimp and lobster to prevent the formation of "black spot." They are sometimes used by cooked octopus processors as an antioxidant, to retain the red color of the octopus skin. FD&C Yellow #5 is used during in-plant processing. These food and color additives are permitted for use in foods—with certain restrictions—but their presence must be declared on the label. This label declaration is particularly important to sensitive individuals.

Certain other food and color additives are prohibited from use in food because of a determination by FDA that they present a potential risk to the public health. Examples of such food and color additives include safrole and FD&C Red #4.

These chemicals are intentionally added to food at some point during the food's growth, processing or distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded. Controls to prevent seafood hazards due to intentional use include monitoring for proper use and testing for resulting residuals, plus labeling information to alert certain consumers with food intolerances (Slide 35).

Slide 35

Controls for intentionally added ingredients in seafood:
- Use proper type and amount of ingredients
- Label product to inform consumers (e.g., sulfites)

Food Allergens

A number of foods contain allergenic proteins that can pose a health risk to certain sensitive individuals. Eight foods account for most of all food allergies (Slide 36). If these foods are part of, or are directly added to your fishery product, you must ensure that the product is properly labeled.

Slide 36

Most common food allergens:
- Milk
- Peanuts
- Soybeans
- Eggs
- Tree Nuts
- Wheat
- Fish
- Crustaceans

Allergen Cross-Contact

However, the controls for informing consumers about the presence of allergens in a processed seafood product are not designed to prevent the unintentional introduction of allergenic proteins from such foods into your fishery product because of cross-contact (e.g. use of common equipment, improper production scheduling, or improper use of rework material). Unintentional introduction of allergenic proteins must be controlled through a rigorous sanitation regime, either as part of a prerequisite program or as part of HACCP itself. The basic controls for allergens involve product declarations and monitoring to prevent cross-contact among foods (Slide 37).

Slide 37

Control for potential allergens in seafood:
- Product labeling to inform consumers
- Institute proper pre-requisite programs and a strong sanitation program to avoid cross-contact for all allergens

Note

Bone and shell fragments are typically considered an intrinsic part of the seafood products (fish fillets and shellfish meat) and not a contaminant. Hazard analysis considers them as quality problems and not a significant safety hazard.

Glass and Metal Hazards

Hazards also include any potentially harmful extraneous matter not normally found in food (Slide 38). When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify.

Slide 38

Physical Hazard:
Any extraneous matter not normally found in food that could cause physical injury

Example:

The following are examples of materials that may be physical hazards:

Material	Why a hazard?
Glass	Cuts, bleeding; may require surgery to find or remove
Metal	Cuts, broken teeth; may require surgery to remove

Glass Inclusion Hazards

Glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. Glass inclusion can occur whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Most products packed in glass containers are intended as a ready-to-eat commodity. Glass fragments originating from other sources must be addressed, where applicable, in a prerequisite sanitation program (Slide 39).

Slide 39

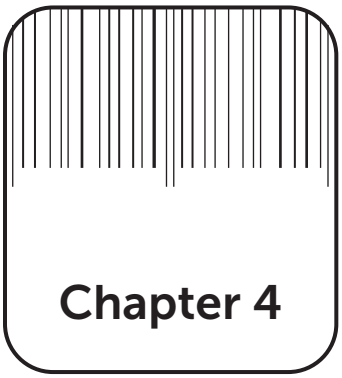
Control for potential glass inclusion in seafood:
- Examination of glass containers for breakage

Metal Hazards

Metal-to-metal contact—especially in mechanical cutting and blending operations, and with equipment that has parts that can break or fall off, such as wire-mesh belts—can introduce metal fragments into products. FDA's Health Hazard Evaluation Board has supported regulatory action against products with metal fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. Such fragments serve as a hazard to the consumer. This hazard can be controlled by subjecting the product to metal detection devices or by regular inspection of at-risk equipment for signs of damage. Controls to prevent potential inclusion of metal fragments include monitoring of the equipment and detection in products.

Slide 40

Controls for potential metal inclusion in seafood:
- Monitoring equipment for wear and breakage
- Screening products with metal detectors



Chapter 4

Preliminary Steps in Developing a HACCP Plan

Before building a HACCP plan, there are preliminary steps that should be considered (Slide 1).

Slide 1

In this chapter, you will learn:
- The importance of preliminary steps in developing the HACCP plan

There are several different preliminary steps that need to be completed before applying HACCP principles. These steps involve gathering information about the products and the process that you will need to conduct a hazard analysis. (Slide 2).

Slide 2

Preliminary steps:
- Assemble HACCP team
- Describe the product, intended use and consumers
- Develop a Process Flow Chart
- Develop a Process Description

Assemble HACCP Team

Assembling a HACCP team is an important step in building a HACCP plan. The team should consist of individuals with different specialties and experience with the process. The HACCP team should include members who are directly involved with the plant's daily operations. The team may include personnel

from maintenance, production, sanitation, quality control and laboratory. They develop the HACCP plan, write SCPs, and verify and implement the HACCP system. The team members should be knowledgeable about food safety hazards and HACCP principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise.

In addition to writing and developing the HACCP plan, the HACCP team provides oversight of the implementation of the plan into the daily operations of the facility. This includes ensuring that applicable personnel are trained appropriately to handle their required duties.

Although one person may be able to analyze hazards and develop a HACCP plan successfully, many companies find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes the risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various divisions, including owners, should be members of the HACCP team. Universities, Cooperative Extension, consulting groups, Sea Grant programs, trade associations, model plans and published guidance can provide additional assistance (see chapter 13 for more information).

Describe the Product, Intended Use and Consumers

The HACCP team should describe the product(s), the type of packaging, the method of distribution, the intended customer (e.g., general public, infants, elderly) and likely use of the product (e.g., consumed without further cooking, heat-and-serve, cooked). It may seem to take a lot of effort to complete a very detailed description of the product and intended use, but this is necessary to assure an accurate hazard analysis (Slide 3).

Slide 3

Product Description should include:

- Type of seafood product (species and finished product form)
- Where product is purchased
- How product is received, stored, and shipped
- How product is packaged
- Intended use

A complete product description should include:

Type of seafood:

- species of fish or shellfish including market name (e.g., tuna) and scientific name (e.g., *Thunnus albacares*), if necessary
- finished product form (e.g., raw, cooked, pasteurized, smoked, etc.)

It is important to know which species are being processed in order to accurately identify potential food safety hazards. For the same reason, it is important to know the finished product form.

Identify where product is purchased:

- directly from the fisherman or harvest vessel;
- directly from the aquaculture grower or farm;
- from another processor; or
- from a combination of these sources.

It is important to know where the product is purchased to identify the correct potential food safety hazards. For example, how a potential hazard is addressed will depend on whether the processor is a "primary processor" or a "secondary processor." The **primary processor** is the processor that takes possession of a seafood product directly from the harvester or fish farm. A **secondary processor** is a processor who receives a seafood product from another processor.

Identify how the fish are received:

- fresh – under refrigeration;
- fresh – under ice or chemical coolant;
- frozen;
- canned or shelf-stable;
- more than one of these methods.

Identify how the fish are stored after receipt:

- fresh – under refrigeration;
- fresh – under ice or chemical coolant;
- frozen;
- dry storage.

Identify how the finished product will be shipped:

- fresh – under refrigeration;
- fresh – under ice or chemical coolant;
- frozen;
- ambient conditions;
- more than one of these methods.

Identify how the finished product will be packaged:

- air-permeable packaging (e.g., foam tray overwrapped with fresh meat film);
- reduced-oxygen packaging (e.g., vacuum packaging, modified-atmosphere packaging, controlled-atmosphere packaging; hermetically-sealed packages; or packed in oil).

It is important to know how products are received, stored, packaged, and shipped to identify any potential food safety hazards during the hazard analysis.

Identify how the products are intended to be used:

- to be cooked by the consumer;
- ready-to-eat (RTE) raw;
- RTE – cooked
- RTE – partially cooked;
- RTE – heat and serve;
- RTE – reheat.

It is important to know how the product will be consumed to identify any potential food safety hazards.

Identify the intended consumer:

Intended consumer information needs to identify whether the end user will be the general public or a specific at-risk consumer group such as infants and the elderly.

- General Public
- At-risk Population

Knowing who the end user will be may be relevant when identifying potential hazards during the hazard analysis.

Product Description Form

A Product Description form (Slide 4) has been developed to help record this information. A blank form can be found in Appendix 2.

Develop an Accurate Process Flow Chart

A flow chart provides an important visual tool that the HACCP team can use to identify and describe the process (Slide 5). When developing a process flow chart, it is important to include all the process steps within the facility's control from receiving through final product storage, including reworked product if applicable. Since the accuracy of the process flow is critical to conduct a hazard analysis, the steps outlined in the chart must be verified at the plant. If a step is missed, a significant food safety hazard may be missed. Include every handling, processing and holding step for primary product as well as ingredients and packaging. The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

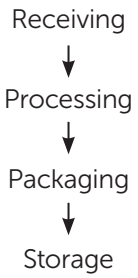
Slide 4

Product Description Form for Fish and Shellfish Species

Acceptable Market Name & Species	Where Product Is Purchased (Source)			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/ Dealer	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	Reduced-Oxygen/ Vacuum Packed	Raw, to be cooked	Raw, RTE	Cooked, RTE	General Public	At-risk Population

Slide 5

The following is an example of a basic process flow chart.



Develop a Process Description

A written **process description** can be a useful tool to explain what happens at each of the process steps needed to produce a product covered by a particular HACCP plan. This description can be used as a working reference for the development of the HACCP plan and to facilitate communication with company personnel and regulators. It is also important to know what occurs at each process step. For example, it is important to know information about process steps such as the maximum length of time that the product could be exposed

Note: Shipping Steps

For seafood processors, the shipping step is not included on the process flow chart as illustrated on Slide 5. Transporting seafood is exempt from the Seafood HACCP regulation but there could be potential hazards that could occur during transit. The responsibility for controls of significant hazards that can be introduced during shipping should be addressed through a receiving CCP by the next receiver of the product.

For seafood processors shipping live clams, oysters and mussels, the shipping step is a CCP in order to comply with state and federal shellfish regulatory requirements.

to unrefrigerated temperatures, the maximum room air temperature, or the maximum internal product temperature. This information is necessary to conduct an accurate hazard analysis.

Example: XYZ Seafood Co.

The model XYZ Seafood Company will be used to illustrate the progressive development of the HACCP program beginning with the preliminary steps through the application of each of the HACCP principles.

Assemble HACCP Team

XYZ Seafood Company has determined that their team will consist of three individuals including: the plant manager, production supervisor and the sanitation supervisor. All have undergone seafood HACCP training.

Describe the Product, Intended Use and Consumers

XYZ Seafood Company used the Product Description Form for Fish and Shellfish Species to complete their preliminary step shown in Slide 6.

Slide 6

XYZ Seafood Company Product Description Form for Fish and Shellfish Species

Acceptable Market Name & Species	Where Product Is Purchased (Source)			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/ Dealer	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	Reduced-Oxygen/ Vacuum Packed	Raw, to be cooked	Raw, RTE	Cooked, RTE	General Public	At-risk Population
Mahi-mahi fillets (*Coryphaena* sp.)			X		X				X				X			X		X			X	

The results from this chart are summarized below:

Product Description: Raw, wild-caught mahi-mahi fillets

Fishery Product Market Name: Mahi-mahi *(Coryphaena* species)

Source of Fishery Product: From other processors, received in ice

Methods of Packaging, Distribution and Storage: Air packed, stored and distributed on ice

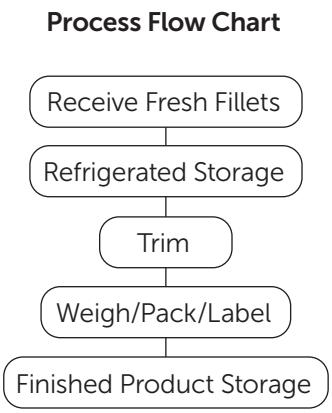
Intended Use and Consumer: To be cooked and consumed by the general public

Develop a Process Flow Chart

XYZ Seafood Company developed a process flow chart (Slide 7).

Slide 7

Example process flow diagram for production of fresh mahi-mahi fillets for XYZ Seafood Company



Develop a Process Description

XYZ Seafood Company's HACCP team developed the following written **process description** for each of the steps in their process flow chart.

Receive fresh fish fillets – Fresh wild caught mahi-mahi (*Coryphaena* species, not aquacultured) fillets are received from several domestic suppliers. Delivery truck transit times range from 2 to 8 hours. Tubs or other containers of mahi-mahi fillets are received along with other fresh seafood products packed in ice and delivered by refrigerated truck. After receipt, products are re-iced if necessary and moved into refrigerated storage.

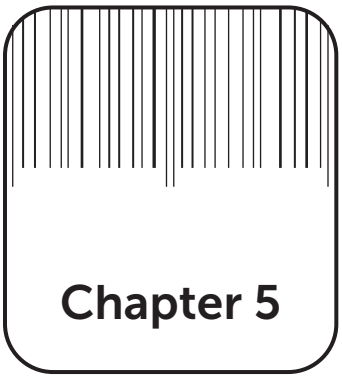
Refrigerated storage – Individual mahi-mahi fillets are completely buried in ice and stored in a refrigerated cooler until needed.

Trim – Individual tubs or containers of mahi-mahi fillets are removed from the cooler as needed to pack customer orders. Fillets are trimmed by hand with knives if necessary to meet customer specifications. Trimming is completed in 30 minutes or less.

Weigh/Pack/Label – Per customer order, mahi-mahi fillets are weighed, packed into containers, and each container is labeled with a handwritten or printed label that contains the market name of the species of fish that it

contains. Individual containers are completely surrounded by ice and assembled into master cartons for each customer order. The weigh/pack/label steps are completed in 30 minutes or less.

Finished product storage – Containers of iced mahi-mahi fillets are placed in master cartons that contain each customer's order and are placed back into refrigerated storage until it is moved directly to refrigerated trucks for delivery to retail or restaurant customers.



Chapter 5

Principle 1: Hazard Analysis

The first step in developing a HACCP plan is to identify all of the significant food safety hazards that are associated with the seafood product(s) and process(es), as well as the control measures. This procedure is called hazard analysis, the first principle of HACCP (Slide 1).

Slide 1

In this chapter you will learn how to:
- Conduct a hazard analysis
- Identify significant hazards
- Identify control measures

A hazard is defined as any biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of control(s). The term hazard, when used in the context of HACCP, is limited to food safety concerns that could cause consumer illness or injury (Slide 2).

Slide 2

Definition: A hazard is any biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of control(s).

Not all potential hazards are significant. A significant hazard is one that is reasonably likely to occur and presents a health risk to the consumer if it is not controlled (Slide 3). Control measures must be identified for all significant hazards.

Slide 3

The hazard analysis is conducted to identify:
- All **potential** food safety hazards,
- Which of these hazards are **significant**, and
- Measures to control the **significant** hazards.

How to Conduct a Hazard Analysis

There is a sequence of steps that need to be completed when conducting a hazard analysis (Slide 4). Each step is an important part of the procedure. These steps will be discussed individually using a worksheet to document the results or conclusions.

Slide 4

There are five steps in a hazard analysis:
1) List process steps
2) Identify **potential food safety hazards**
3) Determine if the hazard is **significant**
4) Justify the decision
5) Identify control measure(s)

Note

Blank hazard analysis worksheets are in Appendix 2.

A standardized hazard analysis worksheet (Slide 5) is designed for this course to ensure that all steps in the hazard analysis process are completed. A written hazard analysis is important because it is the best way to determine if there are significant food safety hazards that need to be controlled. You may have seen other worksheets or approaches but this is the format used for this course. A copy of a blank form is in Appendix 2.

The worksheet is used to:

- List each of the process steps from the process flow chart (Column 1).
- List all potential species-related and process-related hazards that are identified during the hazard identification step (Column 2).
- Record the result of the hazard evaluation. A "Yes" or "No" answer to the question: "Is the potential food safety hazard significant?" is entered in this column (Column 3).
- Explain why the hazard is significant or not (Column 4).
- List control measures for those hazards that have been identified as significant and need to be controlled at a specific operational step (Column 5).

Slide 5

Blank Hazard Analysis Worksheet

Hazard Analysis Worksheet					
Firm Name:			**Product Description:**		
Firm Address:			**Method of Storage & Distribution:**		
			Intended Use & Consumer:		
(1) **Processing Steps**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**

Set Up the Hazard Analysis Worksheet

Set up the hazard analysis worksheet by entering the firm's name and address. Then enter the information that was gathered during the preliminary steps, including the product description, the method of storage and distribution, and the intended use and consumer. A separate hazard analysis worksheet may be needed for each product type. Grouping of product types may be done so long as the hazards and controls are the same. For example, fresh tuna, mackerel and bluefish have a common hazard for elevated histamine levels if temperature abused, and they have the same temperature controls for prevention of histamine levels.

STEP 1. Processing Steps (Worksheet Column 1). A process flow chart was developed (Chapter 4) as part of the preliminary steps. List each of these process steps in Column 1 of the hazard analysis worksheet (Slide 6). When completed, column 1 should contain every processing step listed in the Process Flow Chart.

Slide 6

Step 1: Enter each of the processing steps from the process flow chart in Column 1 of the hazard analysis worksheet. Each step will have its own block on the worksheet, and should be listed in the same order as on the process flow chart.

STEP 2. Food Safety Hazards (Worksheet Column 2). List all of the potential food safety hazards related to each type of fish or fishery product and the process in column 2 of the hazard analysis worksheet (Slide 7). To begin, every potential seafood safety hazard must be identified. Then all of the potential hazards should be listed at each processing step (Slide 7). It is important to list 'every identified seafood hazard' in column 2 for each of the listed processing steps in column 1.

Slide 7

Step 2. List potential food safety hazards. It is important to list every identified hazard at each listed processing step.

One approach to identify potential seafood safety hazards is to use the FDA *Fish and Fishery Products Hazards and Controls Guidance* (Hazards Guide). It lists all of the potential seafood safety hazards that are likely to be associated with specific species of fish and shellfish and specific types of finished products or processing operations. The Hazards Guide is based on the best currently available scientific information (Slide 8).

Slide 8

Use the Hazards Guide as a tool to identify **potential hazards.**

Using the Hazards Guide to Identify Potential Seafood Safety Hazards

Keyword Search

Seafood List
FDA Seafood List

Chapter 3 in the Hazards Guide provides tables of information that can be used to identify potential species- and process-related hazards.

Species-Related Hazards

The Hazards Guide's "**potential vertebrate species-related hazards**" table contains a list of all species of **vertebrate fish** (fish with backbones) in alphabetical order (Slide 9). Slide 9 shows a partial section of table 3-2 of the Hazards Guide. The first column lists the "market names" for each type of fish. FDA's "The Seafood List" contains the acceptable market names for all fish and shellfish species in commerce. These market names can be matched with common and regional names.

The scientific or Latin name for each type of fish is listed in the second column. The scientific name consists of two Latin words in *italics*. The first word is capitalized and denotes the *"Genus"* name and the second designates the *"species."* The scientific name is universally recognized throughout the world. This name may be needed to properly identify the species of fish being considered to ensure that the correct food safety hazards are identified. In some cases the fish will be grouped by genus only in the Hazards Guide. Slide 9

lists the scientific name for mahi-mahi as "*Coryphaena* spp." This means that all species (spp.) in the Genus *Coryphaena* are covered by this entry.

The remaining columns in the Hazards Guide list the potential hazards that are known to be associated with vertebrate fish. These hazards are referred to as **"species-related hazards."** If the potential hazard is reasonably likely to occur in a certain species of fish, there is a checkmark in the column for that particular hazard. This means that this hazard should be listed as a "potential" hazard in column 2 of the hazard analysis worksheet. Under each hazard at the top of this chart, "CHP" refers to the chapter in the Hazards Guide that describes that hazard.

The Hazards Guide's "**potential invertebrate species-related hazards**" table (not shown in this manual) lists the same information for species of **invertebrate fish** (fish without backbones) in alphabetical order. All edible species of bivalve shellfish, mollusks, and crustaceans are included in this table.

Slide 9

Identifying potential species-related hazards

Excerpt from Hazard Guidance Table 3-2
Potential Vertebrate Species-Related Hazards Table

Market Names	Latin Names	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
Mahi-mahi	*Coryphaena* spp.			√		
Mahi-mahi, Aquacultured	*Coryphaena* spp.			√	√	√
Marlin	*Makaira* spp.			√		
	Tetrapturus spp.			√		

[3]This hazard applies 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.

[13]Many of the fish and families of fish listed in this table have been identified with specific natural marine toxins as a result of illnesses/ outbreaks which have occurred or have been identified through research. For further information regarding each toxin refer to Chapter 6 and its references.

Process-Related Hazards

The Hazards Guide's "**potential process-related hazards**" table lists the potential hazards that are associated with all finished product forms and

Slide 10

Identifying potential process-related hazards

Excerpt from Hazard Guidance Table 3-4
Potential Process-Related Hazards Table

Finished Product Food[1]	Package Type	Hazards									
		CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: *C. botulinum* Toxin	CHP 14: *S. aureus* Toxin - Drying	CHP 14: *S. aureus* Toxin - Batter	CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization	CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	CHP 19: Allergens and Food Intolerance Substances[4]	CHP 20: Metal Inclusion	CHP 21: Glass Inclusion
Raw fish other than oysters, clams, and mussels (finfish and non-finfish)	Reduced-oxygen packaged (e.g. mechanical, vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed or packed in oil)	√	√						√	√	
Raw fish other than oysters, clams, and mussels (finfish and non-finfish)	Other than reduced-oxygen packaged	√							√	√	
Partially cooked or uncooked prepared foods	Reduced-oxygen packaged (e.g. mechanical, vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed or packed in oil)	√	√						√	√	√
Partially cooked or uncooked prepared foods	Other than reduced-oxygen packaged	√							√	√	√

[1] *You should include potential hazards from more than one finished product food category if your product fits more than one description.*

[4] *Applies to finfish and crustacean only in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004. Molluscan shellfish are not subject to FALCPA.*

package types (Slide 10). This table is also formatted in columns. The first column lists the "**finished product food types**." The second column lists the "**package type**", which is divided into two categories: products packaged in a reduced oxygen environment and products that are not packaged in a reduced oxygen environment. This column also gives examples of package types that would represent a reduced oxygen environment including: vacuum packed, steam flushed, hot filled, modified atmosphere packed (MAP), controlled atmosphere packed (CAP), hermetically sealed packages, or products packed in oil. The remaining columns in the table list all of the potential process-related food safety hazards safety hazards that might occur might occur in seafood products or processing operations. When selecting a finished food and package type it is important to review all of the entries in this table and look for the best fit for the product being considered. You may need to include potential hazards

from more than one 'category' if your product fits more than one description. For example, a hot smoked fish could require controls for a smoked and cooked seafood.

Example: Fresh mahi-mahi/XYZ Seafood Co.

The Hazards Guide's "**potential species-related hazards**" table was used to identify potential species-related hazards for the fresh mahi-mahi fillets received by XYZ Seafood Company. XYZ Seafood Company is receiving wild-caught mahi-mahi fillets from another processor. The hazard of histamine is checked and should be listed in Column 2 of the hazard analysis worksheet. This table is used in the same way to determine potential food safety hazards for any species of fish.

To complete the hazard identification, find the process-related hazards for this product from the Hazards Guide's **"potential process-related hazards"** table (Slide 10). Begin by identifying the finished product food description that best fits this product. For fresh mahi-mahi fillets, there is an entry for: **Raw fish other than oysters, clams, and mussels (finfish and non-finfish)**. This entry is the best match for the fresh mahi-mahi fillets.

The next step is to determine whether or not this product is received, stored or placed in a reduced-oxygen package while in this firm's control. If no reduced-oxygen packaging is used, select the entry for "**Raw fish other than oysters, clams, and mussels + other than reduced-oxygen packaged.**" Hazards Guide Table #3-4 shows that there are three potential food safety hazards for this product form:

- Pathogen growth – temperature abuse
- Allergens and/or FIS
- Metal inclusion

Using the information from Chapter 4 for the XYZ Seafood Company, its Process Flow Chart, and the information on potential hazards obtained from the Hazards Guide the following information should be entered on the hazard analysis worksheet (Slide 11):

- Company and product information at the top of the worksheet. This information was gathered in the preliminary steps (Chapter 4).
- The first step from the process flow chart (Receiving Fresh Fillets) was entered in column 1.
- The species-related hazard, histamine, found in Hazards Guide Table #3-2 for mahi-mahi was entered in column 2.
- The process-related hazards, pathogen growth - temperature abuse, food allergens, food intolerance substances and metal inclusion, found in Hazards Guide Table 3-4, for raw fish other than reduced oxygen packaged were entered in column 2.

Note

If the product was vacuum-packed or packed in a reduced-oxygen package, you would select the "Reduced-oxygen packaged" entry in the Hazards Guide, which also identifies the hazard of *"C. botulinum* toxin."

Slide 11

XYZ Seafood Company – Fresh Mahi-mahi Fillets

Hazard Analysis Worksheet					
Firm Name: XYZ Seafood Company			**Product Description:** Fresh mahi-mahi fillets		
Firm Address: 238 Coastal Lane, Happy Beach, XX			**Method of Storage & Distribution:** Stored and distributed on ice		
			Intended Use & Consumer: To be cooked and consumed by the general public		
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving Fresh Fillets	Histamine				
	Pathogen Growth - Temperature Abuse				
	Food Allergens				
	Food Intolerance Substances				
	Metal Inclusion				

Hazards Not Identified in the Hazards Guide

In addition to using the Hazards Guide to identify species and process-related hazards, the hazard analysis must also identify hazards associated with non-seafood ingredients. It is recommended that firms also perform an on-site assessment of the activities and conditions at each operational step. Firms may note unique product sources, conditions, activities, or new research information that is not identified in the Hazards Guide tables and could negatively impact product safety.

There may be situations where a firm identifies a hazard that is not listed in the Hazards Guide. For example, environmental chemical contaminants are not identified for many species. However, if a processor knows that fish they received are caught in an area that experienced a recent accidental spill of one or more chemical contaminants then this hazard should be considered in the hazard analysis.

Sanitation-Related Hazards

The HACCP team may identify hazards caused by conditions or activities in the plant such as employee, practices cross-contamination, or food allergen cross-contact. Rather than controlling these sanitation-related hazards in a HACCP plan, it is recommended that the sources of contamination be controlled in a separate, but equally important, Sanitation Control Procedures (SCPs). A Sanitation Control Procedures (Chapter 2) applies to all parts of the operation and is designed to prevent the many different sources of contamination from the plant environment.

STEPS 3 and 4. Hazard Evaluation and Justification (Worksheet columns 3 and 4). After the hazard identification (step 2) is completed, the HACCP team must evaluate the hazards (Slide 12). Each potential hazard will be evaluated to determine if it is **significant** at each process step. The hazard evaluation, or risk assessment, is designed to determine which hazards are reasonably likely to occur and need to be controlled.

Slide 12

Steps 3 and 4: Hazard Evaluation and Justification. Determine which hazards are significant and explain why.

HACCP focuses solely on food safety hazards that are **reasonably likely to occur and are likely to result in an unacceptable health risk to consumers if they are not controlled**. The hazard evaluation is designed to determine which hazards are relevant (Slide 13).

Slide 13

To determine if a hazard is significant, consider two questions:
1) Is the hazard reasonably likely to occur in the finished product in the absence of control?
2) Is the hazard likely to cause consumer illness?

Some processors will have the expertise necessary to complete the hazard evaluation, while others may need to seek outside assistance to complete this step. The HACCP team should use the Hazards Guide, experience, and other tools (e.g. test results, studies, FDA Alerts, recalls, etc.) that are available to help them determine whether or not a hazard is significant. There may be differences of opinion, even among experts, regarding whether or not a hazard is significant in a given situation.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Hazard Evaluation and Justification (Columns 3 and 4)

The potential hazards identified for XYZ Seafood Company (Slide 14) include:

- one species-related hazard: **histamine**, and
- four process-related hazards: pathogen growth - **temperature abuse, food allergens, FIS** and **metal inclusion**.

Slide 14

Example – Fresh Mahi-mahi
Which Hazards are Significant at the first process step, Receiving?
Histamine (Yes or No?)
Pathogen Growth - Temperature Abuse (Yes or No?)
Allergens (Yes or No?)
Food Intolerance Substances (Yes or No?)
Metal Inclusion (Yes or No?)

Important

It is important to list each identified seafood safety hazard in column 2 next to each step listed in column 1. This may appear redundant, but practice has shown that it assures more thorough consideration for all necessary food safety controls.

Each of these potential hazards must be evaluated for significance at each processing step listed on the hazard analysis worksheet. The hazard evaluation will determine whether or not this hazard is likely to result in an unacceptable health risk to consumers if it is not properly controlled at each processing step.

Process Step: Receiving Fresh Fillets
Hazard: Histamine

The Hazards Guide identified histamine as a species-related hazard in mahi-mahi that is reasonably likely to occur. To determine if this potential hazard could be introduced, enhanced (made worse), or eliminated at this process step, use the information in Chapter 7 of the Hazards Guide.

This chapter of the Hazards Guide states that histamine can form in certain species of fish, including mahi-mahi, when they are subject to time and temperature abuse. If abuse occurs at any time, from the time the fish is caught until the consumer eats it, this hazard could develop and cause illness. The Hazards Guide also states that histamine cannot be removed or eliminated once it has developed in the fish. This hazard must be **prevented** by making sure that these fish are not exposed to temperatures above 40°F for an extended period of time.

To determine if histamine is a **significant** hazard at the receiving step, answer two questions:

1) Is the histamine hazard reasonably likely to occur in the absence of control? The answer is "Yes" because the Hazards Guide indicates that histamine is likely to develop in species like mahi-mahi if they are temperature abused, and controls are needed at receiving to ensure that temperature abuse has not occurred during transit.

2) If not properly controlled (at receiving) is it likely to result in an unacceptable health risk to consumers? Again, the answer is "Yes" because consumers are likely to get sick if temperature abuse occurs during transit and histamine levels increase in the mahi-mahi.

Conclusion: Since the answer to both of the hazard evaluation questions is yes, the hazard of histamine is significant at the receiving step.

Process Step: Receiving Fresh Fillets
Hazard: Pathogen Growth-Temperature Abuse

To determine if Pathogen Growth-Temperature Abuse is a **significant** hazard at the receiving step, answer two questions:

1) **Is the pathogen growth-temperature abuse hazard reasonably likely to occur in the absence of control?** The answer is "Yes" because the Hazards Guide indicates in Chapter 12 that pathogen growth-temperature abuse is likely to develop in fish and fisheries products if they are temperature abused.
2) **If not properly controlled (at receiving) is it likely to result in an unacceptable health risk to consumers?** Here, however, the answer is "No" because if it is not properly controlled, the product will be cooked for or by the consumer and the process of thorough cooking would reduce the pathogenic bacteria to a level that would not result in an unacceptable heath risk to consumers.

Conclusion: Since the answer to one of the hazard evaluation questions is no, the hazard of pathogenic bacteria-temperature abuse is not significant at the receiving step.

Process Step: Receiving Fresh Fillets
Hazard: Food Allergens

To determine if food allergen is a **significant** hazard in the process, answer two questions:

1) **Is the food allergen hazard reasonably likely to occur in the absence of control?** The answer is "yes" because the Hazards Guide (Chapter 19) indicates that finfish is one of the eight major food allergens.
2) **If not properly controlled (in the process) is it likely to result in an unacceptable health risk to consumers?** Again, the answer is "yes" because finfish is one of the eight major food allergens and can cause consumer illness.

Conclusion: Since the answer to both of the hazard evaluation questions is yes, the hazard of food allergens is significant at the receiving step.

Note

The processor correctly identified the Allergen/ Additive category from the FDA table for Potential Process-Related Hazards, but the hazard analysis only finds allergens as the involved seafood safety hazard for the described product and process for Mahi-mahi.

Process Step: Receiving Fresh Fillets
Hazard: Food Intolerance Substances

To determine if Food Intolerance Substances is a **significant** hazard at the receiving step, answer two questions:

1) **Is the FIS hazard reasonably likely to occur in the absence of control?** The answer is "No" because the Hazards Guide indicates in Chapter 19 that only certain additives cause food intolerance and XYZ Seafood does not source mahi-mahi with those substances and does not add any.
2) **If not properly controlled (at receiving) is it likely to result in an unacceptable health risk to consumers?** "No" it is not likely to result in an unacceptable health risk to consumers because XYZ Seafood Company does not use food intolerance substances, nor do they source their mahi-mahi with them.

Conclusion: Since the answer to one of the hazard evaluation questions is no, the hazard of food intolerance substances is not significant at the receiving step.

Process Step: Receiving Fresh Fillets
Hazard: Metal Inclusion

To determine if metal inclusion is a **significant** hazard at the receiving step, answer two questions:

1) **Is the metal inclusion hazard reasonably likely to occur in the absence of control?** The answer is "no" because it is not reasonably likely to occur for this process at any step because no metal is used so there is no chance for metal inclusion (Hazards Guide Chapter 20).
2) **If not properly controlled (in the process) is it likely to result in an unacceptable health risk to consumers?** Again, the answer is "no" because this hazard is not likely to occur.

Conclusion: Since the answer to both of the hazard evaluation questions is no, the hazard of metal inclusion is not significant at the receiving step.

Hazard Analysis Worksheet

The XYZ Seafood Company continued filling out the hazard analysis worksheet (Slide 15) by entering:

- Yes, in column 3 indicating that the species-related hazard of **histamine is significant** at the receiving step. In column 4 this decision is justified by stating that time/temperature abuse could occur during transit.
- No, in column 3 indicating that the process-related hazard of **pathogen growth - temperature abuse is not significant** at the receiving step. In column 4, this decision is justified by stating that it is not likely to cause illness as the intended use for the product is to be cooked prior to consumption.

- Yes, in column 3 indicating that the process-related hazard of food **allergens is significant** at the receiving step. In column 4 the decision is justified by stating that fish is one of the eight major food allergens.
- No, in column 3 indicating that the process-related hazard of **food intolerance substances is not significant** at the receiving step. In column 4, this decision is justified by stating that no additives are used on fresh fillets.
- No, in column 3 indicating that the process-related hazard of **metal inclusion is not significant** at the receiving step. In column 4 the decision is justified because it is not reasonably likely to occur.

Slide 15

XYZ Seafood Company – Fresh Mahi-mahi Fillets

Hazard Analysis Worksheet

Firm Name: XYZ Seafood Company	**Product Description:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage & Distribution:** Stored and distributed on ice
	Intended Use & Consumer: To be cooked and consumed by the general public

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving Fresh Fillets	Histamine	Yes	Time/temp. abuse during transit could cause histamine to form in the fish		
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen		
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Identifying Control Measures (Column 5)

The final step in the hazard analysis process is to determine the appropriate **control measures** you intend to use to prevent, eliminate or reduce to an acceptable level each of the significant hazards identified in your hazard evaluation (Slide 16). This is important because if the hazard is truly significant there must be an appropriate control measure or your product would not be safe (Slide 17).

Slide 16

Step 5: Identify Control Measures for each significant hazard.

Control measures are actions and activities that can be used to prevent, eliminate, or reduce a food safety hazard to an acceptable level. In practice, control measures could include a wide array of activities that will be effective for a specific hazard.

Slide 17

Control measures can be used to:

- **Prevent** a food safety hazard,
- **Eliminate** a food safety hazard, or
- **Reduce** a food safety hazard to an acceptable level.

Different control measures for pathogenic bacteria, viruses and parasites may be used to control a hazard (Slide 18).

Slide 18

Control Measures for Pathogenic Bacteria, Viruses, Parasites

Bacteria

1) Time/temperature controls
2) Heating and cooking
3) Freezing
4) Fermentation and/or pH controls
5) Salt or other preservatives
6) Drying
7) Source controls
8) Other processes (e.g. high hydrostatic pressure and irradiation)

Viruses

1) Cooking
2) Source controls

Parasites

1) Cooking
2) Freezing

Control measures for pathogenic bacteria could include:

1) Time/temperature controls: proper control of refrigeration and storage time to minimize or prevent bacterial pathogen growth.
2) Heating and cooking processes to eliminate (kill) bacterial pathogens.
3) Freezing to prevent bacterial pathogen growth.
4) Fermentation and/or pH controls to ensure that foods are acidic enough to prevent bacterial pathogen growth.
5) Addition of salt or other preservatives to prevent bacterial pathogen growth.
6) Drying to ensure that enough water has been removed from the food to prevent bacterial pathogen growth.
7) Source control or buying raw material from acceptable sources to reduce the risk of bacterial pathogens to an acceptable level.

Control measures for pathogenic viruses could include:

1) Cooking methods designed to eliminate (destroy) viruses.
2) Source control or buying raw material from acceptable sources to reduce the risk of viruses to an acceptable level.

Control measures for parasites could include:

1) Cooking at the proper temperature for the proper amount of time to eliminate (kill) parasites.
2) Freezing at the proper temperature for the proper amount of time to eliminate (kill) parasites.

Different control measures for chemical and physical hazards may be used to control a hazard (Slide 19).

Slide 19

Control Measures for Chemical and Physical Hazards

Chemical Hazards *(Natural toxins, pesticides, drug residues, unapproved food and color additives, histamine)*

1) Source controls
2) Time/temperature controls
3) Production controls
4) Labeling controls

Physical Hazards *(Metal, glass, etc.)*

1) Source controls
2) Production controls

Control measures for chemical hazards, such as natural toxins, pesticides, drug residues, unapproved food and color additives, and histamine, could include:

1) Source controls to reduce the risk that fishery products were harvested from areas where chemical hazards like environmental pollutants or natural toxins like ciguatera are present at levels that could cause consumer illness or harm.
2) Time/temperature controls for chemical hazards such as histamine that prevent the hazard from forming in certain fish species.
3) Production controls to ensure that the proper amount of any food additives is used.
4) Labeling controls to ensure that consumers are aware that any known allergens are present in the product.

Control measures for physical hazards, such as metal and glass, could include:

1) Source controls that reduce the risk that products supplied by vendors will contain any physical hazards like metal or glass.
2) Production controls such as visual inspections of the equipment or container, using magnets, metal detectors, sifter screens or other devices to prevent any finished products that contain metal or other physical hazards from entering the marketplace.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

The XYZ Seafood Company continued the hazard analysis worksheet by adding control measures (column 5) for the identified hazards (Slide 20):

- The mahi-mahi fillets will be received in containers buried in ice, to prevent time/temperature abuse during transit.
- The mahi-mahi fillets will be properly labeled at a later processing step, to control the food allergen hazard.

Slide 20

XYZ Seafood Company – Fresh Mahi-mahi Fillets

Hazard Analysis Worksheet

Firm Name: XYZ Seafood Company	**Product Description:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage & Distribution:** Stored and distributed on ice
	Intended Use & Consumer: To be cooked and consumed by the general public

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving Fresh Fillets	Histamine	Yes	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi fillets are shipped in containers buried in ice (proper icing)	
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Summary

The hazard analysis is important because the decisions that are made will determine what is included in the HACCP plan. Tools, like the FDA's Hazards Guide, along with some thought and discussion, will ensure that the hazard analysis is completed successfully.

The hazard analysis worksheet (see Appendix 2) can be used to document the decisions that are made. This documentation is not required by regulations, but it is strongly recommended for future reference and justification for the selection of hazards that are reasonably likely to occur and their controls.

Different Approaches and Teaching Strategies for Hazard Analysis

Originally training approaches taught identification of seafood-safety hazards according to the various categories for Biological, Chemical and Physical hazards. Although this information can be useful in explaining the various types of hazards and controls, it does not necessarily improve the hazard analysis. Experience indicates that it is more important to identify all potential involved hazards as a list of inclusive hazards for analysis.

During the hazard analysis, all identified seafood-safety hazards should be included as a list of potential problems that could occur or be controlled at each individual processing step. Progressing through the hazard analysis will determine the most appropriate controls to prevent the hazards (Slide 21).

Slide 21

All food safety hazards must be considered in the Hazard Analysis, but it is not necessary to distinguish the hazards as biological, chemical or physical hazards.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Hazard Analysis Worksheet

The hazard analysis worksheet summarizes the results of the completed hazard analysis for XYZ Seafood Company (Slide 22).

Slide 22

XYZ Seafood Company – Fresh Mahi-mahi Fillets

Hazard Analysis Worksheet					
Firm Name: XYZ Seafood Company			**Product Description:** Fresh mahi-mahi fillets		
Firm Address: 238 Coastal Lane, Happy Beach, XX			**Method of Storage & Distribution:** Stored and distributed on ice		
			Intended Use & Consumer: To be cooked and consumed by the general public		
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receive Fresh Fillets	Histamine	Yes	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi fillets are shipped in containers buried in ice (proper icing)	
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Slide 22 (cont.)

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Refrigerated Storage	Histamine	Yes	Time/temp. abuse during storage could cause histamine to form in the fish	Mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Fish is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		
Trim	Histamine	No	Not likely to occur, time at this trim step is 30 min or less		
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Fillet knives are not likely to chip and contaminate product with metal		

Slide 22 (cont.)

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Weigh/Pack/Label	Histamine	No	Not likely to occur, time at this labeling step is 30 min or less		
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets are labeled with market name at this step (proper labeling)	
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		
Finished Product Refrgerated Storage	Histamine	Yes	Time/temperature abuse could uccur during storage	Mahi-mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	No	Fillets were labeled with market name at weigh/pack/label step		
	Food Intolerance Substances	No	No substances are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Chapter 6

Principle 2: Determine Critical Control Points

This chapter will cover the second principle of HACCP – Critical Control Point (CCP) determination. For each significant hazard that was identified during the hazard analysis, there are one or more points or steps in the process **where** the hazard can be controlled. These points or steps are called Critical Control Points (Slide 1).

Slide 1

In this chapter you will learn:

- The definition of a Critical Control Point (CCP).
- The relationship between significant hazards, control measures, and CCPs.
- How CCPs may be different for different products and processes.
- Tools to help you determine which steps are CCPs.
- Examples of CCPs for various food safety hazards.

A CCP should be a specific point in the process flow where application of a control measure effectively prevents, eliminates or reduces the hazard to an acceptable level (Slide 2).

Slide 2

Definition: A Critical Control Point is a step at which control can be applied to prevent, eliminate a food safety hazard, or reduce it to an acceptable level.

Critical Control Point Placement

If there are no control measures that can be applied at a particular process step, that step cannot be the CCP. In some cases control measures should be applied at a particular step, but that step may not be the best place to control the hazard. In that case, a processing step that occurs later in the process flow may be the best place to control that hazard (Slide 3).

Slide 3

CCP placement must be at the processing step or steps that adequately control the significant hazard.

For example, when producing a cooked product, the hazard of pathogen growth would first be identified at the receiving step. This hazard could be controlled at any process step where the hazard can be adequately controlled. However, the best place to control this hazard would be the cooking step, where the hazard is eliminated. The cook step would be the CCP for this hazard.

There may be different control options for a single hazard. For example, a metal hazard can be controlled at different processing steps such as:

- At receiving step, ingredients are sourced that are free of metal fragments,
- At a screening step, screens are used to remove any metal fragments,
- At a metal detection step, a detector is used to find any finished products that are contaminated with metal fragments.

Only one of these processing steps would likely be the best CCP to control this hazard.

Examples of Critical Control Points

A CCP is a step where a hazard can be prevented, eliminated or reduced to an acceptable level.

Examples of CCPs where a hazard can be **prevented** are (Slide 4):

- Chemical hazards caused by excessive application of a certain food additive can be **prevented** at the step where the ingredient is added.
- Histamine formation in certain fish species can be **prevented** at all steps where the proper use of ice, refrigeration, or managing the time out of refrigeration can prevent the product from being exposed to a temperature above 40°F for an extended period of time.
- Chemical hazards such as drug residues in aquaculture products can be **prevented** at the receiving step by using controls such as supplier declarations or testing.

Slide 4

CCPs can be steps where hazards can be **prevented.**

Examples of CCPs where a hazard can be **eliminated** are (Slide 5):

- Pathogens can be **eliminated** (killed) at the cooking step by controlling the time and temperature used for cooking.
- Metal fragments that may be in the finished product can be **eliminated** at a metal detector step because any product containing metal fragments would be removed from the processing line.
- Parasites can be **eliminated** (killed) at a freezing step by controlling the freezer temperature and how long the product is held at that temperature.

Slide 5

CCPs can be steps where hazards can be **eliminated.**

Examples of CCPs where the hazard can be **reduced to an acceptable level** are (Slide 6):

- The possibility that biological hazards, such as pathogens, and chemical hazards, such as natural toxins, can be **reduced to acceptable levels** in shellfish at the receiving step if controls are used to ensure that all shellfish are purchased from certified dealers and are properly tagged to document the product has been harvested from approved waters.
- The possibility that unacceptable levels of environmental chemical hazards such as PCBs will be present in fish can be **reduced to acceptable levels** at the receiving step by ensuring that the fish were not harvested from waters that have been closed by local or state health authorities.
- The possibility of pathogen growth can **be reduced to acceptable levels** at a storage step by controlling cooler temperatures or using adequate ice.

Slide 6

CCPs can be steps where hazards can be **reduced to acceptable levels.**

Multiple CCPs and Multiple Hazards

A single CCP can be used to control more than one hazard. For example, the step where live oysters or clams are received provides an example of when a single CCP could control multiple hazards. Source related hazards for this product such as harvest site pathogens, natural toxins and chemical contaminants could all be controlled at the receiving step by making sure that the shellstock is from an approved source and properly tagged (Slide 7).

In some circumstances, more than one CCP may be needed to control a single significant hazard. For example, receiving and refrigerated storage steps may be CCPs for a histamine hazard. This is because histamine can develop in these fish at any time if there is time and temperature abuse. Any step in the process where there is a potential for significant time/temperature abuse must be identified as a CCP (Slide 7).

Slide 7

Multiple Hazards and Single CCP
Product = Live oysters (shellstock)
Hazards = Harvest site pathogens + Natural Toxins + Chemical Contaminants
Single CCP = Receiving

Single Hazard and Multiple CCPs
Product = Fresh Tuna loins
Hazard = Histamine
Multiple CCPs = Receiving + Refrigerated Storage

CCPs are Product- and Process-Specific

CCPs that have been identified for a product on one processing line may be different for the same product on another processing line. This is because the hazards and their processing controls are impacted by the layout of the plant or processing line, the formulation of the finished product, the process flow diagram or sequence of processing steps, the processing equipment that is used, the sanitation and support programs that are used, and ingredients that may be used (Slide 8).

Slide 8

CCP are product- and process-specific and impacted by:
- Layout of the plant or processing line,
- Finished product formulation,
- Process flow or sequence of processing steps,
- Processing equipment,
- Ingredients,
- Sanitation or other support programs.

Tools to Help Identify CCPs

There are several tools available to help identify which steps are likely to be CCPs for various types of hazards.

Hazards Guide – The Hazards Guide provides guidance on likely CCPs for each of the potential seafood safety hazards associated with seafood products. The Hazards Guide has a chapter for each of these food safety hazards. There

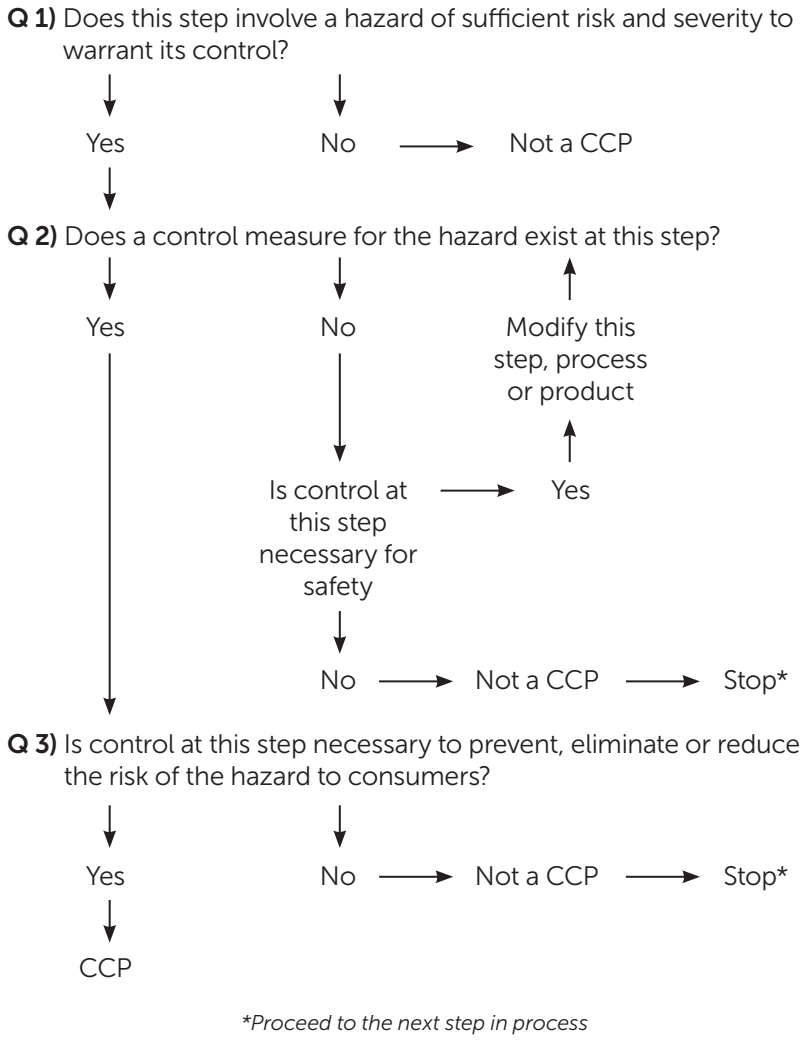
is a specific section in each of these chapters that provides information for decisions regarding CCP placement.

CCP Decision Tree – Another tool that can help identify which steps are CCPs is the CCP Decision Tree. This tool has a series of questions that can help identify the CCPs in the process. These questions can be applied at each of the processing steps where a significant hazard was identified in the hazard analysis.

The CCP Decision Tree asks a series of three questions that will lead you to decide if a specific processing step is a CCP (Slide 9).

Slide 9

CCP Decision Tree



**Proceed to the next step in process*

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Receiving

In the hazard analysis, XYZ Seafood Company identified histamine as a significant food safety hazard at the receiving step. The CCP Decision Tree can be used to determine if the receiving step is a CCP to control the hazard of histamine.

Question 1) Does this step involve a hazard of sufficient risk and severity to warrant its control?

Answer: Yes – Histamine is a significant hazard for mahi-mahi that could cause consumer illness. Time-temperature abuse during transit could cause histamine to form in fillets.

Question 2) Does a control measure for the hazard exist at this step?

Answer: Yes – Mahi-mahi fillets are received in containers buried in ice.

Question 3) Is control at this step necessary to prevent, eliminate or reduce the risk of the hazard to consumers?

Answer: Yes – The hazard of histamine must be prevented at this step.

Conclusion: The receiving step is a CCP for the hazard of histamine.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Complete Hazard Analysis Worksheet

The hazard analysis worksheet summarizes the results of the complete hazard analysis for XYZ Seafood Company (Slide 10).

XYZ Seafood Company has identified the following CCPs for fresh mahi-mahi fillets:

- Three CCPs to control histamine
  1) Receiving fresh fillets
  2) Refrigerated storage
  3) Finished product refrigerated storage
- One CCP to control food allergens
  1) Weigh/Pack/Label

Slide 10

XYZ Seafood Company – Fresh Mahi-mahi Fillets

Hazard Analysis Worksheet					
Firm Name: XYZ Seafood Company			**Product Description:** Fresh mahi-mahi fillets		
Firm Address: 238 Coastal Lane, Happy Beach, XX			**Method of Storage & Distribution:** Stored and distributed on ice		
			Intended Use & Consumer: To be cooked and consumed by the general public		
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receive Fresh Fillets	Histamine	Yes	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi fillets are shipped in containers buried in ice (proper icing)	Yes
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	No
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Slide 10 (cont.)

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Refrigerated Storage	Histamine	Yes	Time/temp. abuse during storage could cause histamine to form in the fish	Mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	Yes
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Fish is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	No
	Food Intolerance Substances	No	No FIS are used on fresh fillets		No
	Metal Inclusion	No	Not likely to occur at this step		
Trim	Histamine	No	Not likely to occur, time at this an dweigh/pack/label step is 30 min or less		
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets will be labeled with market name at weigh/pack/label step (proper labeling)	No
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Fillet knives are not likely to chip and contaminate product with metal		

Slide 10 (cont.)

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Weigh/Pack/Label	Histamine	No	Not likely to occur, time at this an dweigh/pack/label step is 30 min or less		
	Pathogen Growth - Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	Yes	Mahi is a food allergen	Fillets are labeled with market name at this step (proper labeling)	Yes
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		
Finished Product Refrgerated Storage	Histamine	Yes	Time/temperature abuse could uccur during storage	Mahi-mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing)	Yes
	Pathogen Growth -Temperature Abuse	No	Not likely to cause illness as the intended use for the product is to be cooked by or for the consumer prior to consumption		
	Food Allergens	No	Fillets were labeled with market name at weigh/pack/label step		
	Food Intolerance Substances	No	No FIS are used on fresh fillets		
	Metal Inclusion	No	Not likely to occur at this step		

Chapter 7

Principle 3: Establish Critical Limits

All of the remaining HACCP principles apply only to critical control points (CCPs).

Critical limits must be established for each hazard at each CCP identified in the hazard analysis (Slide 1). This is the third principle of HACCP.

Slide 1

In this chapter, you will learn:
- Definition of critical limit.
- How to determine critical limits for a CCP.
- The relationship between critical limits and operating limits.
- Use of the HACCP plan form.

A critical limit represents the boundaries that are used to ensure that a hazard has been controlled (prevented, eliminated, or reduced to an acceptable level) at each CCP (Slide 2). Critical limits must be based on what science or industry experience has demonstrated is necessary to control the hazard.

Slide 2

Definition:
Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.

Information Sources for Establishing Critical Limits

The Hazards Guide provides critical limit information for most seafood safety hazards. Other information may be needed to establish valid critical limits for a CCP. These other sources of information (see chapter 13) could include process authorities, scientific studies, trade associations, other state or federal regulations. However, in some cases, the appropriate critical limit may not be readily apparent or available. Information may need to be gathered from other sources such as scientific publications, experts or experimental studies (Slide 3).

Slide 3

Sources of Information on Critical Limits (see chapter 13)

Information Source	Examples
FDA	Hazards Guide
Regulations and guidelines	State and local regulations, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances and action levels, and the National Shellfish Sanitation Program (NSSP) Model Ordinance for Molluscan Shellfish
Experts	Process authorities; university food scientists/microbiologists, consultants, equipment manufacturers, sanitarians, and trade associations
Scientific studies	In-house experiments and contract labs or universities
Scientific information	Journal articles, food science texts, microbiology texts, and National Seafood HACCP Alliance Compendium

There are many different types of critical limits. They must be specific for the critical control point and the hazard that is being controlled (Slide 4 and 5). Different critical limits may be needed for species-related hazards and process-related hazards.

Each CCP must have one or more critical limits for each food-safety hazard (Slide 6). An effective critical limit will define what can be measured or observed to demonstrate that the hazard is being controlled at that CCP. For example, both time and temperature are necessary elements of a critical limit to eliminate food safety hazards like pathogens at a cook step.

Slide 4

Examples of Critical Limits for species-related hazards

Product	Significant Hazard	Critical Control Point	Critical Limits
Aquacultured shrimp	Aquaculture drugs	Receiving (from farm)	Suppliers certificate on file (indicating proper drug use)
Oysters (live)	Natural toxins	Receiving (from harvester)	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel and all shellstock from waters approved by State Shellfish Authority and all shellstock from a licensed harvester
Raw Tuna	Histamine	Storage	Fish are completely surrounded by ice

Slide 5

Examples of Critical Limits for process-related hazards

Product	Significant Hazard	Critical Control Point	Critical Limits
Battered fish	*Staphylococcus aureus* growth and toxin formation	Batter application	Hydrated batter does not exceed 50°F for more than 12 hrs. or 70°F for more than 3 hrs., cumulative.
Imitation crabmeat	Metal inclusion	Metal detector (after packaging)	No detectable metal fragments in finished product
Hot smoked fish, vacuum packaged	*Clostridium botulinum* toxin formation (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes
Ready-to-eat seafood salad	Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F

Slide 6

Examples of Critical Limits

Hazard	CCP	Critical Limits
Pathogen survival through cooking	Cooker	≥160°F internal product temperature for ≥1.5 minutes for elimination of pathogens of concern in cooked crabs (e.g. *Listeria monocytogenes*)
Pathogen growth	Drying oven	Drying schedule — oven temperature: ≥ 200°F, time ≥120 min., air flow rate: ≥ 2 ft^3/min, product thickness ≤0.5 inches (to achieve a_w of 0.85 to control pathogens in dried foods)
Pathogen growth	Acidification	Batch schedule — product weight, ≤ 100 lbs.; soak time, ≥ 8 hrs; acetic acid concentration, ≥ 3.5 percent; volume ≤ 50 gal. (to achieve maximum pH of 4.6 to control *Clostridium botulinum* in pickled foods)

Critical Limit Options

Processors may have different options for controlling a particular hazard. Each control option usually requires the use of different critical limits. The selection of the best control option and the best critical limit is often driven by practicality and experience. The following examples describe three different options for effective control measures and critical limits that could be applied at a fryer (cooking) CCP to eliminate the hazard of bacterial pathogens in fried fish cakes.

Option 1 is not typically the best option (Slide 7). Setting a critical limit such as "no pathogens detected" is rarely appropriate. This type of critical limit is difficult to monitor, and testing to determine critical limit deviations may require several days. Critical limits must allow monitoring on a timely basis. Sampling and testing is normally more appropriate as a verification step, described later in this course.

Slide 7

Option No. 1
Product: Fish cakes
Hazard — pathogen survival through cooking
CCP — fryer
Critical limit — no pathogens detected

Option 2 uses the internal product temperature and time achieved during frying as a critical limit (Slide 8). This critical limit option is more practical than finished product pathogen testing. However, internal product temperature and time cannot be easily monitored for all of the products that are cooked, and heat transfer rates during cooking could vary for a variety of reasons. For this reason, it would be difficult to measure whether or not this critical limit has been met for all products.

Slide 8

Option No. 2
Product: Fish cakes
Hazard — pathogen survival through cooking
CCP — fryer
Critical limit — minimum internal temperature of 165°F for 36 seconds

It seldom is practical to continually monitor the internal temperature of the food product to ensure conformance with a critical limit. As an alternative, critical limits such as those in Option 3 may establish conditions necessary to ensure that the cooking process achieves the minimum product temperature and time. In this option, the oil temperature, the fish cake thickness and the time that the cake stays in the hot oil are all factors that affect the final fish cake temperature (Slide 9). These factors are easy to monitor and measurements are obtained quickly to determine that critical limits have been met. A scientific study (validation) must be performed to ensure that controlling these factors will always result in an internal product temperature that will destroy pathogens of concern. Typically, this option is better than the two previous options even though more critical limits are involved.

Slide 9

Option No. 3
Product: Fish cakes
Hazard —pathogen survival
CCP — fryer
Critical limit — minimum fryer oil temperature of 350°F
Critical limit — maximum fish cake thickness of ¾ inch
Critical limit — minimum cook time in the oil of two minutes

Operating Limits and Critical Limits

An operating limit allows the detection of a potential problem before a critical limit is violated (Slide 10). Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated. The process should be adjusted when the operating limit is reached to avoid violating critical limits. These actions are called

process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product re-work, or worse yet, product destruction.

Slide 10

Definition:
Operating Limits: Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

Operating limits may be selected for various reasons:

- For quality reasons (e.g., higher cooking temperatures may enhance flavor development or to control organisms that can cause spoilage);
- To avoid deviating from a Critical Limit, processors often establish an Operating Limit that is more stringent that the Critical Limit. For example, a processor could establish a cooking temperature Operating Limit that is higher than the HACCP Critical Limit. If monitoring indicated that temperatures fell below the Operating Limit, the processor would have time to initiate a Process Adjustment to avoid a Critical Limit deviation;
- To account for normal variability (e.g., a fryer with a 5°F variability should be set at least 5°F above the critical limit to avoid violating it).

Slide 11 illustrates several important points:

- Operating limits and process adjustments,
- Critical limits and corrective actions, and
- Importance of lot size.

Note

For 'lots' or 'batches', it is important to distinguish the lot size, batches or similar portions of products involved in processing. These designations can determine the products involved in various HACCP procedures.

In this example, of a cooking process, an operating limit is established at 200°F and a critical limit at 190°F. Somewhere in the 10°F range between these two points, processors will make a process adjustment to bring the cook temperature back above 200°F. Because an adjustment is made before the temperature drops below the critical limit of 190°F, no corrective action record is required. However, if an adjustment is not taken until after the temperature drops below the critical limit, as shown in Slide 11, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file (corrective actions and records will be discussed in subsequent chapters).

Distinguishing Product Involved in 'Lots' or 'Batches'

Often processing operations handle a quantity of products that are identified as a lot, batch or similar name for the portion of items involved. Likewise, a group of products could be part of a batch, and the batch was part of an initial lot. These terms are useful for routine operations but they can be very significant designations regarding HACCP plans and procedures. For example, when a corrective action is necessary, processors must be able to identify and segregate the affected lots. If lot sizes are big (Figure 1), large quantities

of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Lot size also relates to effective traceability and recalls. Coding production into smaller lots (Figure 2) means less product may be involved when violation of a critical limit occurs. Therefore, processors should change codes often and match monitoring frequency with code changes.

Slide 11

Figure 1

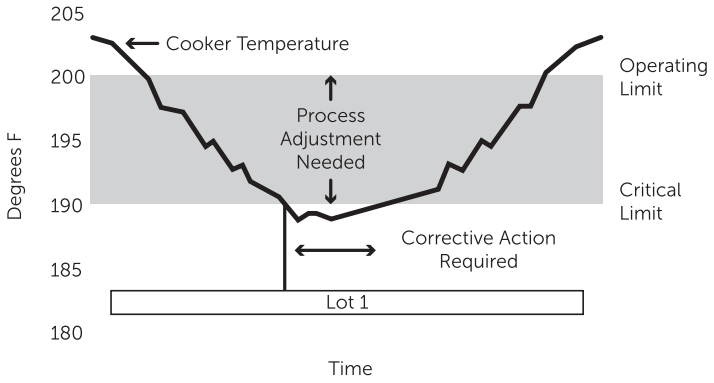
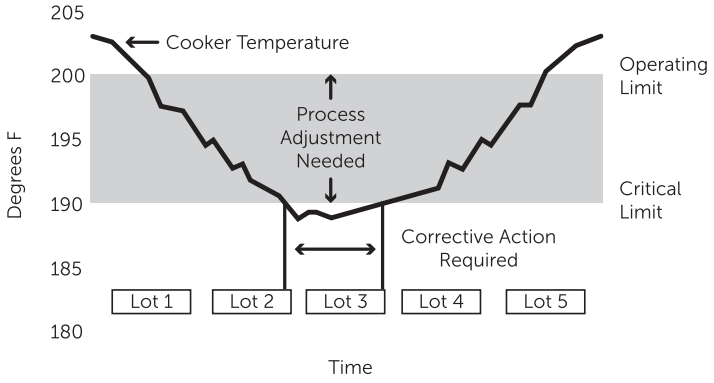


Figure 2



HACCP Plan Form

A standardized HACCP plan form (Slide 12) is designed to ensure that HACCP Principles 3 through 7 are adequately described when the HACCP plan is developed. A written HACCP plan is required by the FDA Seafood HACCP Regulation when the hazard analysis determines that there are one or more significant safety hazards, and this plan must be made available to inspectors.

Slide 12

Blank HACCP Form

Firm Name: _____ HACCP Plan Form Product: _____

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

The HACCP plan form is used to:

- List the CCPs from the hazard analysis worksheet in the first column.
- List the significant hazards at each CCP in the second column.
- List the critical limits for each significant hazard in the third column.
- List all elements of monitoring (what, how, frequency, and who) in the fourth column.
- List corrective actions in the fifth column.
- List verification procedures in sixth column.
- List records in the last column.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company's hazard analysis, described in the previous two chapters, identified four critical controls points, including: 1) the receiving step is a CCP for the hazard of histamine; 2) the refrigerated storage step is a CCP for the hazard of histamine; 3) the weigh/pack/label step is a CCP for the hazard of food allergens; and 4) the finished product storage step is a CCP for the hazard of histamine.

Receiving CCP: The HACCP team used the Hazards Guide to determine the critical limits for this CCP. XYZ Seafood Company is a secondary processor who receives and stores mahi-mahi fillets on ice. Control Strategy 3, Transit Control, in Chapter 7 (Histamine) of the Hazards Guide is the best control strategy. This strategy recommends a critical limit of: **fish completely surrounded by ice at the time of delivery**.

This critical limit is entered in the HACCP plan form.

Refrigerated Storage is the second CCP for the hazard of histamine. This step and the **Finished Product Storage** CCP occur in the same cooler. Both steps also have same hazard (histamine), and the same control strategy is used for each step. The HACCP Team identified Storage Controls in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their CCP. This strategy recommends a critical limit of: **Mahi-mahi fillets are completely surrounded by ice throughout storage time**.

This critical limit is entered in the HACCP plan form for each of these two CCPs.

Weigh/Pack/Label CCP: The HACCP Team identified Control Strategy 8. Finished Product Labeling Controls, in Chapter 19 (Major Food Allergens and Food Intolerance Substances) of the Hazards Guide as the best control strategy for their situation. This strategy recommends a critical limit of: **all finished product containers will be labeled with the correct market name of the fish**.

This critical limit is entered in the HACCP plan form for this CCP.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Complete HACCP Plan Form – Critical Limits

The HACCP plan form must list the critical limits at each CCP. The first three columns of the HACCP plan form have been completed for XYZ Seafood Company's fresh mahi-mahi fillets (Slide 13).

Slide 13

Firm Name: *XYZ Seafood Company*

HACCP Plan Form

Product: *Fresh mahi-mahi fillets*

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt.							
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.							
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name of the fish.							
Finished Product Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.							

Firm Name: XYZ Seafood Company	**Product:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature: _____ Print name: _____	Date: _____

Chapter 8

Principle 4: Critical Control Point Monitoring

CCP monitoring is used to ensure that a critical limit is met (Slide 1). Monitoring is the fourth principle of HACCP.

Slide 1

In this chapter, you will learn:
- Definition of monitoring,
- Purpose of monitoring,
- Design of a monitoring system,
- Methods and equipment for monitoring critical limits.

Monitoring involves the selection of appropriate **measurements** or **observations** at a specified frequency to ensure that a CCP is under control (Slide 2).

Slide 2

Definition:
Monitoring: A planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record to demonstrate that critical limits have been met.

The purpose of monitoring is to ensure that the critical limit has been met and the food safety hazard is being controlled. Monitoring also provides data for records to document that products were produced in compliance with the HACCP plan. It is important that monitoring procedures are specific for the identified critical limit. For example, if the critical limit requires adequate ice,

the monitoring procedure would be a visual check for ice and not a check for product temperature. When a critical limit is not met, a corrective action is needed (Slide 3).

Slide 3

Purpose of Monitoring:
- To ensure that a critical limit is met,
- To provide documentation that critical limits have been met,
- To identify when there is loss of control (a deviation occurs at a CCP).

There are four elements that are required in an effective monitoring system (Slide 4).

Slide 4

Elements of Monitoring
- What will be monitored?
- How will monitoring be performed?
- What is the frequency of monitoring?
- Who will conduct the monitoring?

What will be monitored?

Monitoring may involve measuring a characteristic of the product or process to determine if a critical limit is met at a CCP (Slide 5).

Examples of monitoring **measurements** could include:

- Cold-storage temperature when cooler temperature is part of the critical limit.
- The pH of an acidifying ingredient when pH is part of the critical limit.
- Line speed and cooker temperature when cook time and temperature are part of the critical limit.

Monitoring may also involve observations to determine if a critical limit is met at a CCP.

Examples of monitoring **observations** could include:

- Look for a vendor's certificate that accompanies a lot of raw material when approved source is part of the critical limit.
- Check if fish are surrounded with ice when adequacy of ice is part of the critical limit.
- Check to see that harvest area is listed on a tag attached to a container of molluscan shellfish when approved source is part of the critical limit.

Slide 5

What will be monitored?
A **measurement** or **observation** to assess if the CCP is operating within the critical limit.

How will monitoring be performed?

Different methods can be used to monitor critical limits (Slide 6). These methods need to be real-time and accurate.

Using instruments to measure a critical limit quantity is an effective way to conduct monitoring at a CCP. Examples of monitoring instruments could include thermometers, pH meters, water activity meters, data loggers, etc.

Monitoring methods can also involve visually checking what you are monitoring. For example a visual check for the adequacy of ice; an evaluation of sensory attributes of products; or a visual check of supplier certificates.

It must be clear from an observation whether or not a Critical Limit has been violated. For example, a Critical Limit of "adequate use of ice" is subjective and imprecise, making it difficult to monitor. Monitoring and records must be unambiguous and can be acted upon. Monitoring should be designed to provide rapid, real-time results. Microbiological testing is seldom effective for monitoring CCPs. Very often the analytical methods are lengthy and large sample sizes are usually needed to ensure all units of product conform to microbiological limits. There is no time for lengthy analytical testing during routine monitoring because critical limit failures must be detected quickly and an appropriate corrective action instituted before product shipment.

Slide 6

How will monitoring be performed?
- Measurements (quantitative critical limits) or observations (qualitative critical limits).
- Needs to be real-time and accurate.

What is the frequency of monitoring?

Monitoring frequency will depend on the critical limit and the types of observations and measurements that are needed. The frequency of monitoring can be at regularly scheduled intervals (non-continuous) or continuous (Slide 7).

Slide 7

What is the frequency of monitoring?
- Monitoring frequency should be sufficient to ensure that the critical limit is met.
- Monitoring frequency can be **non-continuous** or **continuous**.

Non-continuous Monitoring

It is necessary to establish a monitoring interval that ensures critical limits are met. The frequency of non-continuous (periodic) monitoring could be influenced by historical knowledge of the product and process.

Questions that could help determine the correct frequency include:

- How much does the process normally vary (e.g., how consistent is the data)? If the monitoring data shows a great deal of variation, the time between monitoring checks should be short.
- How close are the normal operating values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much product is the processor prepared to risk if the critical limit is exceeded?

Examples of non-continuous monitoring include:

- Visual daily checks that fish are adequately iced.
- Sensory examination for decomposition in histamine-forming seafood at receipt from the vessel.
- End Point Internal Product Temperature (EPIPT) of cooked crab sections.

Continuous Monitoring

When possible, continuous monitoring procedures should be used. Continuous monitoring is generally performed by an instrument that produces a continuous record. The record needs to be checked periodically to ensure that the critical limit is being met. The length of time between checks will directly affect the amount of rework or product loss when a critical limit deviation is found.

Examples of continuous monitoring could include:

- The time and temperature of a batch pasteurization process for crabmeat may be continuously monitored and recorded on a temperature-recording chart.
- The temperature of a molluscan shellfish storage cooler is continuously monitored and recorded.

Who will Monitor?

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan (Slide 8).

Slide 8

Who will monitor?
Person(s) trained to perform the specific monitoring activity and/or a continuous monitoring device.

Individuals assigned to CCP monitoring can be:

- Line personnel,
- Equipment operators,
- Supervisors,
- Maintenance personnel, or
- Quality assurance personnel.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously watching the product and/or equipment. Including production workers in HACCP activities has the advantage of building a broad base of understanding and commitment to the HACCP program.

The monitor's duties should require that all deviations from operating limits and critical limits be reported immediately to make sure process adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring (Slide 9).

Slide 9

Those responsible for monitoring a CCP should:
- Be trained in the CCP monitoring techniques.
- Fully understand the importance of CCP monitoring.
- Have ready access to the monitoring activity.
- Accurately report each monitoring activity.
- Immediately report critical limit deviations.

Properly trained personnel must be available at all times that the CCP requires monitoring. Additional monitoring personnel may be needed when monitoring is required during breaks, weekends, or when monitoring is required throughout multiple work shifts.

Some examples of **measurements** and **observations** that could be used for monitoring a critical limit at a CCP are provided below (Slide 10).

Slide 10

Monitoring Examples:
- Time and temperature of process
- Time and internal temperature combinations
- Water activity (a_w)
- pH
- Internal product temperature
- Salt concentration in brine
- Metal inclusion screening

Critical Limit for a Cooking CCP: minimum cooker temperature of 212°F for a minimum of three minutes

- **What will be monitored?** cooker temperature and time
- **How will it be monitored?** time/temperature recording device and visual observation
- **Frequency of monitoring:** continuous with visual check for each batch
- **Who will monitor?** cooker/operator

Critical Limit for Refrigerated Storage Step: all fish completely surrounded by ice

- **What will be monitored?** adequacy of ice
- **How will it be monitored?** visual
- **Frequency of monitoring:** twice a day
- **Who will monitor?** cooler person

Critical Limit at Acidification Step: acidity (pH) less than 4.6

- **What will be monitored?** pH
- **How will it be monitored?** pH meter
- **Frequency of monitoring:** each batch
- **Who will monitor?** QC person

Critical Limit at Labeling Step: product label identifies market name of seafood

- **What will be monitored?** finished product label
- **How will it be monitored?** visual
- **Frequency of monitoring:** at the start of the production lot AND at least every 2 hours OR when new containers of labels are opened or rolls of labels are changed.
- **Who will monitor?** packaging manager

Monitoring Equipment

The selection of the proper monitoring equipment, which could include instruments such as thermometers and rapid test kits, is a major consideration during development of a HACCP plan. There are many different kinds of monitoring instruments or tools that may be appropriate for different critical limits (Slide 11).

Slide 11

Examples of monitoring equipment could include:

- thermometers
- recorder charts
- clocks
- pH meters
- water activity meters
- data loggers
- metal detectors
- salometer

The equipment chosen for monitoring at the CCP must be accurate to ensure control of the hazard. Equipment used to monitor critical limits must be calibrated at a frequency that ensures accuracy. For example, the accuracy and calibration of temperature measuring instruments should be checked frequently or as recommended by the device manufacturer. Accuracy and calibration are further discussed in Chapter 10 (Principle 6: Establish Verification Procedures).

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company identified four critical controls points in the hazard analysis. There are three CCPs for the hazard of histamine: receiving, refrigerated storage, and finished product storage. There is one CCP for the hazard of food allergens: weigh/pack/label.

Receiving CCP: The HACCP team used the Hazards Guide to determine the monitoring procedures for the CCP. The HACCP Team identified Control Strategy 3, Transit Control, in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their situation. This strategy recommends a monitoring procedure that includes the following elements:

- What: adequacy of ice surrounding containers of fillets at delivery
- How: visual check of adequacy of ice in a representative number of containers at delivery
- Frequency: every delivery
- Who: receiving manager

This monitoring information is entered in the HACCP plan form.

Refrigerated Storage and Finished Product Storage CCPs: The HACCP team identified "Control Strategy 5, Storage Control," in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their CCP. This strategy recommends a monitoring procedure that includes the following elements:

- What: adequacy of ice surrounding containers of fillets in the cooler
- How: visual check of adequacy of ice in a representative number of containers in the cooler
- Frequency: at the beginning and end of the work day
- Who: cooler manager

This monitoring information is entered in the HACCP plan form.

Note

Representative numbers can be based on the size of the lot or total number of containers and experience regarding the possible amount of variation within the lot.

Weigh/Pack/Label CCP: The HACCP team identified "Control Strategy 8, Finished Product Labeling Controls," in Chapter 19 (Undeclared Major Food Allergens and Food Intolerance Substances) of the Hazards Guide as the best control strategy for their situation. This strategy recommends a monitoring procedure that includes the following elements:

- What: the market name on each container of finished product
- How: visual check finished product label
- Frequency: at the start of the production lot AND at least every 2 hours OR when new containers of labels are opened or rolls of labels are changed.
- Who: packing manager

This monitoring information is entered in the HACCP plan form.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Complete HACCP Plan Form – Monitoring

The HACCP plan form must list the monitoring procedures at each CCP (Slide 12).

Note

Because the firm in the example, XYZ Seafood Company, is a small operation and completes customer orders in less than 2 hours, the frequency listed on the example HACCP Plan (Slide 12) states "Each customer order."

Slide 12

HACCP plan form for XYZ Seafood Company completed through monitoring

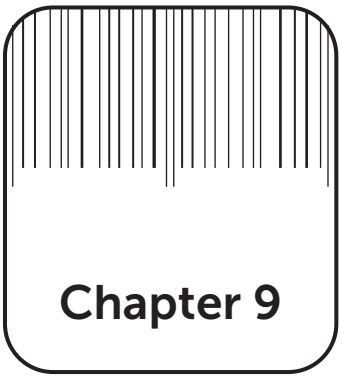
Firm Name: XYZ Seafood Company

HACCP Plan Form

Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt.	Adequacy of ice surrounding mahi-mahi fillets at delivery	Visual check of adequacy of ice in a representative number of containers in each delivery	Every Delivery	Receiving Manager			
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager			
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name	The market name on each container of finished product	Visual check of a representative number of containers and their label	Each customer order	Packing Manager			
Finished Product Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager			

Firm Name: XYZ Seafood Company	**Product:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature: _____ Print name: _____	Date: _____



Chapter 9

Principle 5: Corrective Actions

Corrective Actions are taken when a critical limit is not met. Corrective action is the fifth principle of HACCP (Slide 1).

Slide 1

In this chapter, you will learn:
- The definition of corrective actions,
- Procedures for corrective actions, and
- Record-keeping requirements for corrective actions.

A HACCP system should be designed to ensure that critical limit deviations are rapidly identified and corrected (Slide 2). The responsibility for taking corrective actions must be assigned to one or more individuals who have a thorough understanding of the operation, the products, the firm's HACCP plan, and the authority to make decisions.

Slide 2

Definition:
Corrective Action: Procedures to be followed when a deviation occurs.

Predetermined Corrective Actions

Predetermined corrective actions provide a "how-to" guide that describes the steps that need to be taken when a critical limit deviation occurs (Slide 3). It

may be possible, and is always desirable, to correct the problem immediately. Although it may not be possible to anticipate all the deviations that could happen, corrective actions still need to be taken even when an unanticipated situation occurs.

Slide 3

Predetermined corrective actions are recommended.

Components of Corrective Actions

There are two essential parts to a corrective action (Slide 4). The objectives of the corrective action are to keep potentially unsafe product from reaching the consumer and to restore control to the process prior to producing more product.

When a deviation is detected, the first action is to identify the product involved. This product should be segregated and evaluated to determine if a food safety hazard exists. If a hazard exists, the affected product must be reworked or destroyed to ensure it will not cause consumer illness.

Process control must also be restored. Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to re-establish control of the process so that production can start again as soon as possible without further deviations.

Slide 4

Corrective action components:
1) Identify the product that was produced during the process deviation, evaluate its safety and determine its disposition.
2) Correct and eliminate the cause of the deviation and restore process control.

Tools to Help Evaluate Product Safety

A qualified individual must be assigned responsibility for evaluating product safety (Slide 5). Not every firm has an expert on staff that can evaluate the safety of products involved in a deviation. It may be necessary to identify additional resources that can help with product safety evaluations.

The Hazards Guide is an important tool that can assist with corrective actions and any necessary product safety evaluations. For example, Appendix 4 of the Hazards Guide provides information on bacterial pathogen growth and inactivation. Hazards Guide Table #A-2 provides maximum cumulative time/temperature guidance for controlling pathogen growth and toxin formation in seafood. Information on appropriate corrective actions is also outlined in

the control strategies provided in each of the hazard specific chapters in the Hazards Guide.

Slide 5

Tools to help evaluate product safety:
- Food Safety Experts
- Production monitoring data/records
- NSSP Shellfish Model Ordinance
- Hazards Guide
  - Appendix 4: Pathogen Tables
  - Appendix 5: Guidance Levels
- Laboratory testing

Examples:

- Using the Hazards Guide, a processor who produces a battered seafood product has determined that the batter step is a CCP for the hazard of *Staphylococcus aureus* toxin. The critical limit is: batter temperature is at or below 50°F. If monitoring shows that the batter temperature is 65°F, the critical limit has not been met and a corrective action must be taken. To help evaluate product safety, Hazards Guide Table #A-2 can be used to determine if toxin production could have occurred. This table shows that cumulative exposure time to temperatures between 50°F and 70°F must be no more than 12 hours for toxin to be produced. The monitoring records show that the exposure time above 50°F and less than 70°F was less than 4 hours. Therefore, the product produced with this batter was not exposed to conditions that would have allowed toxin to be produced and created a food safety hazard.
- For bivalve molluscan shellfish operations, the NSSP Shellfish Model Ordinance (www.issc.org) provides information that may be used to evaluate product safety when a deviation occurs.
- Laboratory testing could also provide valuable information to evaluate product safety. Important considerations when using test results include: a valid sampling protocol must be used, the pertinent pathogen or chemical of interest must be accurately identified, and an approved/recognized testing method must be used. If a product is to be tested and released, the sampling method is very important. The use of a faulty sampling protocol can result in accepting, rather than rejecting, an undesirable product. The limits of sampling plans must be understood. It may be prudent to consult an expert.

Determine Product Disposition

A proper and thorough safety evaluation is necessary to determine the disposition of the product (Slide 6). It is best to be cautious, but product destruction may not always be necessary. Decisions related to the disposition of the affected product must be based on sound evidence that the deviation did not create a food safety hazard. This evidence must be documented to

support the decision. Like other Corrective Actions, if the product is rejected or destroyed, the processor needs to document that this has been done.

Slide 6

Steps to determine the disposition of product:
Step 1: Determine if the product presents a safety hazard.
Step 2: If no hazard exists, the product may be released.
Step 3: If a potential hazard exists, determine if the product can be:
a) Reworked/reprocessed, or
b) Diverted for a safe use.
Step 4: If a food safety hazard does exist, the product must be rejected or destroyed.

Correct and Eliminate the Cause of the Deviation and Restore Process Control

It is necessary to determine the cause of the deviation to prevent the same problems from occurring again (Slide 7). **When critical limit deviations frequently reoccur, the process and the HACCP plan must be re-evaluated**. The initial cause or causes of the process deviation must be identified and corrected so that process control can be restored.

Slide 7

Corrective actions must identify the cause of the deviation and restore process control.

Documenting Corrective Actions

Corrective actions must be documented (Slide 8). Corrective action records will show how the safety of the product was evaluated and its disposition. This record will also document the actions taken to fix the problem that caused the deviation and restore process control. These records will help the firm identify recurring problems. This information can be used to evaluate and modify the HACCP plan, if necessary.

Slide 8

Corrective actions must be documented to indicate the safety status and consequences for the products and process involved.

Processors must develop a corrective-action record to ensure that all of the necessary information is documented (Slide 9). This corrective action report is required by the FDA Seafood HACCP regulation.

Slide 9

Sample Corrective Action Report

Company Name: Street Address, City Name, State:

Product Identification:

Date: Code or Lot Number:

Date and Time of Deviation:

Description of Deviation:

What Actions were taken to Restore Order to the Process:

Person (name and signature) of Person Taking Action:

Amount of Product Involved in Deviation:

Evaluation of Product involved with Deviation:

Final Disposition of Product:

Reviewed by (Name and Signature): Date:

A corrective action record would typically include:

a) Product identification (product description and the amount on hold)
b) Description of the deviation, including time and date of deviation
c) Results of the food safety evaluation including test results, when necessary
d) Corrective action taken including:
   • How the cause of the deviation was corrected
   • Final disposition of the affected product
e) Name and signature of the individual responsible for taking the corrective action
f) Signature and date of the review

Corrective Action Examples

Slides 10 and 11 provide examples for simple corrective actions for various types of food safety hazards. They are best written in an "If/Then" format. The "If" part of the corrective action describes the deviation condition, and the "then" part describes the action taken.

Slide 10

Corrective action examples for species-related hazards

Critical Control Point	Significant Hazard	Critical Limit	Corrective Actions
Receiving aquacultured shrimp from the farm	Aquaculture drugs	Supplier certificate on file (indicating proper drug use)	**If:** supplier certificate is not on file; **Then:** reject lot and discontinue using supplier until appropriate, accurate certificate obtained.
Receiving live oysters from the harvester	Natural toxins	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel and All shellstock from waters approved by State Shellfish Authority and All shellstock from a licensed harvester.	**If:** shellstock tags are missing and/or do not have required information; **Then:** reject shellstock. **If:** harvester not licensed or harvest waters are not approved; **Then:** reject shellstock and discontinue purchasing from harvester until properly licensed.

Slide 11

Corrective action examples for process-related hazards

Critical Control Point	Significant Hazard	Critical Limit	Corrective Actions
Batter application	*Staphylococcus aureus* growth and toxin formation	Hydrated batter does not exceed 50°F for more than 12 hrs. or 70°F for more than 3 hrs., cumulatively	**If:** batter temperature and time (cumulative) exceeds critical limits; **Then:** destroy batter and product produced during period of deviation or hold and evaluate product for for product safety, and adjust/repair refrigeration equipment for batter.
Metal detector (after packaging)	Metal inclusion	No detectable metal fragments in product	**If:** product is rejected by metal detector; **Then:** rework product to remove metal if possible and pass through metal detector or destroy product, and re-calibrate metal detector to determine if it is working properly and adjust as necessary and determine the source of metal and fix the problem.
Hot smoking (vacuum packaged)	*Clostridium botulinum* toxin formation (in finished product)	Internal fish temperature held at or above 145°F for at least 30 minutes	**If:** product does not reach required internal temperature for the required time; **Then:** extend cook time until proper internal temperature is met or re-cook product to 145°F for 30 minutes or destroy product, and make repairs/ adjustments to equipment to ensure process meets critical limits.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company identified four critical controls points in the hazard analysis. There are three CCPs for the hazard of histamine: receiving, refrigerated storage and finished product storage. There is one CCP for the hazard of food allergens: weigh/pack/label. The HACCP team used the Hazards Guide to determine what corrective action procedures are needed in their HACCP plan.

Note

In some instances where there is historical information on the transport of the product, the Corrective Action could state:

If: the amount of ice is not adequate; Then: check the internal temperature of the exposed fish. Reject all fish that exceed 40°F internal temperature or lack sufficient transport history.

Receiving CCP: The HACCP Team identified "Control Strategy 3, Transit Control," in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their situation. This control strategy recommends a corrective action of:

If: the amount of ice is not adequate;

Then: reject product. Call supplier to let them know critical limit was not met and provide product delivery specifications. Discontinue use of supplier until their transport procedures are corrected.

This corrective action is entered in the HACCP plan form.

Refrigerated Storage and Finished Product Storage CCPs: The HACCP Team identified Storage Controls in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their CCP. This strategy recommends a corrective action of:

If: the amount of ice is not adequate;

Then: Add ice and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations. Determine the cause of the problem and fix it.

This corrective action is entered in the HACCP plan form.

Weigh/Pack/Label CCP: The HACCP Team identified Finished Product Labeling Controls in Chapter 19 (Undeclared Major Food Allergens and Food Intolerance Substances) of the Hazards Guide as the best control strategy for their situation. This strategy recommends a corrective action of:

If: a container is improperly labeled,

Then: segregate it and properly label it before the customer order is placed in the finished product cooler. Modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.

This corrective action is entered in the HACCP plan form.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Complete HACCP Plan Form – Corrective Action

Slide 12 HACCP plan form for XYZ Seafood Company completed through Corrective Action

Slide 12

HACCP plan form for XYZ Seafood Company completed through corrective action

Firm Name: XYZ Seafood Company

HACCP Plan Form

Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt.	Adequacy of ice surrounding mahi-mahi fillets at delivery	Visual check of adequacy of ice in a representative number of containers in each delivery	Every Delivery	Receiving Manager	**If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.		
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process.		
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representative number of containers and their label	Each customer order	Packing Manager	**If:** a container is improperly labeled, **Then:** segregate it and properly label it before the customer order is placed in the finished product cooler, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.		

Slide 12 (cont.)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Finished Product Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it.		

Firm Name: XYZ Seafood Company	**Product:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature: _____ Print name: _____	Date: _____

Chapter 10

Principle 6: Establish Verification Procedures

The sixth principle of HACCP requires that verification procedures be established to assure the HACCP program is effective (Slide 1).

Slide 1

In this module, you will learn:
- The definition of verification
- Validation is part of verification
- Verification procedures

Verification includes the procedures that are needed to ensure that the HACCP plan is designed properly and has been implemented correctly (Slide 2). The validity of the HACCP plan is determined before the plan is implemented. Routine verification is used to determine if the plan is working properly.

Slide 2

Definition:
Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.

Verification

The purpose of the overall HACCP plan is to control food safety hazards. The purpose of verification is to provide a level of confidence that the plan is based

on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed. A key concept in the verification principle is "Trust what you can verify" (Slide 3).

Slide 3

"Trust what you can verify."

Verification can be complex because there are several elements associated with this principle (Slide 4). The types of verification activities that may be needed include: validation, CCP verification, HACCP system verification, and regulatory verification. Each processor must determine which activities are necessary for their unique situation.

Slide 4

Types of Verification Procedures:

1) Validation (before the HACCP plan is implemented)
2) CCP verification (regularly scheduled activities):
   - Calibration of process-monitoring devices,
   - Record review,
   - Targeted sampling and testing.
3) HACCP system verification (periodic activity):
   - HACCP plan reassessment
   - Microbiological end-product testing and third party audits
4) Regulatory verification (periodic activity)

1) Validation

Validation is an essential component of verification and requires substantiation that the HACCP plan, if implemented effectively, is sufficient to control the significant food-safety hazards (Slide 5). Validation of the plan occurs **before** the plan is actually implemented. The purpose of validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a "valid" approach to controlling the food-safety hazards associated with a specific product and process.

Slide 5

Definition:
Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Validation requires a scientific and technical review of the rationale behind each part of the HACCP plan (Slide 6). Validation activities may involve a scope, cost, and time commitment similar to the development of the original HACCP plan. In-plant validations should be performed before the HACCP plan is implemented, and when factors warrant. Validation activities can be performed by the HACCP team or by an individual qualified by training or experience.

Slide 6

Validation involves establishing the scientific basis for the HACCP plan.

Strategies that can be used to validate the HACCP plan include:
- using scientific principles and data,
- relying on expert opinion, or
- conducting in-plant observations or tests.

A number of different events or situations may affect when validation activities are needed (Slide 7). These factors could include changes in the raw materials, product or process; adverse review findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices.

Slide 7

Validation frequency:
- Before the HACCP plan is implemented
- When factors warrant, such as:
  - changes in raw materials and/or suppliers
  - changes in product or process
  - adverse review findings
  - recurring deviations
  - new scientific information on hazards or control measures
  - on-line observations
  - new distribution or consumer handling practices

Examples of Validation Procedures:

- A seafood processor who is trying to determine an effective cook time and temperature to kill *Listeria monocytogenes* in their seafood products may use Table #A-3 in Appendix 4 of the Hazards Guide to validate their process. This table contains science-based information on the time and temperature combinations necessary for the destruction of *Listeria monocytogenes,* the primary pathogen of concern in raw seafood products. The length of time at a particular internal product temperature that is needed to accomplish the recommended reduction in the number of *L. monocytogenes* is, in part, dependent upon the food in which it is being heated. The values in the

table are generally conservative and apply to all foods. It may be possible to establish a shorter process time for a particular food by conducting scientific thermal death time studies, or by obtaining information from scientific studies that proves that the normal levels of this pathogen are lower than the expected levels.

- Processors may need to conduct in-plant thermal validation studies for a specific piece of equipment or process using science-based time temperature scenarios to achieve the necessary reduction in pathogens. These in-plant validation studies should be done with the assistance of a food processing authority.
- A validation activity for a primary processor of molluscan shellfish could involve contacting the responsible authorities to identify the location of approved waters for raw shellfish before developing a harvest schedule. These authorities determine the status of harvesting waters using science-based sampling and testing protocols.
- A validation study for a brining process may involve science-based in-plant trials and product testing to determine the variables (e.g. size, fat content and amount of fish, salt level in the brine, brining time, etc.) that must be consistently achieved to assure that the required water phase salt will be reached in all finished products.

2) CCP Verification Activities

Several types of verification activities may be necessary for each CCP to ensure that the control procedures used are effective (Slide 8). A CCP verification procedure is needed to ensure that monitoring instruments are accurate and calibrated within appropriate ranges. CCP verification may also include targeted sampling and testing to demonstrate that the chosen critical limit is controlling the food safety hazard. Supervisory review of monitoring, corrective action and calibration or testing data is another type of CCP verification that is used to verify that the HACCP plan is working properly.

Slide 8

CCP verification activities:
- Calibration of process-monitoring devices
- Calibration record review
- Targeted sampling and testing
- CCP record review

Calibration of Process-monitoring Devices

Routine accuracy checks and periodic calibration of process-monitoring devices are CCP verification activities used to ensure that the measurements taken by the process-monitoring devices are accurate and reliable (Slide 9).

Accuracy checks and calibration are fundamental to the successful implementation and operation of the HACCP plan. If monitoring devices do not provide accurate measurements, then monitoring results will be unreliable. If

this happens, the CCP should be considered out of control (see Chapter 9 for corrective actions) since the last documented acceptable accuracy check and/or calibration.

Slide 9

Accuracy checks and calibrations are performed:
- On equipment and instruments used in the HACCP plan
- At a frequency that ensures accuracy of measurements

For example, suppose a thermometer is used to measure the temperature of frying oil, which is part of the critical limit at a cooking CCP. The HACCP plan requires monthly calibration of this thermometer. If a scheduled calibration shows that the thermometer is actually reading 10°F less than the standardized thermometer, the accuracy of all monitoring results since the last monthly calibration is uncertain. Therefore, monitoring results for the last month are unreliable and it is impossible to know if the critical limit has been met during this period of time. Corrective action must be taken to determine if the products produced during this time period are safe and/or need to be recalled.

Calibration and accuracy are different but are related concepts (Slide 10). Ideally a measurement device is both accurate (correct or true) and precise (repeatable or reproducible). The accuracy and precision of a measurement process is usually established by measuring against a traceable reference standard.

Calibration involves determining, by measurement or comparison with two known standards, that the value of each reading on a particular measuring instrument is in fact correct or against a known calibrated instrument. For example, a thermometer could be calibrated by comparing it to a National Institute of Standards and Technology (NIST) traceable thermometer at two different temperatures in the range (above and below) in which it will be used.

Accuracy checks determine if the instrument is reading a true or correct value at a single point. For example, routine accuracy checks of a thermometer could involve immersing the probe into an ice slurry to determine if the thermometer measures a temperature of 32°F. For specific information about calibrating thermometers, you can download this publication at no charge.
Visit: A Thermometer Calibration Guide (8-page publication)
http://www.bookstore.ksre.ksu.edu/pubs/MF2440.pdf

Examples of accuracy checks and calibration activities:

- A thermometer used to monitor temperature at a cooking CCP may be checked for accuracy by comparing it against a certified thermometer in a hot-water bath.
- The continuous temperature chart recorder on a pasteurizer may be compared during each batch against a certified accurate thermometer.
- A pH meter is calibrated against pH buffer standards of 7.0 and 4.0 when it is used to test products with a final pH of 4.2 to 4.8.

Slide 10

Examples of calibration and accuracy activities

Calibration (Periodic)	Accuracy (Routine)
Thermometer	
A dial thermometer is checked against a standardized (e.g. NIST* traceable) thermometer for two or more temperature points	Thermometer measures the correct temperature of an ice slurry (32°F)
pH Meter	
Meter is adjusted to read between two pH points or buffer standards	pH is measured correctly under conditions in the plant with a single standard
Metal Detector	
Instrument is adjusted to detect standard sized metal slugs provided by manufacturer	Detector rejects product with metal standards
Histamine Test Kit	
Kits are pre-calibrated by the manufacturer	Level of histamine is determined using known standards provided by the manufacturer

**NIST = National Institute of Standards and Technology*

Examples of accuracy checks:

- A thermometer used to routinely check the internal temperature of incoming fish is checked daily by immersing the probe in an ice slurry to determine that it reads 32°F.
- The accuracy of a metal detector is checked by running products with metal standards at the minimum detection limit through the unit.

Frequency of Accuracy Checks and Calibration

A number of factors should be considered when determining the frequency of accuracy checks and calibration for monitoring devices that is needed (Slide 11).

Slide 11

Frequency of accuracy checks and calibration can depend on:
- Design of the monitoring device
- Reliability and sensitivity of the device
- The environment or conditions in which it is used

The design of a measuring instrument has to ensure that the device is capable of making accurate measurements when used within expected environmental conditions over some reasonable period of time.

Calibration frequency is dependent upon the type of device used, its condition and past performance, as well as the environment in which it will be used (operating environment). The reliability and sensitivity of the monitoring instrument should also be considered when determining the frequency of accuracy checks and calibration.

Consistent temperature variations away from the actual value (drift) found during checks and/or calibrations may indicate that more frequent calibration is needed or the device needs to be replaced (perhaps with a more durable device).

One of the most frequently used monitoring devices for perishable food products such as seafood is a thermometer. Some factors to consider when determining the frequency for thermometer accuracy checks and calibration include:

- **Inherent reliability:** Daily accuracy checks may be needed for the least reliable instruments (i.e. dial thermometers and bi-metallic). Periodic checks may be sufficient for more reliable instruments (i.e. digital thermometers with a history of good performance).
- **Manufacturer recommendation:** The design and expected conditions of use for each individual product is considered when manufacturers make accuracy and calibration recommendations. This information should be used to determine the frequency that is needed for these activities in the HACCP plan.

Accuracy and Calibration Records and Reviews

Records must be kept to document the results of accuracy checks and calibrations of monitoring devices (Slide 12). These records must be reviewed by a person who has the training or experience necessary to evaluate the results and determine that all monitoring instruments are accurate and properly calibrated. Reviewing these records may involve checking the dates and methods of calibration and the test results (e.g., equipment passing or failing). Calibration records must be reviewed within a reasonable time after completing the reports. These reviews are part of the plant's verification activities. Inspectors and third-party auditors may also review calibration records.

Slide 12

Accuracy checks and calibration records must:
1) Document results of accuracy checks and calibration procedures
2) Provide a reference to the standard
3) Be reviewed by qualified, trained personnel

Targeted Sampling and Testing

Verification may also include targeted sampling, testing, and other periodic activities (Slide 13). For example, vendor compliance with a standard may be checked by targeted periodic sampling and testing when receipt of material is a CCP and purchase specifications outlined in a supplier guarantee are used as a critical limit. Typically, when a monitoring procedure does not involve a quantitative measurement, it should be coupled with a strong verification strategy. **Similar to calibration records, sample test results must be reviewed within a reasonable time after completing the reports. These reviews are part of the plant's verification activities.**

Slide 13

Periodic verification may also include targeted sampling and laboratory tests of in-process or finished products.

Other examples of targeted sampling and testing:

- An initial, followed by quarterly sampling of shrimp at receiving and laboratory analysis for sulfite levels to verify that the incoming products do not exceed food safety specifications for this food additive.
- Periodic sampling and testing of water phase salt levels in finished smoked fish products to verify that the brining process is achieving the required water phase salt levels.
- Periodic sampling and histamine testing of fish from a harvest vessel to verify that the elements of the vessel's handling and sampling procedures included in the processor's critical limits do not create conditions that could lead to histamine formation.
- Periodic sampling and microbiological testing of cooked products to verify that the cooking process is sufficient to kill pathogens of concern.

CCP Record Review

The FDA regulation requires that all monitoring and corrective action records be reviewed within a week from the time that they are generated by a trained person (Slide 14). This review is a verification activity. These records are valuable tools that document that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them on a periodic basis to "verify" that critical limits have been met and the HACCP plan is being followed.

3) HACCP Program Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system (Slide 15). The frequency of a system-wide verification or reassessment shall be yearly, at a minimum, or whenever there is a system failure or a significant change

in the product or process. The HACCP team is responsible for ensuring that this verification activity is performed. The HACCP team may contract with an independent third party to conduct system-wide verification activities.

Slide 14

Verification through Record Reviews:
- All monitoring and correction action records
- Records must be reviewed within one week from time they were made by an individual who meets the training requirements of the FDA seafood HACCP regulation.

Slide 15

HACCP system verification or reassessment frequency:
- Annually,
- Occurrence of a system failure or significant change in product or process.

System-wide verification activities may include on-site observations and record reviews (Slide 16). Reviews are usually performed by the HACCP Team or other unbiased individuals not responsible for performing the monitoring activities. It is recommended that the system verification occurs at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

Slide 16

System-wide HACCP plan verification reviews include:
- Verifying that the hazard analysis and HACCP plan are still accurate, and
- Reviewing records to determine trends and verify that the plan is being followed.

Activities that should be conducted in a **system-wide HACCP plan verification** include:

- Check the accuracy of the product description and flow diagram.
- Check for new guidance or scientific information related to critical limits or other HACCP principles.
- Check that CCPs are monitored as required by the HACCP plan.
- Check that processes are operating within established critical limits.
- Check that appropriate corrective actions have been taken and verification activities have been completed.
- Check that records are completed accurately and at the time intervals required.

- Review sanitation records and other procedures that support the HACCP system.
- Review of consumer/customer complaints related to food safety.

During a system-wide HACCP plan verification, conduct a review of records to determine if the following have occurred:

- Monitoring activities have been performed at the locations specified in the HACCP plan.
- Monitoring activities have been performed at the frequencies specified in the HACCP plan.
- Corrective actions have been performed whenever monitoring indicated deviation from critical limits.
- Equipment has been calibrated at the frequencies specified in the HACCP plan.
- Check to be sure that all records are reviewed by a trained person within a week of the time they were generated.

It may be useful to include activities such as finished product testing and third-party audits when conducting a system wide HACCP verification (Slide 17).

Slide 17

Other system-wide verification strategies
- Finished product testing for microbiological, chemical or physical hazards
- Third-party audits

Finished product testing may include chemical or microbiological tests to ensure that the plan is controlling the food safety hazard identified at a CCP. As explained earlier, laboratory testing is generally ineffective for routine monitoring, but it can be used as a verification tool to determine if the overall operation is under control.

An independent third party audit can also be included in a system wide HACCP plan verification. Third party auditors can provide an unbiased assessment to help determine if the plan is working properly. Food processing authorities may also need to be consulted to re-validate a particular processing step.

Many different situations or conditions may trigger the need to reassess the HACCP plan to be sure that all food safety hazards are being effectively controlled (Slide 18).

FDA's Seafood HACCP regulation requires reassessment of the hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. The reassessment shall be performed by an individual or group of individuals who have been trained in HACCP principles.

Slide 18

Situations that may trigger a HACCP plan reassessment:
- A change in products or the process
- A change in the critical limit at a CCP
- Relocation of your plant
- Installation of a new piece of equipment
- A HACCP system failure
- Adverse findings from a regulatory inspection or third party audit

4) Regulatory Verification

The major role of regulatory agencies in a HACCP program is to verify that HACCP plans are effective and are being followed and to make sure processors are in compliance with HACCP and other regulations (Slide 19). This inspection-based verification activity occurs on-site in the processing facility that has implemented the HACCP plan.

Note

If you change/revise your HACCP plan, save the previous one for future reference.

Slide 19

Regulatory agencies conduct inspection to verify that a processor:
- Has developed a HACCP plan that controls all significant food safety hazards;
- Has implemented the HACCP plan and it is consistently being used; and
- Is in compliance with HACCP and other regulations.

Verification procedures conducted by a regulatory agency may include:

- Review of the HACCP plan and any modifications
- Review of CCP monitoring records
- Review of corrective action records
- Review of the verification records
- Visual inspections of operations to determine if the HACCP plan is followed and records are properly maintained
- Random sample collection and analysis
- Evidence of training and that all training requirements have been met

HACCP plans are unique documents prepared by a processor to ensure the control of a specific process or procedure and to ensure compliance with regulations. The plans may contain proprietary information and must be appropriately protected by the regulatory agency. Agency personnel must have access to the HACCP plan plus monitoring, corrective action and verification records and other information pertinent to the HACCP plan that may be required for regulatory verification.

Establishing a Schedule for Verification Activities

Slide 20 provides an example of a company-established HACCP verification schedule. The frequency of all verification activities can change over time. A history of review findings that indicate that the processes are consistently in control may justify reducing the frequency. On the other hand, adverse findings, such as inconsistent monitoring activities, inconsistent record keeping, or improper corrective actions may indicate that more frequent verification reviews are necessary and/or that the HACCP plan may need to be modified.

Slide 20

Example of a company-established HACCP verification schedule

Activity	Frequency	Responsibility	Reviewer
Verification activities scheduling	Yearly or upon HACCP program change	HACCP coordinator	Plant manager
Initial validation of HACCP plan	Prior to and during initial implementation of plan	Independent expert(s)[a]	HACCP team
Reassessment of HACCP plan	When critical limits changed, significant changes in process, equipment changes, after system failure, etc.	Independent expert(s)[a]	HACCP team
Verification of CCP monitoring as described in the plan (e.g., monitoring of patty cooking temperature)	According to HACCP plan (e.g., once per shift)	According to HACCP plan (e.g., line supervisor)	According to HACCP plan (e.g., quality control)
Review of monitoring, corrective action records to show compliance with the plan	Weekly	HACCP trained person	HACCP trained person
Comprehensive HACCP system verification	Yearly	HACCP team and/or independent expert(s)[a]	HACCP team

[a] *May require additional technical expertise as well as laboratory and plant test studies.*

Examples of Verification Activities for Specific Hazards at a CCP

Examples of appropriate verification procedures for various hazards at specific CCPs are provided in Slide 21. The verification procedures must be directly

Slide 21

Examples of verification activities for specific critical limits

Significant Hazard	Critical Control Point	Critical Limits	Verification
Aquaculture drugs	Receiving (from farm)	Suppliers certificate on file (indicating proper drug use).	Visit new suppliers within a year and existing suppliers on a pre-determined schedule to review drug use policies; and Conduct quarterly sampling of raw material and test for drug residue likely to be present; and All records will be reviewed by a HACCP trained person once per week.
Natural toxins	Receiving (from harvester)	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel; and all shellstock from waters approved by State Shellfish Authority; and all shellstock from a licensed harvester.	Review all monitoring and corrective action records once per week.
Histamine	Receiving (from supplier)	Fish are completely surrounded by ice.	Check the accuracy of new thermometers before they are used and daily thereafter and calibrate thermometers once per year; and Check internal temperature of iced fish at receipt before accepting fish from new suppliers and quarterly for existing suppliers to verify adequacy of ice; and All records will be reviewed by a trained person once per week.
C. botulinum toxin formation (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes.	Check the accuracy of the smokehouse temperature sensor before it is used and daily thereafter and calibrate at least once per year; and all records will be reviewed by a trained person once per week.
Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F.	Check the accuracy of the cooler temperature sensor before it is used and daily thereafter and calibrate at least once per year; and All records will be reviewed by a trained person once per week.

related to the critical limits, monitoring procedures and corrective action strategies identified in the HACCP plan.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company identified four critical controls points in the hazard analysis. There are three CCPs for the hazard of histamine: receiving, refrigerated storage and finished product storage. There is one CCP for the hazard of food allergens: weigh/pack/label. The HACCP team used the Hazards Guide to determine what verification procedures are needed in their HACCP plan.

Receiving CCP: The HACCP Team identified "Control Strategy 3, Transit Control," in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for their situation. This strategy recommends verification procedures that include:

- Weekly review of Receiving Log (Monitoring record) and Corrective Action records
- Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that icing procedures used by suppliers maintain product temperature
- Check accuracy of thermometer daily
- Calibrate thermometer used to check internal temperature annually

The verification procedures are entered in the HACCP plan form.

Refrigerated Storage and Finished Product Storage CCPs: The HACCP Team identified Storage Controls in Chapter 7 (Histamine) of the Hazards Guide as the best control strategy for both of their refrigerated storage CCPs. This strategy recommends verification procedures that include:

- Weekly review of the cooler ice log (monitoring record) and corrective action records
- Check internal temperature of fish quarterly to ensure that procedures used to ice fish for cooler storage maintains product temperature
- Check the accuracy of the thermometer for checking internal temperatures daily
- Calibrate the thermometer used to check internal temperatures annually

The verification procedures are entered in the HACCP plan form.

Weigh/Pack/Label CCP: The HACCP Team identified Finished Product Labeling Controls in Chapter 19 (Undeclared Major Food Allergens and Food Intolerance Substances) of the Hazards Guide as the best control strategy for their situation. This strategy recommends verification procedures that include:

- Weekly review of Packing Room Log (monitoring record) and corrective action records

The verification procedures are entered in the HACCP plan form.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

Complete HACCP Plan Form – Verification

Slide 22 – HACCP plan form for XYZ Seafood Company completed through Verification.

Slide 22

Firm Name: XYZ Seafood Company

HACCP Plan Form

Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt.	Adequacy of ice surrounding mahi-mahi fillets at delivery	Visual check of adequacy of ice in a representative number of containers in each delivery	Every Delivery	Receiving Manager	**If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.	Weekly review of Receiving Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process.	Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	

Slide 22 (cont.)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representative number of containers and their label	Each customer order	Packing Manager	**If:** a container is improperly labeled, **Then:** segregate it and properly label it before the customer order is placed in the finished product cooler, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.	Weekly review of Packing Room Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.	
Finished Product Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it.	Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	

Firm Name: XYZ Seafood Company	**Product:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature: _____ Print name: _____	Date: _____

Chapter 11

Principle 7: Record-Keeping Procedures

Accurate recordkeeping is an essential part of a successful HACCP system (Slide 1). Recordkeeping is the seventh principle of HACCP.

Slide 1

In this chapter you will learn:
- What records are needed
- How to develop appropriate records
- How to conduct a record review
- How computerized records may be used

Types of Records Needed

Written records provide documentation of the HACCP plan, and demonstrate that critical limits have been met and appropriate corrective actions and verification procedures have been taken (Slide 2). Chapter 11 describes, with examples, the first four type of records numbered below. For a discussion of Sanitation Control Procedure records and Importer Verification records, see Chapter 12, the Seafood HACCP Regulation, pages 176-179.

Slide 2

Six types of records are needed in a HACCP system:
1) The HACCP plan and supporting documentation
2) CCP Monitoring records
3) Corrective Action records
4) Verification records
5) Sanitation Control records
6) Importer Verification records

The FDA Seafood HACCP regulation requires firms to retain HACCP records for one year for fresh products and for two years for frozen or processed products with extended shelf-life. This regulation also requires that all records, plans, and procedures specified in a firm's HACCP plan shall be made available for review and copying by public health officials at reasonable times. These requirements will be discussed in detail in Chapter 12.

1) The HACCP Plan and Supporting Documents

The written HACCP plan is a required record that describes exactly how all significant food safety hazards will be controlled (Slide 3). The HACCP plan is an official document that must include the name of the firm and its location, the products covered by the plan, and their method of storage, packaging, distribution, and intended use. The HACCP plan must also be signed and dated by a high level official or the most responsible individual to indicate that it has been accepted by the firm.

Slide 3

1) The HACCP plan and its supporting documentation

Documents that support the control strategies outlined in the HACCP plan could include any information used in completing the hazard analysis or in establishing critical limits (Slide 4).

Slide 4

Examples of HACCP Plan Support Documents:
- Data from published scientific studies
- Data from in-plant studies conducted by processing authorities
- Data from equipment manufacturers or other authorities
- Data gathered in the Preliminary Steps
- Pre-requisite programs including sanitation control procedures
- Written hazard analysis worksheets

Examples of documents that support the critical limits in a HACCP plan could include:

- Data from published scientific studies that demonstrate the adequacy of the control measures used to inhibit bacterial pathogen growth,
- Data from studies conducted by a processing authority to establish the safe shelf life of the product (if age of the product can affect safety),
- Data from an equipment manufacturer and an in-plant study conducted by a processing authority to establish the critical limit variables necessary for a cooking process to destroy bacterial pathogens.
- Data from an in-plant study conducted to determine the critical limit variables necessary to ensure that a brining process consistently achieves the minimum water phase salt levels necessary to prevent *C. botulinum* toxin production.

Examples of documents that support the overall HACCP plan and its strategies to control food safety hazards could include:

- A list of the firm's HACCP team and their individual responsibilities
- The information gathered in the preliminary steps used to develop the HACCP plan
- Prerequisite programs including GMPs and sanitation control procedures
- A copy of the firm's written hazard analysis worksheets

2) CCP Monitoring Records

CCP monitoring records are used to document that food safety hazards have been properly controlled at each CCP (Slide 5). Monitoring records show that critical limits are being met, and if not met, when appropriate corrective actions are needed. These records must be reviewed with sufficient frequency to ensure that food safety hazards are being controlled as required by the HACCP plan and regulatory requirements. Monitoring records are also used by regulators to determine whether a firm is in compliance with its written HACCP plan.

Slide 5

CCP monitoring records are used to document that food safety hazards have been controlled at each CCP.

Monitoring records can be routinely used by an operator or manager to determine if a process is approaching its critical limit. This enables the operator to make process adjustments before the critical limit is exceeded, which can reduce or eliminate the labor and material costs associated with corrective actions.

All monitoring information should be recorded at the time the observation is made. Accurate recordkeeping ensures the firm is meeting the critical limits and provides documentation that food safety hazards are being controlled. False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system and may lead to legal actions if found to be fraudulent.

Each monitoring record must be designed to capture the information required to document that the critical limit has been met at the CCP (Slide 6). The record must have a title that corresponds to the title of the record written in the HACCP plan. The actual measurement or observation that is taken must also be written on the record along with the time and date that the measurement or observation was taken and the signature or initials of the person who made it. There are additional record requirements in the FDA Seafood HACCP regulation related to the firm and its location, product identification, and record reviews that will be described in Chapter 12.

Note

Optional information, such as the Critical Limits from the HACCP plan, may be helpful to be included in the CCP monitoring record forms for reference.

Slide 6

Information required on CCP monitoring records:

- Title of record (e.g. Shellfish Receiving Log)
- Firm name and location
- Product identification (if applicable)
- Date and time of monitoring observation
- Actual measurement or observation taken
- Signature or initials of the person performing the monitoring activity
- Signature of the trained person reviewing the monitoring record and the date of review

Examples of Monitoring Records for Specific Hazards at a CCP

Monitoring records must be designed to capture the measurements or observations that are included in the critical limit. Examples of the relationship between a CCP, critical limit, and monitoring records could include (Slide 7):

- A "Drug Use Certificate" may be required from the supplier of farm-raised fish to comply with the receiving CCP in order to reduce the hazard of aquaculture drugs to an acceptable level.
- A “Shellfish Receiving Log” is the record that would be filled out at a receiving CCP for shellfish when the critical limit requires properly filled tags that reduce the hazard of natural toxins to an acceptable level.

Slide 7

Significant Hazard	Critical Control Point	Critical Limits	Monitoring Record
Aquaculture drugs	Receiving (from farm)	Suppliers certificate on file (indicating proper drug use)	Suppliers certificate on file (indicating proper drug use)
Natural toxins	Receiving (from harvester)	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel AND All shellstock from waters approved by State Shellfish Authority AND All shellstock from a licensed harvester	Shellfish receiving log
Histamine	Receiving	Fish are completed surrounded by ice	Histamine fish receiving log
C. botulinum toxin formation (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes	Smokehouse temperature record chart
Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F	Cooler storage log

- A "Histamine Fish Receiving Log" is the record that would be filled out at a receiving CCP for histamine producing fish when the critical limit for a secondary processor is that all fish will be adequately surrounded with ice.
- A "Smokehouse Temperature Recording Log" is the record at a hot smoking CCP that would be examined and filled when the critical limit includes a minimum product internal temperature and processing time that is a necessary barrier to eliminate pathogens.
- A "Cooler Temperature Log" is the record that would be filled out at a refrigerated storage CCP when the critical limit is a maximum cooler storage temperature to prevent pathogen growth.

Examples of CCP Monitoring Records

Processors must design a form for each record listed in their HACCP plan to capture the information that is necessary to document monitoring results which show that critical limits have been met, what corrective actions have been taken, and that the necessary verification procedures have been completed. Because conditions in each facility are different, there is no single form that will be appropriate for all operations.

Routine CCP Monitoring Records

Daily Cooker Temperature Log Form (Slide 8)

This form documents the periodic recording of time and temperature under normal operating conditions of a cooker.

Slide 8

Daily Cooker Temperature Log (Monitoring Record)

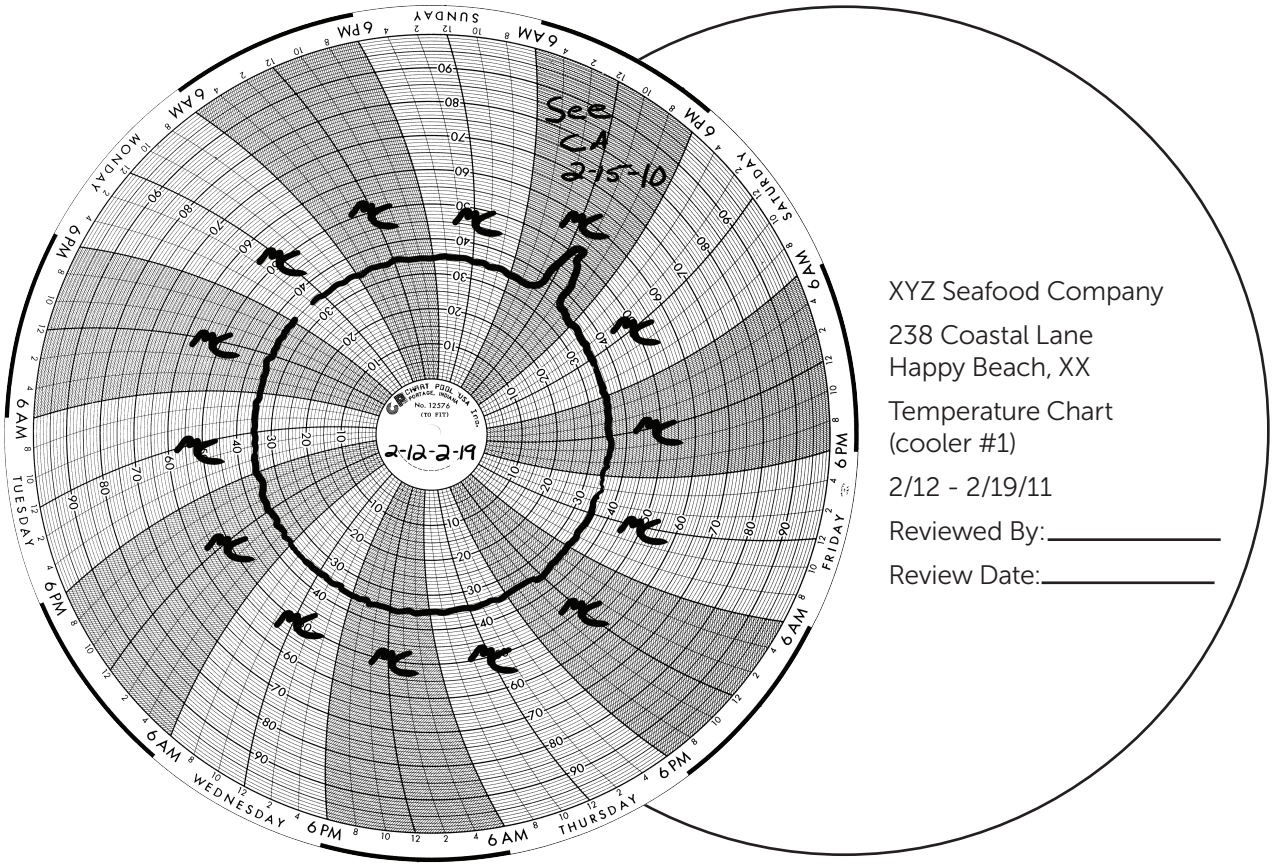
Form Title: Daily Cooker Temperature Log						
Firm Name:				**Firm Location:**		
Product Identification: Cooked, peeled shrimp 21-25.						
Critical Limits: ≥ 212°F for ≥ 3 minutes				**Monitoring Activities:**		
Date	**Time**	**Line Number Product Code**	**Cooker Temp (°F)**	**Cook Time (minutes)**	**Critical Limit Met (Yes/No)**	**Line Operator (Initials)**
Reviewer Signature:				**Date of Review:**		

Continuous Temperature Record with Periodic Monitoring (Slide 9)

This record is used to continuously monitor the operations of a refrigerated storage. This record must be complemented by periodic visual checks by the operator to assure compliance with the CCP.

Slide 9

Continuous Temperature Record with Periodic Monitoring.



Note

Periodic readings of the temperature recording chart must be made to ensure that critical limits are met. Temperature monitoring records should be signed and dated by the line operator on the production day(s).

Weigh/Pack/Label Log (Slide 10)

This form documents the proper use of labels that identify potential hazards associated with the product or the product ingredients. Firms should affix one copy of the current label used to each report.

Slide 10

Weigh/Pack/Label Log (Monitoring Record)

Form Title: Weigh/Pack/Label Log					
Firm Name: XYZ Seafood Company			**Firm Location:** 238 Coastal Lane, Happy Beach, CA		
Product Identification: Fresh mahi-mahi fillets					
Critical Limits: Proper label - seafood product market name and ingredients.			**Monitoring Activities:**		
Date	**Time**	**Lot Number**	**Label Applied (Yes/No)**	**Label Type (description)**	**Line Operator (Initials)**
Reviewer Signature:			**Date of Review:**		

3) Corrective Action Records

Corrective action records were discussed in Chapter 9 and are repeated here to emphasize their importance in a firm's HACCP system.

A corrective action must be taken each time a critical limit is not met and a corrective action record must show what products were affected, how the safety of these products was evaluated, the disposition of the affected product, the cause of the deviation, and how it was fixed (Slide 11).

Corrective actions records must capture information similar to that required for monitoring records, including:

- Product identification (e.g., product description, amount of product on hold)
- Description of the critical limit deviation
- Corrective action(s) taken including the final disposition of product and actions taken to prevent recurrence
- Results of the evaluation or testing of product placed on hold, if necessary
- Name and signature of the person responsible for the corrective action(s)
- Name and signature of the person reviewing the corrective action(s) report

Slide 11

3) Corrective action records

Corrective Action Report (Slide 12)

This is an example of a corrective action form that is used to document the action taken when a critical limit is exceeded.

Slide 12

Corrective Action Report (Corrective Action Record)

Form Title: Corrective Action Report Form			
Firm Name:		**Firm Location:**	
Product Description:			
Date:	**Line Number:**	**Lot Number:**	**Code Number:**
Date and time of process deviation:			
Describe the process deviation and what happened to the product?			
What action(s) was taken to restore order to the process?			
Name and signature of person reporting deviation and responsible for taking the correction action:			
Amount of product affected by the process deviation:			
Evaluation of product involved by the process deviation:			
Final disposition of the affected product:			
Reviewer Signature:		**Date of Review:**	

4) Verification Records

Verification records were discussed in Chapter 10 and are repeated here to emphasize their importance in a firm's HACCP system (Slide 13).

Slide 13

4) Verification records

Records of routine and periodic verification activities must be kept to demonstrate that the HACCP plan has been implemented properly, monitoring measurements or observations are accurate and reliable, and the HACCP system is working as intended. Different records may be needed to capture the verification information that is specified in the HACCP plan.

Examples of records for routine verification activities might include:

- Logs that document the results obtained when routine checks are made of the accuracy of thermometers, pH meters or other instruments used to monitor critical limits;

- Record review signature line and date on monitoring records to document the weekly review of monitoring and corrective action records by a trained person.

Slide 14

Verification Records document the results of:
- Accuracy checks and calibration of process-monitoring instruments
- Record reviews
- Laboratory test results
- In-plant studies or challenge tests
- Audits and inspections

Examples of records for validation or periodic verification activities might include:

- A report that describes modifications made to the HACCP plan because of a change in products, ingredients, formulations, processes, or packaging and distribution methods;
- Processor audit records verifying supplier compliance with guarantees or certifications;
- Results of microbiological, chemical or physical tests of raw materials, in-process or finished products, or the plant environment;
- Results of equipment-evaluation tests, heat penetration or temperature distribution studies for thermal processes;
- Results from third-party audits or regulatory agency inspections.

Routine Verification Records

Daily Thermometer Accuracy Log (Slide 15)

This form documents the daily accuracy check of all thermometers used in the daily process monitoring operations.

Quarterly Thermometer Calibration Log (Slide 16)

This form records the quarterly calibration check of thermometers.

Periodic Verification and Validation Records

Finished Product Microbiological Evaluation Report (Slide 17)

This report documents the results of finished product laboratory analyses for total plate count (TPC), coliform bacteria, *Escherichia coli, Staphylococcus aureus* and *Salmonella.*

Raw Product Chemical Evaluation Report (Slide 18)

This report documents the results of laboratory analysis for sulfites in finished products.

Annual Thermal Process Validation Report (Slide 19)

This letter and supporting documents confirm the critical limits are scientifically valid and will deliver sufficient heat to destroy target organisms of public health concern.

Slide 15

Daily Thermometer Accuracy Log (Verification Record)

Form Title: Daily Thermometer Accuracy Log					
Firm Name:			**Firm Location:**		
Product Identification:					
Verification:					
Date	**Time**	**Instrument Number**	**Boiling Water Check**	**Critical Limit Met (Yes/No)**	**Line Operator (Initials)**
Reviewer Signature:				**Date of Review:**	

Slide 16

Quarterly Thermometer Calibration Log (Verification Record)

Form Title: Thermometer Calibration Log					
Firm Name:			**Firm Location:**		
Product Identification:					
Verification:					
Date of Calibration	**Instrument Number(s)**	**Method of Calibration**	**Calibration Results**	**Critical Limit Met (Yes/No)**	**Line Operator (Initials)**
Reviewer Signature:				**Date of Review:**	

Slide 17

Finished Product Microbiological Evaluation Report (Verification Record)

Form Title: Product Microbiological Evaluation Report						
Firm Name:				**Firm Location:**		
Product Identification:						
Verification:						
Date of Sampling	**Line Number**	**Total Plate Count (cfu/g)**	**Total coliforms (MPN/g)**	***E. coli* (Pos./Neg.)**	***S. aureus* (Pos./Neg.)**	***Salmonella* (Pos./Neg.)**
Reviewer Signature:				**Date of Review:**		

Slide 18

Raw Product Chemical Evaluation Report (Verification Record)

Form Title: Chemical Evaluation Report			
Firm Name:		**Firm Location:**	
Product Identification:			
Verification:			
Date	**Line Number**	**Sulfites (ppm)**	**Line Operator (Initials)**
Reviewer Signature:		**Date of Review:**	

Slide 19

Annual Thermal Process Validation Report (Verification Record)

May 9, 2016

John J. Smith, President
XYZ Seafood Company
238 Coastal Lane
Happy Beach, XX 33333

Dear Mr. Smith,

Heat penetration tests have been completed for your "Ready-to-eat, peeled and deveined shrimp" processed in a continuous steam cooker at your facility on April 19, 2016 using a portable data logger and 12 thermocouple leads.

Observations were made of internal product temperatures for six shrimp from individual lots of large (3.5 to 5.0 shrimp per oz.), medium (5.0 to 9.0 shrimp per oz.) and small (9.0 to 17.0 shrimp per oz.) processed in the steam cooker during production runs at 212°F for three minutes.

The internal temperature of large shrimp exceeded 165°F; medium shrimp, 170°F and small shrimp, 180°F. The internal product temperatures noted during these tests exceed your firm's HACCP critical limits of an internal temperature of 165°F for 40 seconds.

Our studies revealed that shrimp processed at 212°F for three minutes delivered an internal product temperature above 165°F for a minimum of 40 seconds. These temperatures are equivalent to a 6-D process for elimination of *Listeria monocytogenes*.

These data serves as your annual thermal process validation study. If parameters change, such as cooking temperature, time, shrimp size, shrimp volumes, then you should repeat the thermal process validation study to ensure an adequate cook is being achieved in your process.

Sincerely,

I.M. Helpful
Seafood Processing and Research Unit
Your Seafood Processing Authority

Annual Thermal Equipment Validation Report (Slide 20)

This letter and supporting documents confirm that the temperature throughout the cooker is at or above the critical limit when the equipment is operating properly.

Annual HACCP Plan Verification Report (Slide 21)

This report document indicates that a firm has performed its annual HACCP system verification and the current HACCP plan was signed and dated.

Slide 20

Annual Thermal Equipment Validation Report (Verification Record)

May 9, 2016

John J. Smith, President
XYZ Seafood Company
238 Coastal Lane
Happy Beach, XX 33333

Dear Mr. Smith,

Temperature distribution tests were performed on April 19, 2016 on the steam cooker located at XYZ Seafood Company in Happy Beach, XX.

Data was collected from ten thermocouples and continuous temperature logger during three production runs. Test results indicate that temperature distribution profiles in your cooker ranged from 212 to 214°F.

These studies show that your steam cooker, when run properly, continues to operate as designed.

Sincerely,
I.M. Helpful
Seafood Processing and Research Unit
Your State University

Slide 21

Annual HACCP Plan Verification Report (Verification Record)

Annual HACCP Plan Verification Checklist	**Date Task Completed:**	**Signature of Person who Completed the Task**
List of HACCP Team with Individual Responsibilities Updated.		
List of Seafood Products and Processes in Place at Facility.		
Product Flow Diagrams Updated		
Hazard Analysis Updated		
HACCP Plan Updated		
Good Manufacturing Practice Plan Updated		
Sanitation Standard Operating Practices Plan Updated		
HACCP Plan Implemented		
Reviewer Signature:	**Date of Annual Review:**	

Employee Training Record (Slide 22)

This report documents employee training activities.

5) Sanitation Control Procedures (SCP) Records

The SCP records include the required routine monitoring and corrections for the 8 key sanitation areas as explained in Chapter 2 Prerequisite Programs. Likewise, they must include the accompanying training records for qualified individuals as illustrated with examples in slide 22.

6) Importer Verification Records

Every importer of fish and fishery products for commerce in the United States must have and implement written verification procedures for the imported products. The procedures must include product specifications for any potential food safety hazards, and affirmative steps to assure the products were processing in accordance with the prevailing Seafood HACCP Regulation. The affirmative steps can include procedures appropriate for the products and related potential hazards and controls:

- Obtaining the foreign processor's HACCP and sanitation monitoring records for the involved lot of imported products;
- Obtaining continuing or lot-by-lot certificates from an appropriate foreign government inspection authority or competent third party certifying that the imported product is or was properly processed;
- Regularly inspect the foreign processor's facilities to ensure the imported products are being properly processed;
- Maintain on file, in English, a copy of the foreign processor's HACCP plan, and a written guarantee from the processor that the products were properly processed;
- Periodically test the imported products to verify compliance with the Seafood HACCP Regulation; and
- Other verification measures as appropriate that provide an equivalent level of assurance of compliance with the Seafood HACCP Regulation.

Slide 22

Example of Training Report (Pre-requisite Document)

Employee Training Record			
Employee: *Anybody Jones*		**Position/Duty:** Processing belt for shrimp cooker	
Firm Name: *XYZ Seafood Company*		**Firm Location:** *238 Coastal Lane, Happy Beach, XX*	
COURSES	**LOCATION**	**DATE COMPLETED**	**SIGNED**
Basic Sanitation Course (Seafood HACCP Alliance)	Headquarters	Nov 01, 2015	*Ben Smith*
GMP's 117	Plant Unit 3	Jan 15, 2017	*BS*
SCP Monitoring	Plant Unit 3	Jan 15, 2017	*BS*
Basic Sanitation Review	Headquarters	Feb 01, 2017	*S Otwell*

Group Employee Training Record	
Firm Name: *XYZ Seafood Company*	**Firm Location:** *238 Coastal Lane, Happy Beach, XX*
Course: Personnel Hygiene and Food Safety Level 1	**Location:** *Headquarters*
DATE COMPLETED: April 15, 2017	**SIGNED** *Ben Smith, Supv. No. 1*
EMPLOYEES	
Nancy Dolittle – Packing and Labeling	
Anyone Jones – Shrimp cooker belt	
Wei Not – Recv Dock	
Bettie Done – Thawing	

Computerized Records

Electronic or computerized records are acceptable in a HACCP system as long as they are equivalent to paper records and electronic signatures are equivalent to traditional handwritten signatures (Slide 23). If a company plans to use computerized records, they should review Title 21 CFR Part 11 for guidance (http://www.fda.gov).

Slide 23

Electronic or computerized monitoring records must be equivalent to paper records and handwritten signatures.

Electronic record systems are classified as either open or closed. A closed system is one in which system access is controlled by the persons who are responsible for the content of the electronic records (e.g., a firm's HACCP coordinator). An open system is one in which system access is not controlled by the persons who are responsible for the content of electronic records (e.g., a software provider).

Controls are necessary for both types of systems to ensure that records are authentic, accurate, and protected from unauthorized changes (Slide 24). If a firm intends to implement an electronic record-keeping system, factors that must be considered in the design and implementation of the system include:

- Electronic records must be authentic, accurate and protected from unauthorized changes.
- They must be reviewed by management with sufficient frequency to ensure the firm's HACCP plan is being followed.
- They must be available for review and copying by public health authorities, if necessary.

Slide 24

An effective electronic record-keeping system must:
- Be authentic, accurate and protected;
- Provide accurate and complete copies of records;
- Protect records for later retrieval;
- Limit access to authorized individuals;
- Provide a secure record audit trail; and
- Be reviewed by HACCP trained individual.

If a firm decides to use a specific electronic or computerized record-keeping system, it should be validated just like any other process or piece of equipment in the processing plant.

Recent advances in electronic communications makes the use of portable electronic devices attractive to firms who seek to reduce the amount of paper records that must be kept in a HACCP system. Any system that is used must ensure that the electronic records are equivalent to paper records and the electronic signatures are equivalent to traditional handwritten signatures.

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company identified four critical controls points in the hazard analysis. There are three CCPs for the hazard of histamine: receiving, refrigerated storage and finished product storage. There is one CCP for the hazard of food allergens: weigh/pack/label. The HACCP team used the Hazards Guide to determine what verification procedures are needed in their HACCP plan.

Receiving CCP: The HACCP Team identified "Control Strategy 3, Transit Control," in Chapter 7 of the Hazards Guide as the best control strategy for their situation. This strategy recommends that processors keep a record (Receiving log) that documents: the number of containers examined, the number of containers in each delivery, and the results of checks for adequacy of ice.

Refrigerated Storage and Finished Product Storage CCPs: The HACCP Team identified Storage Controls in Chapter 7 of the Hazards Guide as the best control strategy for both of their refrigerated storage CCPs. This strategy recommends that processors keep a record (Cooler ice log) that documents: the number of containers examined, the adequacy of ice in each, the approximate number of containers in the cooler.

Weigh/Pack/Label CCP: The HACCP Team identified Finished Product Labeling Controls in Chapter 19 of the Hazards Guide as the best control strategy for their situation. This strategy recommends that processors keep a record (packing room log) that documents: the results of finished product labeling checks.

Examples of the monitoring records for XYZ Seafood Company are provided to illustrate how the basic record format developed in our previous examples can be adapted for different CCPs and critical limits. Similar adaptations can be made for the other records that would be needed including: a corrective action record, a thermometer accuracy check record, and an annual HACCP plan verification record.

Corrective Action Report (Slide 25)

This form is used to document the action taken by XYZ Seafood Company when a critical limit is exceeded.

Daily Thermometer Accuracy Log (Slide 26)

This form documents the daily accuracy check of all thermometers used in the daily monitoring operations as part of XYZ Seafood Company's verification records.

Thermometer Calibration Log (Slide 27)

This form records the quarterly calibration check of thermometers for the XYZ Seafood Company.

Slide 25

Corrective Action Report (Corrective Action Record)

Form Title: Corrective Action Report Form			
Firm Name: XYZ Seafood Company		**Firm Location:** 238 Coastal Lane, Happy Beach, XX	
Product Description: Fresh mahi-mahi fillets			
Date:	**Line Number:**	**Lot Number:**	**Code Number:**
Date and time of process deviation:			
Describe the process deviation and what happened to the product?			
What action(s) was taken to restore order to the process?			
Name and signature of person reporting deviation and responsible for taking the correction action:			
Amount of product affected by the process deviation:			
Evaluation of product involved by the process deviation:			
Final disposition of the affected product:			
Reviewer Signature:		**Date of Review:**	

Slide 26

Daily Thermometer Accuracy Log (Verification Record)

Form Title: Daily Thermometer Accuracy Log					
Firm Name: XYZ Seafood Company			**Firm Location:** 238 Coastal Lane, Happy Beach, XX		
Product Description: Fresh mahi-mahi fillets					
Verification: Check each thermometer daily for accuracy. Temperature must be ± 2°F from the standard.					
Date	**Time**	**Instrument Number**	**Boiling Water Check**	**Critical Limit Met (Yes/No)**	**Line Operator (Initials)**
Reviewer Signature:				**Date of Review:**	

Slide 27

Quarterly Thermometer Calibration Log (Verification Record)

Form Title: Thermometer Calibration Log					
Firm Name: XYZ Seafood Company			**Firm Location:** 238 Coastal Lane, Happy Beach, XX		
Product Description: Fresh mahi-mahi fillets					
Verification: Check each thermometer daily for accuracy. Temperature must be ± 2°F from the standard.					
Date of Calibration	**Instrument Number(s)**	**Method of Calibration**	**Calibration Results**	**Critical Limit Met (Yes/No)**	**Line Operator (Initials)**
Reviewer Signature:				**Date of Review:**	

XYZ Seafood Company Record Examples

Histamine Fish Receiving Log (Slide 28)

This record captures the results of the routine evaluations for the adequacy of ice surrounding all mahi-mahi fillets when they are received.

Slide 28

Histamine Fish Receiving Log (CCP Monitoring Record)

Form Title: Histamine Fish Receiving Log						
Firm Name: XYZ Seafood Company				**Firm Location:** 238 Coastal Lane, Happy Beach, XX		
Product Identification: Fresh mahi-mahi fillets						
Critical Limits: Mahi-mahi fillets are completely surrounded with ice at receipt.				**Monitoring Activities:** Check for adequacy of ice on receipt		
Date Received	**Time**	**Number of containers received**	**Number of containers checked**	**Number of checked containers with adequate ice**	**Critical Limit Met? (Yes/No)**	**Receiving Manager (Initials)**
Reviewer Signature:				**Date of Review:**		

Histamine Fish Refrigeration Log (Slide 29)

This record documents the results of the routine evaluations for the adequacy of ice surrounding all mahi-mahi fillets that are stored in the refrigerated cooler.

Histamine Fish Packing Room Log (Slide 30)

This record captures the results of the routine monitoring of packaged product to ensure that it is properly labeled by market name for food allergen control.

Slide 29

Histamine Fish Refrigeration Log (CCP Monitoring Record)

Form Title: Histamine Fish Refrigeration Log						
Firm Name: XYZ Seafood Company				**Firm Location:** 238 Coastal Lane, Happy Beach, XX		
Product Identification: Fresh mahi-mahi fillets						
Critical Limits: All containers of mahi-mahi fillets will be completely surrounded with ice				**Monitoring Activities:** Check for adequacy of ice at the beginning and the end of the day		
Date	**Time**	**Number of containers in cooler**	**Number of containers checked**	**Number of containers with adequate ice**	**Critical Limit Met? (Yes/No)**	**Receiving Manager (Initials)**
Reviewer Signature:				**Date of Review:**		

Slide 30

Packing Room Log (CCP Monitoring Record)

Form Title: Packing Room Log						
Firm Name: XYZ Seafood Company				**Firm Location:** 238 Coastal Lane, Happy Beach, XX		
Product Identification: Fresh mahi-mahi fillets						
Critical Limits: All finished product containers will be labeled with the correct market name				**Monitoring Activities:** Check that each container is labeled with the correct market name.		
Date	**Time**	**Number of containers in the order**	**Number of containers checked**	**Number of containers correctly labeled**	**Critical Limit Met? (Yes/No)**	**Packing Manager (Initials)**
Reviewer Signature:				**Date of Review:**		

Example: Fresh Mahi-mahi/XYZ Seafood Co.

XYZ Seafood Company identified four critical controls points in the hazard analysis and has completed all elements of their HACCP plan except records. The final column of the HACCP plan form is completed using the information described above to describe the records that will be used to document their CCP monitoring procedures.

Complete HACCP Plan Form – Records

Slide 31 HACCP plan form (landscape format) for XYZ Seafood Company completed through records.

Slide 32 contains the same HACCP plan information, but displayed in portrait format. The Seafood HACCP Plan format is optional. FDA inspectors are taught using the traditional landscape format. However, the portrait format is often preferred for ease of use. Both versions are available in Appendix 2.

Slide 31

Firm Name: XYZ Seafood Company

HACCP Plan Form

Product: Fresh mahi-mahi fillets

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt.	Adequacy of ice surrounding mahi-mahi fillets at delivery	Visual check of adequacy of ice in a representative number of containers in each delivery	Every Delivery	Receiving Manager	**If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.	Weekly review of Receiving Log (Monitoring record) and Corrective Action and Verification records. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice. Corrective Action records Verification Record • Accuracy Check Log • Calibration Log
Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process.	Weekly review of Cooler Ice Log (Monitoring Record) and Corrective action and Verification records. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration Log

Slide 31 (cont.)

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name of the fish.	The market name on each container of finished product	Visual check of a representative number of containers and their label	Each customer order	Packing Manager	**If:** a container is improperly labeled, **Then:** segregate it and properly label it before the customer order is placed in the finished product cooler, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.	Weekly review of Packing Room Log (Monitoring record) and Corrective action and Verification records. Review of the Verification records within a reasonable time frame. Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.	Packing Room Log that documents: the number of containers checked, the number of containers in the order, and the results of the label check. Corrective Action records Verification Records
Finished Product Refrigerated Storage	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding mahi-mahi fillets	Visual check of representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager	**If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it.	Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration Log

Firm Name: XYZ Seafood Company	**Product:** Fresh mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature: John Doe Print name: _____	Date: 2/29/20

Slide 32

HACCP Plan Form

Firm Name: XYZ Seafood Company	**Product: Fresh mahi-mahi fillets**
Firm Address: 238 Coastal Lane, Happy Beach XX	**Method of Storage & Distribution: Stored and distributed buried in ice**
	Intended Use and Consumer: To be cooked and consumed by the general public

Critical Control Point (CCP)		**CCP 1: Receiving**
Significant Hazard(s)		Histamine
Critical Limits for each Control Measure		Mahi-mahi fillets are completely surrounded with ice at receipt.
Monitoring	What	Adequacy of ice surrounding mahi-mahi fillets at delivery
	How	Visual check of adequacy of ice in a representative number of containers in each delivery
	When	Every Delivery
	Who	Receiving Manager
Corrective Action		**If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.
Verification		Weekly review of Receiving Log (Monitoring record) and Corrective Action and Verification records. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.
Records		Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Log • Calibration Log

Signature: John Doe	Date: 2/29/20

Page _ of _

HACCP Plan Form

Firm Name: XYZ Seafood Company		**Product: Fresh mahi-mahi fillets**
Firm Address: 238 Coastal Lane, Happy Beach XX		**Method of Storage & Distribution: Stored and distributed buried in ice**
		Intended Use and Consumer: To be cooked and consumed by the general public
Critical Control Point (CCP)		**CCP 2: Refrigerated Storage**
Significant Hazard(s)		Histamine
Critical Limits for each Control Measure		Mahi-mahi fillets are completely surrounded with ice throughout storage time
Monitoring	What	Adequacy of ice surrounding mahi-mahi fillets
	How	Visual check of representative number of containers in cooler storage
	When	At the beginning and end of the work day
	Who	Cooler Manager
Corrective Action		**If:** the amount of ice is not adequate; **Then**: chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process
Verification		Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature. Thermometer accuracy check. Annual calibration of thermometer used to check internal temp.
Records		Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage and the results of checks for adequacy of ice. Corrective Action records Verification records
Signature: John Doe		Date: 2/29/20

Page _ of _

HACCP Plan Form

Firm Name: XYZ Seafood Company		**Product: Fresh mahi-mahi fillets**
Firm Address: 238 Coastal Lane, Happy Beach XX		**Method of Storage & Distribution: Stored and distributed buried in ice**
		Intended Use and Consumer: To be cooked and consumed by the general public
Critical Control Point (CCP)		**CCP 3: Weigh/Pack/Label**
Significant Hazard(s)		Food Allergens
Critical Limits for each Control Measure		All finished product containers will be labeled with the correct market name of the fish
Monitoring	What	The market name on each container of finished product
	How	Visual check of a representative number of containers and their label
	When	Each customer order
	Who	Packing Manager
Corrective Action		**If:** a container is improperly labeled, **Then:** segregate it and properly label it before the customer order is placed in the finished product cooler, and modify labeling procedure and conduct training as necessary to ensure that all products are properly identified.
Verification		Weekly review of Packing Room Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.
Records		Packing Room Log that documents: the number of containers checked, the number of containers in the order, and the results of the label check. Corrective Action records Verification records
Signature: John Doe		Date: 2/29/20

Page _ of _

HACCP Plan Form

Firm Name: XYZ Seafood Company	**Product: Fresh mahi-mahi fillets**
Firm Address: 238 Coastal Lane, Happy Beach XX	**Method of Storage & Distribution: Stored and distributed buried in ice**
	Intended Use and Consumer: To be cooked and consumed by the general public

Critical Control Point (CCP)		**CCP 4: Finished Product Refrigerated Storage**
Significant Hazard(s)		Histamine
Critical Limits for each Control Measure		Mahi-mahi fillets are completely surrounded with ice throughout storage time.
Monitoring	What	Adequacy of ice surrounding mahi-mahi fillets
	How	Visual check of representative number of containers in cooler storage
	When	At the beginning and end of the work day
	Who	Cooler Manager
Corrective Action		**If:** finished product containers do not have adequate ice; **Then**: chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it.
Verification		Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature. Thermometer accuracy check. Annual calibration of thermometer used to check internal temp.
Records		Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage and the results of checks for adequacy of ice. Corrective Action records Verification records

Signature: John Doe	Date: 2/29/20

Page _ of _

Chapter 12

The Seafood HACCP Regulation

In December 1997, FDA's regulation called "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" became final. The regulation is based on the seven principles of HACCP and is known as "the Seafood HACCP Regulation." The Seafood HACCP Regulation will be referred to as "the regulation" for the rest of the chapter. A copy of the entire text of the regulation is found in Appendix 1 of this manual. This chapter will review the requirements of the regulation (Slide 1).

Slide 1

In this module, you will learn:
- The requirements of the regulation
- How to reference the specific requirements

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. Subpart A is generally referred to as the "umbrella" section of the regulation as it applies to all processors of fish and fishery products. Subparts B and C are specific to processors of smoked fish and raw molluscan shellfish (Slide 2).

Subpart A contains twenty definitions that help a processor gain an understanding of the scope of the regulation and specific regulatory requirements (Slide 3).

Slide 2

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

Slide 3

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

Definitions 123.3

Of the twenty definitions, a few need to be emphasized (Slide 4).

Slide 4

Regulatory terms "shall" and "should"

Regulations typically use the terms "shall" and "should"

"Shall" is used to state mandatory requirements of the regulations.
"Should" is used to state recommended or advisory procedures or to identify recommended equipment.

Two terms define which products are subject to the regulation (Slide 5).

Slide 5

Products that are subject to the regulation:
- Fish
- Fishery Product

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. Note: it is important to carefully read the definition of fish and note that mollusks (molluscan shellfish) are considered fish for purposes of this regulation.

Fishery product means any human food product where fish is a characterizing ingredient, such as clam chowder or fish sauce.

Two terms define who must comply with the regulation (Slide 6).

Slide 6

Who must comply with the regulation:
- Importer 123.3 (g)
- Processor 123.3 (k) — domestic and foreign

An **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.

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. The importer 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

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.

Note

The ownership of an imported product can change many times in a short period of time after entry into the United States.

A **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**.

One term defines what constitutes processing and is subject to the regulation (Slide 7).

Slide 7

What constitutes processing:
- Processing 123.3 (l)

Note

The term process also includes firms involved in developing fish and fishery products exclusively for market use or consumer tests (such as R&D products) as that is considered processing.

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.

Processing is not defined by ownership of the product. A cold storage warehouse that stores product for different owners is responsible for complying with the regulation as they are "storing" fish and/or fishery products.

Certain processing practices/operations are exempt from the regulation (Slide 8).

- Fishing vessels and transporters who do not engage in processing are not subject to the regulation. However, primary processors that receive these products will need to evaluate the hazards associated with harvest and transportation and control significant hazards at receipt.
- Practices such as heading, gutting or freezing solely to prepare a fish for holding on board the harvest vessel are not subject to the regulation. For example, a fishing vessel may head and gut a halibut in order to better preserve it while holding on the vessel prior to unloading for further processing.
- Retail establishments are not subject to federal regulations, however, they 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) requires that raw materials for retail establishments come from approved sources.

Note

Products that do not move in interstate commerce are not subject to this federal regulation. Products are considered to have entered into interstate commerce if raw materials, ingredients, packaging, etc. have originated outside the state. Products that strictly move in "intrastate" commerce are subject to state requirements. Many states have adopted HACCP regulations similar to the FDA Seafood HACCP Regulation.

Note

Fishing vessels that engage in processing – a.k.a. factory trawlers or catcher processors – are subject to the regulation.

Note

Aquaculture facilities that process at the same site as harvesting are subject to the regulation.

Slide 8

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

Current Good Manufacturing Practices (as referenced in the Seafood HACCP Regulation 21 CFR 123.5)

FDA's Seafood HACCP Regulation section 21 CFR Part 123.5 references the use of current Good Manufacturing Practices (cGMPs), which outlines the conditions and practices the food industry must follow for processing safe food under sanitary conditions (Slide 9). The regulation is broad and includes all foods, including fish and fishery products. The regulatory requirements of the regulation are 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.

Note

Previous regulatory reference to GMPs Part 110 have been replaced by the new GMPs 117.

Slide 9

Current Good Manufacturing Practices:
- Regulations found in Title 21, Part 117 of the Code of Federal Regulations
- Proper practices for the safe and sanitary handling of all foods

The seafood HACCP regulation complements the cGMPs by requiring seafood processors to monitor and document the results of monitoring for eight key areas of sanitation derived from the cGMPs.

HACCP Plan 123.6

Hazard Analysis 123.6(a)

The regulation requires that every processor perform a hazard analysis (Slide 10). There are two major steps in a hazard analysis:

1) Determine whether there are hazards that are reasonably likely to occur
2) Identify control measures to control the identified hazards

Note

In Part 123.6 (a), the regulation references the term "preventive measure". After the publication of the regulation, the term "preventive measure" was superceded by the more current term "control measure".

Slide 10

Hazard Analysis 123.6(a)
Every processor shall conduct, or have conducted for it, a hazard analysis.

Processors must consider hazards that are introduced both within and outside the processing plant and must consider food safety hazards that occur before, during or after harvest or transport. This means if you are a primary processor, in addition to considering hazards within your control, you must consider all hazards associated with your product that may occur prior to receipt. A secondary processor is responsible for considering hazards that might occur in-transit as well as hazards occurring within their processing facility.

The regulation defines a hazard that is reasonably likely to occur as "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 (the hazard) will occur in the particular type of fish or fishery product being processed in the absence of those controls (Slide 11)."

Slide 11

Determining those 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 in the absence of controls. To make this decision, examine:

- Experience,
- Illness data,
- Scientific reports, and
- Other information. A useful source of information is the FDA Hazards Guide. It provides tables that outline the potential species- and process-related hazards that should be considered during the hazard analysis.

Even though every processor needs to conduct a hazard analysis, the regulation does not require it to be written. This is because it is the end product of the hazard analysis – the HACCP plan and its implementation – that will be evaluated by the regulatory authority.

However, a written hazard analysis will help the processor remember the thought process used to identify hazards and their controls. This is useful when periodic plan reassessments, a requirement of the regulation, are conducted and when the plan is reviewed by regulators.

To assist the industry, hazard analysis worksheet templates that can be used can be found in Appendix 2 of this manual.

HACCP Plan 123.6(b)

If the hazard analysis identifies one or more food safety hazards that are reasonably likely to occur, the processor shall have and implement a HACCP plan. Each HACCP plan must be specific to the processing location and each type of fish and fishery product. However, fish and fishery products that have the same hazards, same controls, same critical control points and same critical limits can be grouped into one HACCP plan (Slide 12).

Slide 12

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.

The plan shall be specific to:
- Each processing location.
- Each species of fish and type of fishery product.

The Contents of the HACCP Plan 123.6(c)

If a HACCP plan is needed it must list (Slide 13):

Slide 13

The HACCP plan shall list:
- the food-safety hazards that are reasonably likely to occur.
- the CCPs.
- the critical limits.
- the monitoring procedures.
- predetermined corrective action plans.*
- the verification measures.
- records that will be maintained.

- The food safety hazards that are reasonably likely to occur. Food safety hazards include biological, chemical and physical hazards.
- The critical control points
- The critical limits that will ensure that the identified hazard(s) are controlled
- The monitoring procedures that will ensure that the critical limits are being met. The frequency of monitoring must also be included.
- The pre-determined corrective actions unless the corrective action outlined in the regulation (21 CFR 123.7(c)) will be used.
- The verification procedures that ensure the system is operating according to plan. The frequency of verification must also be included.
- The records that will record the result of monitoring. Records must provide actual values or observations noted during monitoring.

These HACCP plan requirements are the same as the seven principles of HACCP discussed previously in this training.

***Note**

Processors are not required to predetermine corrective actions.

Signing and Dating the HACCP Plan 123.6(d)

The regulation requires that the HACCP plan be signed by the most responsible individual at the processing facility or a higher level official. The signature signifies that the plan has been accepted for implementation by the firm. The person who signs the plan is responsible for ensuring its accuracy, effectiveness and implementation and can be held responsible under the Seafood HACCP rule (Slide 14).

Note

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

- HACCP plans and HACCP plan implementation are 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.

Slide 14

The HACCP plan shall be signed and dated:

- By the most responsible individual at the processing facility or a higher level official.
  - Signed and dated:
    - Upon initial acceptance.
    - Upon any modification.*
    - At least annually.*

*This is a verification requirement.

The signature and date on the HACCP plan is also outlined in the regulation. It must be signed and dated upon initial acceptance, upon any modification, and at least annually when it is reassessed.

Low Acid Canned Foods and Acidified Foods 123.6(e)

Processors of acidified and low acid canned foods are required to have controls in place for *Clostridium botulinum* under 21 CFR Part 113 and Part 114 (Slide 15). Because of this, processors who must comply with the requirements of Title 21 CFR Part 113 or 114 (acidified and low-acid canned foods) 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 21 CFR Part 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.

Note

When a processor controls a hazard such as cross-contamination of a ready-to-eat food through sanitation controls, the controls must be adequate to control the hazard and the monitoring procedures must be frequent enough to reliably indicate that the hazard is being controlled. In this example, cross-contamination of ready-to-eat foods is controlled.

Slide 15

Processors of acidified or low acid canned foods do not need to include controls for *C. botulinum* in their HACCP plan.

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) (Slide 16). 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 sanitation provisions of the regulation. Sanitation requirements are discussed in 21 CFR Part 123.11.

Slide 16

Sanitation controls may be difficult to manage in a HACCP plan.

Legal Basis 21 CFR 123.6(g)

FDA issued the HACCP regulation under various sections of the Food Drug and Cosmetic Act, including, most significantly, sections 402(a)(1) and (a)(4). Together these sections state that a food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health, or if it is been prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health (Slide 17).

Slide 17

It is unlawful to process food under conditions that may render it injurious to health.

It is important to recognize that the later section, 402(a)(4) addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. Any fish or fishery products processed or imported in violation of this regulation can be considered adulterated and subject to regulatory action.

Corrective Action 21 CFR 123.7

The regulation requires that a corrective action take place whenever a critical limit deviation has occurred (Slide 18). A corrective action that meets the requirements of the regulation must be 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.

Slide 18

Corrective Action 123.7
Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

This two-fold approach ensures that the corrective action is applied to the **product** affected by the critical limit deviation, AND to the root cause of the **process** failure.

Processors have a choice of either 1) developing a predetermined corrective action plan in advance as part of their HACCP plans or 2) following the alternate procedure for corrective actions provided in the regulation (Slide 19). 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).

Slide 19

Corrective Actions — Two Choices:
1) Predetermined
2) Alternate Procedure – outlined in the regulation
- Segregate and hold product
- Determine product acceptability
- Apply corrective action to product and process
- Reassess the HACCP plan

Note

A predetermined corrective action plan can be beneficial because it provides the processor with an outline to initiate a corrective action faster. The more quickly a corrective action can be initiated, the more quickly production can safely resume.

Unusual situations may arise that may not be addressed by a predetermined corrective action plan. In these cases, the alternate corrective action procedure outlined in 21 CFR Part 123.7 (c) must be followed.

The alternate corrective action procedures listed in the regulation are:

- Segregating and holding the affected product until:
  - It is determined whether or not 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 adequate for the person to understand the public health consequences of the critical limit deviation.
  - Corrective action is taken, as necessary, to ensure no unsafe product enters commerce.
- Corrective action is taken, as necessary, to fix the problem that caused the deviation.
- A reassessment is performed to 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 assessment and determination must be made by someone who has met the training requirements covered in section 123.10.

All corrective actions must be documented in records that include actions taken to ensure that affected unsafe product was not entered into commerce and the cause of the deviation was corrected.

Verification 123.8

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 (Slide 20). Verification must include, at a minimum, reassessment of the HACCP plan, ongoing verification activities, and record reviews.

Slide 20

Every processor shall verify:
- That the HACCP plan is adequate to control the food-safety hazards that are reasonably likely to occur; and
- That the HACCP plan is implemented effectively.

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 continues to be 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 21 CFR, part 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 original hazard analysis.

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 process controls are effectively implemented on an ongoing basis. Verification activities must be listed in the HACCP plan. One of the functions of verification is to ensure a company's adherence to its written HACCP plan. It is essential that HACCP plan components, including verification activities, are followed as written.

Consumer complaints must be reviewed by the processor to determine whether they relate to problems at a CCP (Slide 21).

Calibration of process monitoring instruments and routine accuracy checks are essential to the continued effective performance of CCPs. In addition to written calibration and accuracy check procedures, companies must perform these procedures at frequency intervals appropriate for the equipment and

instruments used to ensure the process controls continue to function as designed. Calibration is a verification procedure that must be listed in the HACCP plan.

Note

Any end product or in process tests that are listed in the HACCP plan must be made available for review by the FDA.

End product or in-process testing methods are an optional verification strategy. However, end product and in-process tests can provide the processor with invaluable information that can be used to corroborate the ongoing effectiveness and adequacy of the process controls.

Slide 21

Ongoing verification:
- Review of consumer complaints
- Calibration of process-monitoring instruments
- Periodic end-product and in-process testing (processor's option)

Records 21 CFR 123.9

Records required by the regulation are (Slide 22):

- HACCP plan(s)
- Monitoring records
- Corrective action records
- Verification records
- Sanitation control records
- Importer verification records

Slide 22

Records required by the regulation:
- HACCP plan(s)
- Monitoring records
- Corrective action records
- Verification records
- Sanitation control records
- Importer verification records

All records required by the regulation shall be made available for review and copying by the regulatory authority.

Records required by the regulation **must** contain certain information (Slide 23):
- 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 production code where appropriate
- Be completed at the time of the activity

Slide 23

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

The regulation requires that processors review certain records as part of verification (Slide 24). 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 21 CFR part 123.10.

Slide 24

Review of records:
- CCP monitoring and corrective action records – within one week
- Calibration and in-process or end-product testing records – timely manner

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

Sometimes the performance of a verification procedure will indicate a potential public health problem. When this happens, the processor must follow the corrective action procedures described in 21 CFR part 123.7.

Records required by the regulation must be retained at the processing facility or importers place of business in the U.S. for at least one year after the date they were prepared in the case of refrigerated products and for or at least two years after the date they were prepared in the case of frozen preserved or shelf-stable products (Slide 25).

Note

It may be desirable to review records more frequently to ensure control of products that are distributed daily, such as fresh seafood.

Slide 25

Record retention:
- One year for refrigerated products
- Two years for frozen or preserved products

Records that relate to the adequacy of equipment or process controls must be maintained at the processing facility or the importer's place of business in the U.S. for at least two years.

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 made available for official review within a reasonable timeframe by a regulatory agency.

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 not be available for public disclosure unless they have been previously disclosed, they relate to an abandoned product, and that they no longer represent a trade secret.

Training 21 CFR 123.10

The regulation requires that certain functions be performed by an individual trained in HACCP principles as applied to fish and fishery product processing. Processors can use a trained employee or a trained third party to perform these functions (Slide 26). 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 the FDA.

Slide 26

The HACCP-trained individual shall:
- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- Review HACCP records.

Note

Previous regulatory reference to GMPs Part 110 have been replaced by the new GMPs 117.

Sanitation Control Procedures (SCP) 21 CFR 123.11

Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. In writing the 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 (Slide 27).

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.

Slide 27

- Processors should have written SCPs.
- Processor shall monitor and document sanitation control procedures.
- Processors shall correct sanitation deficiencies in a timely manner.

The regulation encourages but does not require "written" sanitation control procedures. However, the regulation does require that processors monitor the sanitary conditions and practices in their facility as well as correct any deficiencies that were noted during that monitoring. The regulation also requires written records documenting the results of the monitoring.

The eight key areas of sanitation include those sections of current Good Manufacturing Practices, which, if not controlled, would affect the safety of food (Slide 28). The purpose of the monitoring is to ensure that the requirements of the cGMPs are met and the purpose of the recordkeeping is to positively document the results of the monitoring. Monitoring frequencies are not specified but must be sufficient to ensure that the current GMP requirements are met.

Note

If the processor develops a written SCP, it should describe how the processor will ensure that certain key sanitation conditions and practices will be met and how they will be monitored.

Slide 28

Eight key sanitation areas:
1) Safety of water,
2) Condition and cleanliness of food-contact surfaces,
3) Prevention of cross-contamination,
4) Maintenance of hand-washing, hand-sanitizing and toilet facilities,
5) Protection from adulterants,
6) Labeling, storage and use of toxic compounds,
7) Employee health conditions,
8) Exclusion of pests.

When sanitation conditions and practices 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 records review (verification) as outlined in 21 CFR part 123.8.

Imported Products 21 CFR 123.12

It has always been the importer's responsibility to offer products for entry into this country 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 in the field (wharf examinations) and sample collections for laboratory analysis of products awaiting entry, and automatic detention of products with a history of problems.

Web Link

Importer Product Specifications model can be found at:

Seafood Network Information Center http://seafood.oregonstate.edu/

Under the Seafood HACCP Regulation, additional 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. Under this section, the U.S. Importer of Record bears the responsibility for verifying that foreign processors fully meet Seafood HACCP Regulations. To do so, the regulation requires that importers take certain steps to verify that their foreign suppliers meet the requirements of the regulation.

Importers may meet their obligation in one of two ways (Slide 29). They may import fish and fishery products that are covered by memorandums of understanding (MOU) between the United States and a foreign country. In this case, they would not need to take any other action to meet the requirements of the regulation.

Slide 29

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

If the U.S. does not have an MOU with the country of origin, importers must have and must implement written importer verification procedures that will ensure that the fish and fishery products offered for import into the United States were processed in accordance with the requirements of the regulation.

Importer Verification Procedures encompass three basic requirements (Slide 30). Importers must:

1) Have and implement written verification procedures that confirm the importer has written product specifications and has taken an affirmative step(s) to ensure that fish and fishery products offered for each entry into the U.S. have been processed in accordance with the regulation.
2) Have written product specifications for each of the products they are importing. Product specifications are designed to address 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. For example, it may be appropriate for a specification for frozen tuna steaks to include a maximum limit for histamine of 50 ppm.

   In the FDA Hazards Guide, Appendix 5 (FDA and EPA Safety Levels in Regulations and Guidance) is an important reference that lists safety levels which can be used for product specifications of various fish and fishery products.

   The product specification should cover any biological, chemical or physical hazard that might be reasonably likely to occur in the product being imported.

Slide 30

Importer Verification Procedures
Importers must have:
1) Written verification procedures
2) Product specifications
3) Affirmative steps

3) Take an affirmative step. An affirmative step may include any of those listed in the regulation, or other such verification procedures that provide an equivalent level of assurance that the fish or fishery product met the HACCP and sanitation requirements of the regulation (Slide 31).

Slide 31

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 the equivalent level of assurance

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.

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.

If an importer does not provide evidence that all of the fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part of the regulation, the imported product will appear to be adulterated and will be denied entry.

Web Link

Letter of guarantee model can be found: http://seafood.oregonstate.edu/.pdf%20Links/Generic-Suppliers-Guarantee.pdf

Note

If an importer decides to obtain a foreign processor's HACCP plan as part of their affirmative step, they should assess the plan to assure that the significant hazards have been listed. FDA can and will cite the importer for a HACCP plan not listing the significant hazards.

If an importer decides to obtain a continuing or lot-by-lot certificate from a competent third party as part of their affirmative step, the importer should review the document to ensure that the product is properly listed and the certificate date has not expired.

If an importer decides to regularly inspect the foreign processor as part of their affirmative step, they should include an inspection report describing their findings during the inspection.

Smoked and Smoke-Flavored Fishery Products 21 CFR 123.15 and 123.16

Subpart B of the regulation is specific to smoked fish (Slide 32). Smoked fish has been linked to a few cases of botulism. *Clostridium botulinum*, the bacterium 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).

Slide 32

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.

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

Raw Molluscan Shellfish 21 CFR 123.20 and 123.28 and Control of Communicable Diseases – Molluscan Shellfish 1240.60

Subpart C of the regulation is specific to raw molluscan shellfish. Two interrelated programs have provided the basis for regulation of molluscan shellfish products by State Shellfish Control Agencies: the Interstate Shellfish Sanitation Conference (ISSC), and the National Shellfish Sanitation Program (NSSP).

The ISSC is an organization of state shellfish control agencies, the shellfish industry, and Federal agencies. The primary goal of the ISSC is to promote the adoption of uniform standards, rules, regulations, and procedures by state shellfish control agencies. Participation in the ISSC is voluntary, but it is supported by state shellfish control officials, participating nations, the shellfish industry, FDA, and the National Marine Fisheries Service.

The NSSP is a voluntary, tripartite program composed of state officials, the shellfish industry, and Federal agencies. FDA coordinates and administers the NSSP. In each participating state, one or more regulatory agencies manage the sanitation programs for domestic and imported shellfish.

With the advent of the regulation, in addition to compliance with State regulations, processors handling molluscan shellfish products must also comply with the Federal provisions outlined in 123.20-123.28.

The largest number of reported illnesses from consumption of seafood is caused by raw molluscan shellfish (oysters, clams and mussels) (Slides 33-39). 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.

Slide 33

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.

Slide 34

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

Slide 35

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.

Slide 36

Raw Molluscan Shellfish 1240.60 (b)
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

Slide 37

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

Slide 38

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

Slide 39

Raw Molluscan Shellfish 1240.60 (c)
Records for shucked product must document:

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

Appendix 1

FDA's Seafood HACCP Regulation

Code of Federal Regulations, Title 21 – Food and Drugs
Chapter 1 – Food and Drug Administration
Department of Health and Human Services

Subchapter B – Food for Human Consumption

Part 123 Fish and Fishery Products [The FDA Seafood HACCP Regulation]

Subpart A—General Provisions

Subpart B—Smoked and Smoke-Flavored Fishery Products

Subpart C—Raw Molluscan Shellfish

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264. Source: 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

Subpart A—General Provisions

§123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. The following definitions shall also apply:

a. ***Certification number*** means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

b. ***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.

c. ***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.

d. ***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.

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

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

g. ***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.

h. ***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.

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

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

k. 1. ***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.
2. The regulations in this part do not apply to:
    i. Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
    ii. Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
    iii. The operation of a retail establishment.

l. ***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. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

m. ***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.

n. ***Shall*** is used to state mandatory requirements.

o. ***Shellfish control authority*** means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

p. ***Shellstock*** means raw, in-shell molluscan shellfish.

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

r. ***Shucked shellfish*** means molluscan shellfish that have one or both shells removed.

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

t. Treating fish with salt (sodium chloride), and

u. 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.

v. ***Tag*** means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§123.5 Current good manufacturing practice.

a. Except as provided by §117.5(b), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

b. The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan.

a. ***Hazard analysis***. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. 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.

b. ***The HACCP plan***. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph of this section. A HACCP plan shall be specific to:
   1. Each location where fish and fishery products are processed by that processor; and
   2. Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

c. ***The contents of the HACCP plan***. The HACCP plan shall, at a minimum:
   1. List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:
      i. Natural toxins;
      ii. Microbiological contamination;
      iii. Chemical contamination;
      iv. Pesticides;
      v. Drug residues;
      vi. Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
      vii. 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;
      viii. Unapproved use of direct or indirect food or color additives; and
      ix. Physical hazards;
   2. List the critical control points for each of the identified food safety hazards, including as appropriate:
      i. Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
      ii. (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;
   3. List the critical limits that must be met at each of the critical control points;
   4. List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
   5. Include any corrective action plans that have been developed in accordance with §123.7(b), to be followed in response to deviations from critical limits at critical control points;
   6. List the verification procedures, and frequency thereof, that the processor will use in accordance with §123.8(a);
   7. 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.

d. ***Signing and dating the HACCP plan.***
   1. The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.
   2. The HACCP plan shall be dated and signed:
      i. Upon initial acceptance;
      ii. Upon any modification; and
      iii. Upon verification of the plan in accordance with §123.8(a)(1).

e. ***Products subject to other regulations***. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

f. ***Sanitation***. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §123.11(b) they need not be included in the HACCP plan, and vice versa.

g. ***Legal basis.*** Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor›s actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§123.7 Corrective actions.

a. Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:
   1. Following a corrective action plan that is appropriate for the particular deviation, or
   2. Following the procedures in paragraph (c) of this section.

b. Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
   1. No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
   2. The cause of the deviation is corrected.

c. When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
   1. Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;
   2. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §123.10;
   3. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
   4. Take corrective action, when necessary, to correct the cause of the deviation;
   5. Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

d. All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §123.8(a)(3)(ii) and the recordkeeping requirements of §123.9.

§123.8 Verification.

a. ***Overall verification.*** Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:
   1. ***Reassessment of the HACCP plan.*** A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §123.6(c).
   2. ***Ongoing verification activities.*** Ongoing verification activities including:
      i. A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

ii. The calibration of process-monitoring instruments; and,
iii. At the option of the processor, the performing of periodic end-product or in-process testing.

3. ***Records review.*** A review, including signing and dating, by an individual who has been trained in accordance with §123.10, of the records that document:
   i. The monitoring of critical control points. purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
   ii. The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §123.7. This review shall occur within 1 week of the day that the records are made; and
   iii. The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

b. ***Corrective actions***. Processors shall immediately follow the procedures in §123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

c. ***Reassessment of the hazard analysis***. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §123.10.

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

§123.9 Records.

a. ***General requirements***. All records required by this part shall include:
   1. The name and location of the processor or importer;
   2. The date and time of the activity that the record reflects;
   3. The signature or initials of the person performing the operation; and
   4. Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

b. ***Record retention***.
   1. All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.
   2. Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.
   3. If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

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

d. ***Public disclosure.***
   1. Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in §20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter.
   2. However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

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

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

§123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under 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 an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

a. Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of §123.6(b);

b. Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in §123.7(c)(5), the HACCP plan in accordance with the verification activities specified in §123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in §123.8(c); and

c. Performing the record review required by §123.8(a)(3); The trained individual need not be an employee of the processor.

§123.11 Sanitation control procedures.

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

b. ***Sanitation monitoring.*** Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter and in subpart B of part 117 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:
   1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
   2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
   3. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
8. Exclusion of pests from the food plant.

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

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

d. ***Relationship to HACCP plan***. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §123.11(b) they need not be included in the HACCP plan, and vice versa.

§123.12 Special requirements for imported products.

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

a. ***Importer verification***. Every importer of fish or fishery products shall either:
   1. Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
   2. Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:
      i. Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,
      ii. Affirmative steps that may include any of the following:
         A. Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

B. Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;
C. Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;
D. Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;
E. Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,
F. Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

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

c. ***Records.*** The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of §123.9.

d. ***Determination of compliance.*** There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Smoked and Smoke-Flavored Fishery Products

§123.15 General.

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

§123.16 Process controls.

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

Subpart C—Raw Molluscan Shellfish

§123.20 General.

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

§123.28 Source controls.

a. In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

b. Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

c. To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in §1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in §1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:
   1. The date of harvest;
   2. The location of harvest by State and site;
   3. The quantity and type of shellfish;
   4. The date of receipt by the processor; and
   5. The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

d. To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with §1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:
   1. The date of receipt;
   2. The quantity and type of shellfish; and
   3. The name and certification number of the packer or repacker of the product.

PART 1240 - Control of Communicable Diseases

1. The authority citation for 21 CFR part 1240 continues to read as follows:
2. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

Sec. 1240.3 General Definitions

c. **Molluscan shellfish.** Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

d. **Certification number** means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

e. **Shellfish control authority** means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

f. **Tag** means a record of harvesting information attached to a container of shellstock by the harvester or processor.
3. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

Sec. 1240.60 Molluscan Shellfish

All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

HACCP Worksheets

Worksheets are recommended to document the hazard analysis and final HACCP plans. The hazard analysis should contain certain information to justify the identification of the proper food safety hazards and critical control points. Information in the HACCP plan must explain the details for each HACCP step. There is no standardized or mandated format for the worksheets, but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the HACCP plan.

The following worksheets are provided as recommended examples. The information is arranged in a similar manner, but the layouts are in either a landscape or portrait form to suit individual preferences.

Special Note: These recommended worksheets can be copied for routine use, but if they are used for official use they must include details that identify the commercial firm and related information. The additional information must include:

- Form title,
- Firm name and location,
- Time and dates,
- Product identification,
- Signature and date (HACCP plan).

Product Description Form

Acceptable Market Name & Species	Where Product Is Purchased (Source)			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/Dealer	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	Reduced-Oxygen/ Vacuum Packed	Raw, to be cooked	Raw, RTE	Cooked, RTE	General-Public	At-risk Population

Hazard Analysis Worksheet

Firm Name:	**Product Description:**
Firm Address:	**Method of Storage & Distribution:**
	Intended Use & Consumer:

(1) **Processing Steps**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**

Page _ of _

Hazard Analysis Worksheet cont'd

(1) **Processing Steps**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**

Page _ of _

HACCP Plan Form

Firm Name:	**Product:**
Firm Address:	**Method of Storage & Distribution:**
	Intended Use and Consumer:
Signature: _____ Print name: _____	Date: _____

		CCP
Critical Control Point (CCP)		
Significant Hazard(s)		
Critical Limits for each Control Measure		
Monitoring	What	
	How	
	Frequency	
	Who	
Corrective Action		
Verification		
Records		

Page _ of _

HACCP Plan Form cont'd

		CCP
Critical Control Point (CCP)		
Significant Hazard(s)		
Critical Limits for each Control Measure		
Monitoring	What	
	How	
	Frequency	
	Who	
Corrective Action		
Verification		
Records		

Page _ of _

Firm Name: _____

HACCP Plan Form

Product: _____

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			

Firm Name:	**Product:**
Firm Address:	**Method of Distribution & Storage:**
	Intended Use and Consumers:
Signature: _____ Print name: _____	Date: _____

HACCP Plan Form cont'd

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			

Page _ of _

Appendix 3

Current Good Manufacturing Practices

Title 21 CFR Part 117 - Subpart B - Current Good Manufacturing Practices

FDA source Dec. 2016: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117)

§117.10 Personnel.

The management of the establishment must take 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, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must 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 must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:
   1. Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and 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. Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.
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.
9. Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§117.20 Plant and grounds.

a. ***Grounds***. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:
   1. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.
   2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
   3. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
   4. 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.
   5. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must 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.

b. ***Plant construction and design.*** The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The plant must:
   1. Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.
   2. Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.
   3. Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:
      i. Using protective coverings.
      ii. Controlling areas over and around the vessels to eliminate harborages for pests.
      iii. Checking on a regular basis for pests and pest infestation.
      iv. Skimming fermentation vessels, as necessary.
   4. 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, food-contact surfaces, or food-packaging materials with clothing or personal contact.
   5. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant 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.
   6. Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.
   7. Provide, where necessary, adequate screening or other protection against pests.

§117.35 Sanitary operations.

a. ***General maintenance.*** Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

b. ***Substances used in cleaning and sanitizing; storage of toxic materials.***
   1. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of 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:
      i. Those required to maintain clean and sanitary conditions;
      ii. Those necessary for use in laboratory testing procedures;
      iii. Those necessary for plant and equipment maintenance and operation; and
      iv. Those necessary for use in the plant's operations.
   2. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

c. ***Pest control.*** Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting 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 must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

d. ***Sanitation of food-contact surfaces***. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.
   1. Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

2. In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must 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 must be cleaned and sanitized as necessary.
3. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

e. ***Sanitation of non-food-contact surfaces***. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

f. ***Storage and handling of cleaned portable equipment and utensils***. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

a. ***Water supply***. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must 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.*** Plumbing must be of adequate size and design and adequately installed and maintained to:
   1. Carry adequate 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 must be disposed of into an adequate sewerage system or disposed of through other adequate means.

d. ***Toilet facilities***. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

e. ***Hand-washing facilities***. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

f. ***Rubbish and offal disposal.*** Rubbish and any offal must 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, food-packaging materials, water supplies, and ground surfaces.

§117.40 Equipment and utensils.

a. 1. All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
   2. Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
   3. Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
   4. Food-contact surfaces must be corrosion-resistant when in contact with food.
   5. Food-contact surfaces must 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, sanitizing agents, and cleaning procedures.
   6. Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

b. Seams on food-contact surfaces must 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 and allergen cross-contact.

c. Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

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

e. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

f. 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 must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

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

§117.80 Processes and controls.

a. ***General.*** 1. All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
   2. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
   3. Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
   4. Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
   5. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
   6. All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

b. ***Raw materials and other ingredients.***

1. Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.
2. Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.
3. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.
4. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.
5. Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.
6. Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.
7. Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.
8. Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

c. ***Manufacturing operations***.

1. Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

2. All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
3. Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
4. Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.
5. Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
6. Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
7. Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
8. Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
9. Food, raw materials, and other ingredients that are adulterated:
    i. Must be disposed of in a manner that protects against the contamination of other food; or
    ii. If the adulterated food is capable of being reconditioned, it must be:
        A. Reconditioned (if appropriate) using a method that has been proven to be effective; or
        B. Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.
10. Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

11. Heat blanching, when required in the preparation of food capable of supporting microbial growth, must 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 or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
12. Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.
13. Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
14. Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.
15. Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.
16. When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§117.95 Holding and distribution of human food by-products for use as animal food.

a. Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:
    1. Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

2. Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
3. During holding, human food by-products for use as animal food must be accurately identified.

b. Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

c. Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

§117.110 Defect action levels.

a. The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

b. The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at *http://www.fda.gov/pchfrule* and at *http://www.fda.gov*

Appendix 4

Glossary of Terms and Acronyms

As an aid to readers, a compilation of terms used in HACCP and food safety regulations and acronyms used in this book is provided below.

Definitions of HACCP Terms[1]

CCP Decision Tree: A sequence of questions to assist in determining whether a control point is a CCP.

Control: (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met.

Control Measure: Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control Point: Any step at which biological, chemical, or physical factors can be controlled.

Corrective Action: Procedures followed when a deviation occurs.

Criterion: A requirement on which a judgement or decision can be based.

Critical Control Point: A step at which control can be applied and is essential to prevent or eliminate a food-safety hazard or reduce it to an acceptable level.

Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

The definitions below were developed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1998 Journal of Food Protection 61(9):1246-1259

Deviation: Failure to meet a critical limit.

HACCP: A systematic approach to the identification, evaluation, and control of food-safety hazards.

HACCP Plan: The written document that is based upon principles of HACCP and that delineates the procedures to be followed.

HACCP System: The result of the implementation of the HACCP plan.

HACCP Team: The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Prerequisite Programs: Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Severity: The seriousness of the effect(s) of a hazard.

Step: A point, procedure, operation or stage in the food system from primary production to final consumption.

Validation: That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

Definitions from the FDA Seafood HACCP Regulation (21CFR Part 123.3)

Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

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 be prevented, eliminated, or reduced to acceptable levels.

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.

Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to alligators, frogs, aquatic turtles, jellyfishes, sea cucumbers, sea urchins and roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

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

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

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.

Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, scallops or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

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

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

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. The regulations in this part do not apply to:

- Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
- 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.

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. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

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.

Shall is used to state mandatory requirements.

Shellfish control authority means a federal, state or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

Shellstock means raw, in-shell molluscan shellfish.

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

Shucked shellfish means molluscan shellfish that have one or both shells removed.

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

- Treating fish with salt (sodium chloride), and
- 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.

Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Definitions from FDA's Good Manufacturing Practices Regulation (21 CFR Part 117.3)

(NOTE: This list is not all-inclusive. Only the definitions that apply to cGMPs and training are listed below.)

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

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

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier's food safety processes and procedures.

Batter means a semifluid 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.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to

partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, 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.

Food Intolerance Substances (FIS) refers to certain potentially hazardous ingredients (e.g. food additives or food colors) that are intentionally added to a food product. The term Food Intolerance Substances that can result in various food sensitivity responses is used to better distinguish from food safety hazards involving a classic food allergen immune response.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating

raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

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.

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, processing, packing, and holding. The safe moisture level for a food is related to 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.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Small business means, for purposes of this part, a business employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Unexposed packaged food means packaged food that is not exposed to the environment.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

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.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Selected Acronyms Used in this Manual

AFDO	Association of Food and Drug Officials
AquaNIC	Aquaculture Network Information Center
ASP	Amnesic shellfish poisoning
B. cereus	*Bacillus cereus*
Bacillus spp.	Several species of Bacillus bacteria
C. bot.	*Clostridium botulinum*
CCP	Critical Control Point
CDC	U.S. Centers for Disease Control and Prevention
CFP	Ciguatera fish poisoning
CFR	Code of Federal Regulations
CFSAN	FDA Center for Food Safety and Applied Nutrition
CGMP	Current Good Manufacturing Practices
CL	Critical Limit
Clostridium spp.	Several species of *Clostridium* bacteria
COOL	Country of origin labeling
DHS	Department of Homeland Security
DSP	Diarrhetic shellfish poisoning
EPIPT	End point internal product temperature
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FR	Federal Register
FSMA	Food Safety Modernization Act
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
MOU	Memorandum of Understanding
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NAS	National Academy of Sciences
NFI	National Fisheries Institute
NLEA	Nutritional Labeling and Education Act
NMFS	NOAA National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NSGO	National Sea Grant Office
NSP	Neurotoxic shellfish poisoning
NSSP	National Shellfish Sanitation Program
PCBs	Polychlorinated biphenyls
PSP	Paralytic shellfish poisoning
ROP	Reduced-Oxygen Packaging
RTE	Ready-to-Eat
S. aureus	*Staphylococcus aureus*
Salmonella spp.	Several species of *Salmonella* bacteria
SCP	Sanitation Control Procedures
SeafoodNIC	Seafood Network Information Center
SHA	National Seafood HACCP Alliance for Training and Education
SSOP	Sanitation Standard Operating Procedures
USC	United States Code
USDA	U.S. Department of Agriculture
V. cholera	*Vibrio cholera*
V. vulnificus	*Vibrio vulnificus*
Vibrio spp.	Several species of *Vibrio* bacteria

Also Available from the National Seafood HACCP Alliance

Guidance for Industry: Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition)

The newly revised FDA Hazards Guide will assist seafood industry compliance with FDA regulations that cover domestic and imported seafood. Key updates include post-harvest treatment information for pathogenic bacteria in shellfish; time and temperature adjustments to control histamine formation and pathogenic bacteria food safety hazards; consistency with changes in statutes regulations, tolerance and action levels for food additives, aquaculture drug approvals, natural toxins, chemicals and pesticides; species hazard identification; and listing potential public health consequences of seafood safety hazards. This is a companion document to SGR 127, the Seafood HACCP Training Curriculum Manual. $25.

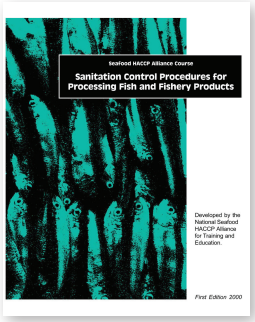
Orientación de controles y peligros de los productos pesqueros y piscícolas (cuarta edición)

La Guía de peligros de la FDA modificada recientemente, ayudará a que la industria de pescados y mariscos cumpla los reglamentos de la FDA sobre pescados y mariscos nacionales e importados. Entre las actualizaciones clave se encuentra la información de tratamiento posterior a la recolección de bacterias patógenas en mariscos; los ajustes del tiempo y la temperatura para controlar la formación de histamina y los peligros para la seguridad de los alimentos de bacterias patógenas; la coherencia con los cambios en los reglamentos, los niveles de tolerancia y acción de aditivos para los alimentos, la aprobación de medicamentos para acuicultura, toxinas naturales, sustancias químicas y pesticidas; la identificación del peligro de las especies y una lista de las posibles consecuencias para la salud pública de los peligros para la seguridad de pescados y mariscos. (SGR 131) $25. Este es un documento que se adjunta al ANÁLISIS DE PELIGROS Y PUNTOS CRÍTICOS DE CONTROL: Programa de Capacitación (SGR 130). $25.

Análisis de Peligros y Puntos Críticos de Control: Programa de Capacitatión (6.th Edición, 2018)

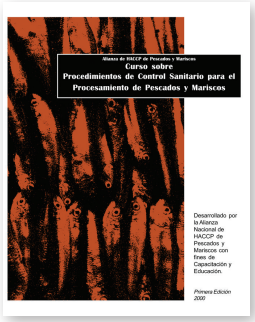
(SGR-134) sexta edición, 2018. Esta es la más reciente edición del manual de entrenamiento básico HACCP. La revisión fue ejecutada para asegurar que el manual sea consistente con los requisitos implementados por la regulación HACCP para productos pesqueros de la FDA (21 CFR 123) y por la última edición de la Guía de Peligros y Controles de la FDA. La sexta edición ha agregado formularios e instrucciones para explicar y respaldar mejor el desarrollo del análisis de peligros apropiado y los planes HACCP. El libro también incluye cambios para abordar los requisitos introducidos por la Ley de Modernización de la Seguridad de los Alimentos (FSMA).

Sanitation Control Procedures for Processing Fish and Fishery Products



This course is intended to assist the seafood industry in developing and implementing sanitation control procedures as mandated by the Food and Drug Administration (FDA). These mandates require seafood processors to monitor sanitary control procedures used during processing in order to show their compliance with approved sanitary conditions and practices. Likewise, seafood importers must verify that the seafood imported was processed in accordance with the same FDA-mandated HACCP requirements that include sanitation procedure monitoring and records. $25.

Curso sobre Prócedimientos de Control Sanitario para el Procesamiento de Pescados y Mariscos



Esta guía es el manual de entrenamiento para el curso dictado con el propósito de asistir a la industria pesquera en el desarrollo e implementación de Procedimientos de Control Sanitarios como requeridos por la Administración de Drogas y Alimentos de Estados Unidos de América (US FDA). Estos mandatos requieren que los procesadores de productos pesqueros monitoreen los procedimientos de control sanitarios utilizados durante el proceso para documentar el cumplimiento con las prácticas y condiciones sanitarias aprobadas. Igualmente, los importadores de productos pesqueros deben verificar que los productos importados fueron procesados bajo los mismos requisitos HACCP de la US FDA que incluyen el monitoreo y registros de los procesos sanitarios. $25.

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