Slides prepared to support **Seafood HACCP Alliance** training courses approved by the Association of Food and Drug Officials (AFDO) which ‘require’ the accompanying training manuals:

**Hazard Analysis and Critical Control Point Training Curriculum** *(SGR 132; Blue Book)*

6th edition  May 2017

**FDA Fish and Fishery Products Hazards and Controls Guidance** *(Gold Book; SGR 129)*

4th edition  April 2011
Program Introduction

National Seafood HACCP Alliance for Training and Education
Introduction to the Alliance Course and HACCP

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

- 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:

- 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
Audience Role

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
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
Definitions and Terms

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

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

- CCP Decision Tree: A sequence of questions to assist in determining whether a control point is a CCP.
- Control: To manage the conditions of an operation to maintain compliance with established criteria. (i) The state when 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.
- Critical Limit: Any step which biological, chemical, or physical factor can be controlled.
- Critical Action: Procedures followed when a deviation occurs.
Slide 7

HACCP stands for Hazard Analysis and Critical Control Points

Slide 8

A HACCP system is:
- Preventive, not reactive
- A management tool used to protect the food supply
- Designed to minimize the risk of food safety hazards, but is not zero risk
Origins of HACCP:
- Pioneered in the 1960s
- First used when foods were developed for the space program
- Adopted by many food processors

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

**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
Layers of Controls

Slide 12

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

- HACCP
- Sanitation Control Procedures
- Good Manufacturing Practices
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
Prerequisites

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

**Slide 5**

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

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
Required Training Records

<table>
<thead>
<tr>
<th>Employee Training Record</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Employee:</strong> anybody Jones</td>
</tr>
<tr>
<td>COURSES</td>
</tr>
<tr>
<td>Basic Sanitation Course (Seafood HACCP Alliance)</td>
</tr>
<tr>
<td>GMP’s 117</td>
</tr>
<tr>
<td>SCP Monitoring</td>
</tr>
<tr>
<td>Basic Sanitation Review</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group Employee Training Record</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Course:</strong> Personnel Hygiene and Food Safety Level 1</td>
</tr>
<tr>
<td><strong>DATE COMPLETED:</strong> April 15, 2017</td>
</tr>
</tbody>
</table>

**EMPLOYEES**
- Nancy Dolittle – Packing and Labeling
- Anyone Jones – Shrimp cooker belt
- Joe Not – Recv Dock
- Betty Done – Thawing

Page 13
GMP’s 117

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.

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.
Seafood HACCP programs must be based on a solid foundation in compliance with the GMPs and SCPs.
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.
SSOP’s - Written Procedures

Sanitation Control Procedures

Recommended:
- Written Sanitation Standard Operating Procedures (SSOPs)

Required:
- Monitoring
- Corrections
- Recordkeeping
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.
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
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:
   - 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 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:
   - Maintenance and location of hand washing, hand sanitizing, and toilet facilities
   - Maintenance of adequate sewage disposal system
5) **Protection from adulterants:**
   - Protect food, food contact surfaces, and food packaging material from contaminants.

6) **Labeling, storage and use of toxic compounds**
7) Employee health conditions:
   - Controls are necessary to ensure that employee health conditions do not cause food contamination.

8) Exclusion of pests:
   - Pests must not be present in the food processing facility.
### SCP’s in GMP’s 117

#### Pages 21-22

#### Table 1

Seafood HACCP Regulation Sanitation Requirements (21 CFR 123.11(b)) and their relation to the current Good Manufacturing Practice Regulation (21 CFR 117)

<table>
<thead>
<tr>
<th>Part 123.11(b) Monitoring Equipment</th>
<th>21 CFR Part 117 Subpart B – Current Good Manufacturing Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Safety of Water</strong></td>
<td>Water Supply</td>
</tr>
<tr>
<td>1.4(a) Water supply must be derived from adequate source and adequate for operations.</td>
<td></td>
</tr>
<tr>
<td>1.4(b) Plumbing</td>
<td>- Prevention of contamination from plumbing</td>
</tr>
<tr>
<td>- Backflow prevention and cross-connections</td>
<td></td>
</tr>
<tr>
<td>1.4(c) Processes and Controls</td>
<td>- Water used for washing, rinsing, or conveying food</td>
</tr>
<tr>
<td>- 10(g) Water for sanitizing</td>
<td></td>
</tr>
<tr>
<td><strong>2. Condition and cleanliness of food contact surfaces</strong></td>
<td>Sanitization of Food Contact Surfaces</td>
</tr>
<tr>
<td>2.4(a) Food contact surfaces, equipment and/or utensils</td>
<td>- Designed and made from materials that are adequately cleanable and maintained to preclude cross-contact and cross-contamination</td>
</tr>
<tr>
<td>- Installed to facilitate cleaning and maintenance</td>
<td></td>
</tr>
<tr>
<td><strong>3. Prevention of cross-contamination</strong></td>
<td>Personnel</td>
</tr>
<tr>
<td>3.4(a) Employee cleanliness</td>
<td>- Outer garments</td>
</tr>
<tr>
<td>- Personal cleanliness</td>
<td>- Handwashing and sanitizing</td>
</tr>
<tr>
<td>- Unsecured jewelry and other objects that cannot be sanitized</td>
<td></td>
</tr>
<tr>
<td>- Clothing and personal belonging storage</td>
<td></td>
</tr>
<tr>
<td>- Eating, drinking, gum, tobacco use</td>
<td></td>
</tr>
<tr>
<td><strong>4. Maintenance of hand washing, hand sanitizing, and toilet facilities</strong></td>
<td>Plumbing</td>
</tr>
<tr>
<td>- Property convey sewage and liquid waste</td>
<td></td>
</tr>
<tr>
<td>- Plumbing must not constitute a source of contamination</td>
<td></td>
</tr>
<tr>
<td>- Plumbing must protect against backflow or cross connections with waste water systems</td>
<td></td>
</tr>
<tr>
<td>- Sanitation disposal</td>
<td></td>
</tr>
<tr>
<td>- Toilet facilities</td>
<td></td>
</tr>
<tr>
<td>- Hand-washing facilities</td>
<td></td>
</tr>
</tbody>
</table>
Monitoring SCP’s

<table>
<thead>
<tr>
<th>Sanitation Condition/Practice</th>
<th>Frequency of Monitoring</th>
<th>Corrections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety of water</td>
<td>Municipal source: Annually&lt;br&gt;Private well: Semi-annually&lt;br&gt;Cross connections: Semi-annually (unless changes are made) for hard plumbing between potable and non-potable lines&lt;br&gt;Cross connections: daily, if hose bibs not protected</td>
<td>Example: If report of water shows high coliform counts, stop processing. Resample water and/or ice to determine required corrections before restarting.</td>
</tr>
<tr>
<td>Condition and cleanliness of food contact surfaces</td>
<td>Condition of processing equipment: Monthly or more often if equipment is repaired or replaced to assure it meets the construction standards&lt;br&gt;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&lt;br&gt;Record sanitizer concentrations.</td>
<td>Example: If sanitizer concentration is too low, stop. Make new sanitizing agent and clean and sanitize again.</td>
</tr>
<tr>
<td>Prevention of cross contamination</td>
<td>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.&lt;br&gt;Separation of raw and cooked products performed daily.&lt;br&gt;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.</td>
<td>Example: If raw product touches or otherwise contaminates cooked product, the cooked product will not be distributed and source of problem will be corrected.</td>
</tr>
</tbody>
</table>
Monitoring SCP’s

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
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.

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

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Control</th>
<th>Type of Control</th>
<th>Control Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histamine</td>
<td>Time and temperature controls for fish</td>
<td>Product specific</td>
<td>HACCP</td>
</tr>
<tr>
<td>Pathogen survival</td>
<td>Time and temperature controls for smoking fish</td>
<td>Processing step</td>
<td>HACCP</td>
</tr>
<tr>
<td>Contamination with pathogens</td>
<td>Wash hands before touching product</td>
<td>Employee</td>
<td>Sanitation or SCP</td>
</tr>
<tr>
<td>Contamination with pathogens</td>
<td>Limit employee movement between raw and cooked areas</td>
<td>Employee</td>
<td>Sanitation or SCP</td>
</tr>
<tr>
<td>Contamination with pathogens</td>
<td>Clean and sanitize food contact surfaces</td>
<td>Plant environment</td>
<td>Sanitation or SCP</td>
</tr>
<tr>
<td>Chemical contamination</td>
<td>Use only food-grade grease</td>
<td>Plant environment</td>
<td>Sanitation or SCP</td>
</tr>
</tbody>
</table>
Example SSOP ‘written program’ and accompanying records

Table 2. Model Sanitation Standard Operating Procedure

1. Safety of water (FDA Key Sanitation Condition No. 3)

   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 the plumbing system is properly constructed. Monitoring Frequency: When plumbing is installed or modified.
   c) All water faucets and fixtures include all anti-siphoning controls.

   Corrections:
   a) In the event of municipal water treatment failure, determine when the failure occurred, and the failure until product safety can be assured. If water meets state and federal water quality standards.
   b) Corrections will not be made to the plumbing’s problems. Production will resume only when water quality standards are met.
   c) Water faucets and fixtures with anti-siphon and anti-siphoning controls have been implemented.

   Records:
   a) Municipal water bill and monthly sanitation
   b) Building plumbing inspection report and periodic
   c) Daily Sanitation Control Record

2. Condition and cleanliness of food contact surfaces

   Controls and Monitoring:
   a) Food contact surfaces are readily cleanable overlapping (plins, mineral scale, etc.) that still sanitize. The sanitation supervisor inspects they are readily cleanable. Monitoring Frequency: Daily
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.
**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
Potential seafood safety hazards can be grouped into two categories:
- Species-related hazards
- Process-related hazards
Species-Related Hazards
- Pathogens from the Harvest Area (molluscan shellfish only)
- Parasites (finfish and shellfish)
- Natural Toxins (finfish and shellfish)
- Scombrotokxin 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 additives
- Metal and glass inclusion
Slide 5

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

Slide 6

Bacterial Hazards:
- Foodborne infection
- Foodborne intoxication
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.
Pathogen Growth

Slide 8

Number of Bacteria

Lag Phase

Stationary Phase

Exponential Phase

Growth Time

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)
Primary Microbial Pathogens

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*)
Specific Pathogen Controls

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.
Specific Pathogen Controls

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
Specific Pathogen Controls

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
Specific Pathogen Controls

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
Specific Pathogen Controls

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
Specific Pathogen Controls

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
Viruses

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
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

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

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)

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
Parasites

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)

Some controls for *Anisakis simplex, P. decipiens* and *D. latum* parasites in seafood:
- Proper freezing
- Proper cooking
Species-Related Hazards from Harvest/Growing Waters

Slide 24

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

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)
Natural Toxin Controls

**Slide 26**

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

**Slide 27**

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

Slide 28
Control for tetrodotoxin in seafood:
- Do not process certain fish (puffer fish) that have been designated as potentially tetrodotoxic

Slide 29
Control for *gempylocrin* in seafood:
- Do not process certain potentially gempylocrin toxic fish
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: Illegal or Improper Use

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)

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

Other Process-Related Food Safety Hazards
- Food Additives
- Food Allergens
- Metal and Glass Inclusion
Process-Related Hazards

**Slide 34**

Examples of Food Additives
- Preservatives (e.g. nitrite, sulfites)
- Nutritional supplements (e.g. vitamins)
- Color additives

**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

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

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass</td>
<td>Cuts, bleeding; may require surgery to find or remove</td>
</tr>
<tr>
<td>Metal</td>
<td>Cuts, broken teeth; may require surgery to remove</td>
</tr>
</tbody>
</table>
Physical Hazard Controls

Slide 39
Control for potential glass inclusion in seafood:
- Examination of glass containers for breakage

Slide 40
Controls for potential metal inclusion in seafood:
- Monitoring equipment for wear and breakage
- Screening products with metal detectors
Preliminary Steps in Developing a HACCP Plan

In this chapter, you will learn:

- The importance of preliminary steps in developing the HACCP plan
Get Ready!

**Slide 2**

Preliminary steps:
- Assemble HACCP team
- Describe the product, intended use and consumers
- Develop a Process Flow Chart
- Develop a Process Description
HACCP TEAM ... Who’s involved?

Managers

Processing

Sanitation
What’s involved?

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
What’s involved?

Product Description Form for Fish and Shellfish Species

<table>
<thead>
<tr>
<th>Acceptable Market Name &amp; Species</th>
<th>Where Product is Purchased (Source)</th>
<th>How Product is Received</th>
<th>How Product is Stored</th>
<th>How Product is Shipped</th>
<th>How Product is Packaged</th>
<th>Intended Use</th>
<th>Intended Consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fisherman</td>
<td>Fish Farm</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Air Packaged</td>
<td>General Public</td>
</tr>
<tr>
<td></td>
<td>Fisheries</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Cooked</td>
<td>At-risk Population</td>
</tr>
<tr>
<td></td>
<td>Processo</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Raw RTE</td>
<td>cooked</td>
</tr>
<tr>
<td></td>
<td>Dealer</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Cooked</td>
<td></td>
</tr>
</tbody>
</table>

Useful Product Description Chart

Page 73
Processing Steps involved?

Slide 5

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

1. Receiving
2. Processing
3. Packaging
4. Storage
### XYZ Seafood Company Product Description Form for Fish and Shellfish Species

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mahi-mahi fillets ( Coryphaena sp.)</td>
<td>Fisherman</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td>Fish Farm</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td>Processor/Dealer</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
<td>Refrigerated</td>
<td>Iced</td>
<td>Frozen</td>
</tr>
</tbody>
</table>
XYZ Processing Steps

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

Process Flow Chart

- Receive Fresh Fillets
- Refrigerated Storage
  - Trim
  - Weigh/Pack/Label
- Finished Product Storage
Principle 1: HAZARD ANALYSIS

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

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).

Food Safety Hazards

• Biological
• Chemical
• Physical
Why conduct a Hazard Analysis?

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 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)
Use the Hazard Analysis Worksheet

Blank Hazard Analysis Worksheet

<table>
<thead>
<tr>
<th>(1) Processing Steps</th>
<th>(2) List all potential food safety hazards that could be associated with this product and process.</th>
<th>(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or No)</th>
<th>(4) Justify the decision that you made in column 3</th>
<th>(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(6) Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Name:</td>
<td></td>
<td></td>
<td>Product Description:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Firm Address:</td>
<td></td>
<td></td>
<td>Method of Storage &amp; Distribution:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended Use &amp; Consumer:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“Fresh Mahi-mahi Fillets”
Processing Steps
Flow Diagram from
Chapter 4, Page 75
List all Processing Steps

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>(2) List all potential biological, chemical, and physical food safety hazards that could be associated with this product and process.</th>
<th>(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or No)</th>
<th>(4) Justify the decision that you made in column 3.</th>
<th>(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(6) Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving Fresh Fillets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trim</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weigh/Pack/Label</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished Product Storage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 2 – List Potential Food Safety Hazards

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

Use the FDA Hazards Guide as a tool to help identify potential hazards.
Search for the potential hazards for the Fresh ‘Wild’ Mahi-mahi Fillets

### Tables 3-2 and 3-3

#### Species-Related Hazards

<table>
<thead>
<tr>
<th>Market Names</th>
<th>Latin Names</th>
<th>Species-Related Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchovy</td>
<td>Anchoia spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Angelfish</td>
<td>Pterocaesio spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aligator</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Alligator, aquacultured</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack</td>
<td>Seriola dumerili</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Yellowtail</td>
<td>Seriola lalandi</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Buri, aquacultured</td>
<td>Seriola quinqueradiata</td>
<td>✓</td>
</tr>
<tr>
<td>Alewife or River Mackerel</td>
<td>Alosa pseudoharengus</td>
<td>✓</td>
</tr>
<tr>
<td>Alfonsino</td>
<td>Beryx spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aholehole</td>
<td>Athilia spp.</td>
<td>✓</td>
</tr>
</tbody>
</table>

#### Process-Related Hazards

<table>
<thead>
<tr>
<th>Package Type</th>
<th>HAZARDS</th>
<th>Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished Product</td>
<td>Food 5</td>
<td>✓</td>
</tr>
</tbody>
</table>

---

**Table 3-2**

<table>
<thead>
<tr>
<th>Market Names</th>
<th>Latin Names</th>
<th>Species-Related Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchovy</td>
<td>Anchoia spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Angelfish</td>
<td>Pterocaesio spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aligator</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Alligator, aquacultured</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack</td>
<td>Seriola dumerili</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Yellowtail</td>
<td>Seriola lalandi</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Buri, aquacultured</td>
<td>Seriola quinqueradiata</td>
<td>✓</td>
</tr>
<tr>
<td>Alewife or River Mackerel</td>
<td>Alosa pseudoharengus</td>
<td>✓</td>
</tr>
<tr>
<td>Alfonsino</td>
<td>Beryx spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aholehole</td>
<td>Athilia spp.</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Table 3-3**

<table>
<thead>
<tr>
<th>Market Names</th>
<th>Latin Names</th>
<th>Species-Related Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchovy</td>
<td>Anchoia spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Angelfish</td>
<td>Pterocaesio spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aligator</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Alligator, aquacultured</td>
<td>Alligator mississippiensis</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack</td>
<td>Seriola dumerili</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Yellowtail</td>
<td>Seriola lalandi</td>
<td>✓</td>
</tr>
<tr>
<td>Amberjack or Buri, aquacultured</td>
<td>Seriola quinqueradiata</td>
<td>✓</td>
</tr>
<tr>
<td>Alewife or River Mackerel</td>
<td>Alosa pseudoharengus</td>
<td>✓</td>
</tr>
<tr>
<td>Alfonsino</td>
<td>Beryx spp.</td>
<td>✓</td>
</tr>
<tr>
<td>Aholehole</td>
<td>Athilia spp.</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Table 3-4**

<table>
<thead>
<tr>
<th>Package Type</th>
<th>HAZARDS</th>
<th>Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished Product</td>
<td>Food 5</td>
<td>✓</td>
</tr>
</tbody>
</table>

---

*Note: You should identify pathogens from the harvest area as a potential species-related hazard if you know, or have reason to know, that the fish will be consumed without a process sufficient to kill pathogens or if you represent, label, or intend for the product to be so consumed.*

See Chapter 4 for guidance on controlling pathogens from the harvest area.
# One Species-related hazard

## Table 3-2

### POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS

**Note:** You should identify pathogens from the harvest area as a potential species-related hazard if you know, or have reason to know, that the fish will be consumed without a process sufficient to kill pathogens or if you represent, label, or intend for the product to be so consumed. (See Chapter 4 for guidance on controlling pathogens from the harvest area.)

<table>
<thead>
<tr>
<th>MARKET NAMES</th>
<th>LATIN NAMES</th>
<th>HAZARDS</th>
<th>Parasites³</th>
<th>Natural Toxins³</th>
<th>Scombrotoxin (Histamine)</th>
<th>Environmental Chemicals</th>
<th>Aquaculture Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACKEREL, SPANISH or NARROW-BARRED</td>
<td><em>Scomberomorus commerson</em></td>
<td>CFP</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI-MAHI</td>
<td><em>Coryphaena</em> spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI-MAHI, aquacultured</td>
<td><em>Coryphaena</em> spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>MARLIN</td>
<td><em>Makaira</em> spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Tetrapurus</em> spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>
# Four Process-related Hazards

**Table 3-4**

<table>
<thead>
<tr>
<th>Finished Product Food 1</th>
<th>Package Type</th>
<th>C. botulinum Toxin</th>
<th>S. aureus Toxin - Drying</th>
<th>S. aureus Toxin - Batter</th>
<th>Pathogenic Bacteria Through Cooking or Pasteurization</th>
<th>Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics</th>
<th>Pathogenic Bacteria Contamination after Pasteurization and Specialized Cooking Processes</th>
<th>Allergens and Food Intolerance Substances</th>
<th>Metal Inclusion</th>
<th>Glass Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw fish other than oysters, clams, and mussels (finfish and non-finfish)</td>
<td>Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Raw fish other than oysters, clams, and mussels (finfish and non-finfish)</td>
<td>Other than reduced oxygen packaged</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Raw oysters, clams, and mussels</td>
<td>Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Raw oysters, clams, and mussels</td>
<td>Other than reduced oxygen packaged</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Notice two hazards in Chapter 19
Hazard Analysis for the XYZ Seafood Company should include 5 potential hazards:

Species-related Hazards  
1. Histamine formation (Chapter 7)

Process-related Hazards  
2. Pathogenic bacterial growth-temperature abuse (Chapter 12)
3. Allergens (Chapter 19)
4. Food Intolerance Substances (Chapter 19)
5. Metal inclusion (Chapter 20)
Inclusive Method

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>(1) Processing Step</th>
<th>(2) List all potential food safety hazards that could be associated with this product and process</th>
<th>(3) Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>(4) Justify the decision that you made in column 3</th>
<th>(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(5) Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Histamine</td>
<td>Pathogen Growth-Temp. Abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Undeclared Food Allergens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Food Intolerance Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Metal Inclusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td>Histamine</td>
<td>Pathogen Growth-Temp. Abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Undeclared Food Allergens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Food Intolerance Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Metal Inclusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Column 2: List every hazard that is reasonably likely to occur at each processing step. Every potential hazard considered at each processing step.
Steps 3 and 4: Hazard Evaluation and Justification. Determine which hazards are significant and explain why.

Simply answer the questions in the Hazard Analysis
Exercise: Complete the Hazard Analysis Worksheet

<table>
<thead>
<tr>
<th>(1) Processing Step</th>
<th>(2) List all potential food safety hazards that could be associated with this product and process</th>
<th>(3) Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>(4) Justify the decision that you made in column 3</th>
<th>(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(6) Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receiving</strong></td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pathogen Growth-Temp. Abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undeclared Food Allergens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Food Intolerance Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metal Inclusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Refrigerated Storage</strong></td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pathogen Growth-Temp. Abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undeclared Food Allergens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Food Intolerance Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metal Inclusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Simply answer the questions in order for each listed potential hazard at each processing step.

FDA Hazards Guide provides some recommendations in the respective hazard chapters.
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?

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?)
Justify your ‘Yes or No’ decisions

XYZ Seafood Company – Fresh Mahi-mahi Fillets

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>Potential Hazard</th>
<th>Qualitative Analysis</th>
<th>Justify the decision that you made in column 3</th>
<th>Control Measure(s)</th>
<th>Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving Fresh Fillets</td>
<td>Histamine</td>
<td>Yes</td>
<td>Time/temp. abuse during transit could cause histamine to form in the fish</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathogen Growth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature Abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Allergens</td>
<td></td>
<td>Yes</td>
<td>Mahi is a food allergen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Intolerance</td>
<td></td>
<td>No</td>
<td>No FIS are used on fresh fillets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td></td>
<td>No</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# BRIEF SUMMARY based on the FDA Guide that provides more recommended details

<table>
<thead>
<tr>
<th>Column 2</th>
<th>Columns 3 &amp; 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Hazards (Likely to Occur)</td>
<td>Is the hazard significant in this processing operation</td>
</tr>
<tr>
<td>Histamine</td>
<td>YES Mahi is potential scombrototoxic fish species subject to temperature abuse</td>
</tr>
<tr>
<td>Pathogen Growth - Temp. Abuse</td>
<td>NO Mahi intended to be cooked before consumption</td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES Fish are food allergens</td>
</tr>
<tr>
<td>Food Intolerance Substances (FIS)</td>
<td>NO No FIS or food additives used or added in this processing operation</td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO Not likely to occur in processing steps</td>
</tr>
</tbody>
</table>
STEP 5 – Identify Control Measures (Column 5)

**Slide 16**

Step 5: Identify Control Measures for each significant 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.
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 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
**BRIEF SUMMARY** based on the FDA Guide that provides more recommended details

<table>
<thead>
<tr>
<th><strong>Column 2</strong></th>
<th><strong>Column 3 &amp; 4</strong></th>
<th><strong>Column 5</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential Hazards</strong> ( Likely to Occur )</td>
<td>Is the hazard significant in this processing operation</td>
<td>Necessary Controls</td>
</tr>
<tr>
<td>Histamine</td>
<td>YES</td>
<td>Mahi is potential scombrototoxic fish species subject to temperature abuse</td>
</tr>
<tr>
<td>Pathogen Growth - Temp. Abuse</td>
<td>NO</td>
<td>Mahi intended to be cooked before consumption</td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Fish are food allergens</td>
</tr>
<tr>
<td>Food Intolerance Substances (FIS)</td>
<td>NO</td>
<td>No FIS or food additives used or added in this processing operation</td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur in processing steps</td>
</tr>
</tbody>
</table>
## 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

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>List all potential food safety hazards that could be associated with this product and process</th>
<th>Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>Justify the decision that you made in column 3</th>
<th>What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Histamine</strong></td>
<td>YES</td>
<td>Time/temp. abuse during transit could cause histamine to form in the fish</td>
<td>Mahi-mahi fillets are shipped in containers buried in ice (proper icing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pathogen Growth-Temp. Abuse</strong></td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Undeclared Food Allergens</strong></td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Food Intolerance Substances</strong></td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Metal Inclusion</strong></td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Refrigerated Storage

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>List all potential food safety hazards that could be associated with this product and process</th>
<th>Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>Justify the decision that you made in column 3</th>
<th>What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Histamine</strong></td>
<td>YES</td>
<td>Time/temp. abuse during transit could cause histamine to form in the fish</td>
<td>Mahi fillets are buried in ice &amp; stored in a refrigerated cooler (proper icing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pathogen Growth-Temp. Abuse</strong></td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Undeclared Food Allergens</strong></td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Food Intolerance Substances</strong></td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Metal Inclusion</strong></td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Every ‘Yes’ in column 3 requires a response in column 5 and 6
### Hazard Analysis Worksheet

Every ‘Yes’ in column 3 requires a response in columns 5 and 6.

<table>
<thead>
<tr>
<th>Trim</th>
<th>Histamine</th>
<th>NO</th>
<th>Pathogen Growth-Temp. Abuse</th>
<th>NO</th>
<th>Not likely to occur, time at this step is 30 min or less</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Fillet knives are not likely to chip and contaminate product with metal</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weigh/Pack/Label</th>
<th>Histamine</th>
<th>NO</th>
<th>Pathogen Growth-Temp. Abuse</th>
<th>NO</th>
<th>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Fillets are labeled with market name at this step (proper labeling)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Finished Product Refrigerated Storage</th>
<th>Histamine</th>
<th>YES</th>
<th>Time/temp. abuse could occur during storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogen Growth-Temp. Abuse</td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td></td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>NO</td>
<td>Fillets are labeled with market name at weight/pack/label step</td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
</tr>
</tbody>
</table>
Be sure to identify all potential FOOD SAFETY Hazards

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.
End Chapter 5: Principle 1

HAZARD ANALYSIS

QUESTIONS?
Principle 2: Determine Critical Control Points

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.
What’s a Critical Control Point?

**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.

**Slide 3**

CCP placement must be at the processing step or steps that adequately control the significant hazard.
CCPs can be steps where hazards can be prevented.

**Control Measures**
- Formulation
- Time/Temp Control
- Supplier Certificates

**CCPs**
- Mixing Step
- Refrigerated Storage Step
- Receiving Step
Hazard Elimination

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

**Control Measures**
- Cooking
- Use of Metal Detection
- Freezing Procedures

**CCPs**
- Cook Step
- Metal Detector Step
- Freeze Step
Hazard Reduction

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

Control Measure
Source Controls
Time/Temp Control

CCP
Receiving Step
Cook Step
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
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.
CCP Decision Tree
(optional tool)

Slide 9

CCP Decision Tree

Q 1) Does this step involve a hazard of sufficient risk and severity to warrant its control?
   - Yes
   - No → Not a CCP

Q 2) Does a control measure for the hazard exist at this step?
   - Yes
   - No → Modify this step, process or product
   - Is control at this step necessary for safety
     - Yes
     - No → Not a CCP → Stop*

Q 3) Is control at this step necessary to prevent, eliminate or reduce the risk of the hazard to consumers?
   - Yes
   - No → Not a CCP → Stop*

CCP

*Proceed to the next step in process
## 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

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>List all potential food safety hazards that could be associated with this product and process</th>
<th>Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>Justify the decision that you made in column 3</th>
<th>What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receiving</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histamine</td>
<td>YES</td>
<td>Time/temp. abuse during transit could cause histamine to form in the fish</td>
<td>Mahi-mahi fillets are shipped in containers buried in ice (proper icing)</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Pathogen Growth-Temp. Abuse</td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Refrigerated Storage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histamine</td>
<td>YES</td>
<td>Time/temp. abuse during transit could cause histamine to form in the fish</td>
<td>Mahi-mahi fillets are buried in ice &amp; stored in a refrigerated cooler (proper icing)</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Pathogen Growth-Temp. Abuse</td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FIS used or added to the fresh fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Every ‘Yes’ in column 3 requires a response in column 6**

**CCP**
### Completed Hazard Analysis 105 - 107

Every ‘Yes’ in column 3 requires a response in column 6

<table>
<thead>
<tr>
<th>Trim</th>
<th>Histamine</th>
<th>Pathogen Growth-Temp. Abuse</th>
<th>Undeclared Food Allergens</th>
<th>Food Intolerance Substances</th>
<th>Metal Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Not likely to occur, time at this step is 30 min or less</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td>Mahi is a food allergen</td>
<td>Containers of fillets will be labeled with market name at labeling step</td>
<td>NO</td>
</tr>
<tr>
<td>Weigh/Pack/Label</td>
<td>Histamine</td>
<td>Pathogen Growth-Temp. Abuse</td>
<td>Undeclared Food Allergens</td>
<td>Food Intolerance Substances</td>
<td>Metal Inclusion</td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Not likely to occur, time at this step is 30 min or less</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td>Mahi is a food allergen</td>
<td>Fillets are labeled with market name at this step (proper labeling)</td>
<td>YES</td>
</tr>
<tr>
<td>Finished Product Refrigerated Storage</td>
<td>Histamine</td>
<td>Pathogen Growth-Temp. Abuse</td>
<td>Undeclared Food Allergens</td>
<td>Food Intolerance Substances</td>
<td>Metal Inclusion</td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Time/temp. abuse could occur during storage</td>
<td>Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption</td>
<td>Fillets are labeled with market name at weigh/pack/label step</td>
<td>No FIS used or added to the fresh fish</td>
<td>NO</td>
</tr>
</tbody>
</table>

**CCP**
Conclusions from the Hazard Analysis

- Histamine is a significant food safety hazard and there are three CCPs for this hazard:
  - CCP 1. Receive fresh fish
  - CCP 2. Refrigerated storage, and
  - CCP 3. Finished product refrigerated storage

- Undeclared food allergen is a significant food safety hazard and there is one CCP for this hazard:
  - CCP 4. Weigh/Pack/Label
Remember to use the recommendations in the FDA Guide

For example, ‘Likely CCPs’ for histamine formation (FDA Guide, Chapter 7)

and food allergens (FDA Guide, Chapter 19)
### Tip

"CCP either here or later"

Every ‘Yes’ in column 3 requires a response in column 6.

#### XYZ Seafood Company – Fresh Mahi-mahi Fillets

**Hazard Analysis Worksheet**

<table>
<thead>
<tr>
<th>Processing Step</th>
<th>(1) List all potential food safety hazards that could be associated with this product and process</th>
<th>(2) Is the potential food safety hazard significant (e.g., increased, enhanced or eliminated) at this step?</th>
<th>(3) Justify the decision that you made in column 3</th>
<th>(4) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(5) Is this step a Critical Control Point? (Yes or No)</th>
<th>(6) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Processing Step</td>
<td>(b) Hazard here</td>
<td>(c) CCP later</td>
<td>(d) Hazard here</td>
<td>(e) CCP later</td>
<td>(f) Hazard here</td>
<td>(g) CCP later</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histamine</td>
<td>No</td>
<td>Not likely to occur, time at this and weight/pack labeling step is 30 minutes or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Allergens</td>
<td>Yes</td>
<td>Fish is a food allergen</td>
<td>Filters will be labeled with hazard name at weight/pack labeling step (proper labeling)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Maca</td>
<td>No</td>
<td>Not likely to occur, time at this and weight/pack labeling step is 30 minutes or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight/Pack Label</td>
<td>Histamine</td>
<td>No</td>
<td>Not likely to occur, time at this and weight/pack labeling step is 30 minutes or less</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Allergens</td>
<td>Yes</td>
<td>Fish is a food allergen</td>
<td>Filters will be labeled with hazard name at weight/pack labeling step (proper labeling)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Maca</td>
<td>No</td>
<td>Not likely to occur, time at this and weight/pack labeling step is 30 minutes or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processed Product Refrigerated Storage</td>
<td>Histamine</td>
<td>Yes</td>
<td>Time temperature allowed could occur during storage</td>
<td>Marts-mahi fillets are stored in ice and stored in a refrigerated cooler (proper labeling)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Food Allergens</td>
<td>No</td>
<td>Fish are not labeled with hazard name at weight/pack labeling step</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maca</td>
<td>No</td>
<td>Not likely to occur, time at this and weight/pack labeling step is 30 minutes or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
End Chapter 6: Principle 2
Determine Critical Control Points

Got it?
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.
What’s a Critical Limit?

**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.
Sources & Examples ...

Sources of Information on Critical Limits (see chapter 13)

<table>
<thead>
<tr>
<th>Information Source</th>
<th>Examples of Critical Limits for species-related hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Regulations and guidance</td>
<td></td>
</tr>
<tr>
<td>Experts</td>
<td></td>
</tr>
<tr>
<td>Scientific studies</td>
<td></td>
</tr>
<tr>
<td>Scientific information</td>
<td></td>
</tr>
</tbody>
</table>

Examples of Critical Limits for process-related hazards

<table>
<thead>
<tr>
<th>Product</th>
<th>Hazard</th>
<th>CCP</th>
<th>Critical Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imitation crabmeat</td>
<td>Pathogen survival through cooking</td>
<td>Cooker</td>
<td>&gt;160°F internal product temperature for ≥1.5 minutes for elimination of pathogens of Concern in cooked crabs (e.g. <em>Listeria monocytogenes</em>)</td>
</tr>
<tr>
<td>Hot smoked fish, vacuum packaged</td>
<td>Pathogen growth</td>
<td>Drying oven</td>
<td>Drying schedule — oven temperature: ≥ 200°F, time ≥120 min., air flow rate: ≥ 2 ft³/min, product thickness ≤0.5 inches (to achieve aw of 0.85 to control pathogens in dried foods)</td>
</tr>
<tr>
<td>Ready-to-eat seafood salad</td>
<td>Pathogen growth</td>
<td>Acidification</td>
<td>Batch schedule — product weight, &lt; 100 lbs.; soak time, ≥ 8 hrs; acetogenic acid concentration, ≥ percent; volume ≤ 50 gal. (to achieve maximum level of 4.6 to control <em>Clostridium botulinum</em> in pickled foods)</td>
</tr>
</tbody>
</table>
Options and details ...

**Slide 7**
Option No. 1
Product: Fish cakes

**Slide 8**
Option No. 2
Product: Fish cakes

**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
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.
Using ‘Lot’ Designations
Critical Limits should be specified in the written HACCP Plan

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazards</th>
<th>Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>What</td>
<td>How</td>
<td>Frequency</td>
<td>Who</td>
</tr>
</tbody>
</table>

Blank HACCP Form
## Optional HACCP Plan Forms

(both must contain same information)
### Expected Information in all HACCP Plans

<table>
<thead>
<tr>
<th>HACCP Plan Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Name:</td>
</tr>
<tr>
<td>Product Description:</td>
</tr>
<tr>
<td>Firm Address:</td>
</tr>
<tr>
<td>Method of Storage and Distribution:</td>
</tr>
<tr>
<td>Intended Use and Consumer:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(1) Critical Control Point (CCP)</th>
<th>(2) Significant Hazard(s)</th>
<th>(3) Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>(8) Corrective Action</th>
<th>(9) Verification</th>
<th>(10) Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Signature:**

**Date:**

---

**Appendix 2**
Building the HACCP Plan for each CCP

### Hazard Analysis Worksheet

<table>
<thead>
<tr>
<th>(1) Processing Step</th>
<th>(2) List all potential food safety hazards that could be associated with this product and process</th>
<th>(3) Is the potential food safety hazard significant (introduced, enhanced, eliminated) at this step? (Yes or No)</th>
<th>(4) Justify the decision that you made in column 3</th>
<th>(5) What control measure(s) can be applied to prevent, eliminate or reduce this significant hazard?</th>
<th>(6) Is this step a Critical Control Point? (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histamine Receivin...</td>
<td>YES</td>
<td>Time/Temp abuse during transit could cause histamine to form in the fish.</td>
<td>Histamine fillets are shipped in containers buried in ice (proper icing).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathogen Growth-Temp. Abuse</td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooled by or for the consumer prior to consumption.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen.</td>
<td>Containers of fillets will be labeled with market name at labeling step.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FSI used or added to the fresh fish.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histamine Receivin...</td>
<td>YES</td>
<td>Time/Temp abuse during transit could cause histamine to form in the fish.</td>
<td>Histamine fillets are shipped in containers buried in ice (proper icing).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathogen Growth-Temp. Abuse</td>
<td>NO</td>
<td>Not likely to cause illness as the intended use of the product is to be cooled by or for the consumer prior to consumption.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undeclared Food Allergens</td>
<td>YES</td>
<td>Mahi is a food allergen.</td>
<td>Containers of fillets will be labeled with market name at labeling step.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Intolerance Substances</td>
<td>NO</td>
<td>No FSI used or added to the fresh fish.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Inclusion</td>
<td>NO</td>
<td>Not likely to occur at this step.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Column 1 & 2:** List all of the identified CCPs and identified hazards

### HACCP Plan form

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RECEIVING</td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REFRIGERATED STORAGE</td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Recommended Critical Limits

REMINDER: The FDA Guide contains control strategies with recommended CL’s

Tip

Processors may select alternative CL’s ‘however’ equivalent effectiveness MUST be demonstrated and documented
Select a Control Strategy

Example: CCP = Receiving
Hazard = Histamine

<table>
<thead>
<tr>
<th>CONTROL STRATEGY</th>
<th>MAY APPLY TO PRIMARY PROCESSOR</th>
<th>MAY APPLY TO SECONDARY PROCESSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvest vessel control</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Histamine testing</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Transit control</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Processing control</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Storage Control</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Proceed through the selected Control Strategies

- Note all listed options to suit different situations
- When applicable, there can be different strategies for primary vs. secondary processors
- Note the details associated with OR’s and AND’s
Select the best control to suit the situation and assure effective control for the potential hazard

TRANSIT CONTROL OPTIONS

• Transit temperature records
• Surrounded by ice on delivery
• **Use of ice;** AND internal fish temperature
• Frozen gel-packs; AND internal fish temperature
• Transit time (< 4 hours); AND internal fish temperature

Tip ‘ORs & ANDs’
### HACCP Plan for XYZ Seafood Company

<table>
<thead>
<tr>
<th>(1) Critical Control Point (CCP)</th>
<th>(2) Significant Hazards</th>
<th>(3) Critical Limits for each Preventative Measure</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
<th>(8) Corrective Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECEIVING</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REFRIGERATED STORAGE</td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEIGH/PACK/LABEL</td>
<td>Undeclared Food Allergens</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FINISHED PRODUCT REFRIGERATED STORAGE</td>
<td>Histamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OR**

- For fish delivered under ice:
  - Fish are completely surrounded by ice at the time of delivery;

**OR**

- For fish delivered under ice on an open-bed truck:
  - Fish are stored completely surrounded by ice;
  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;
HACCP Plan for XYZ Seafood Company

### Critical Limits based on recommendations in the FDA Hazards Guide

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits for each Control Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt</td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time</td>
</tr>
<tr>
<td>Weight/Package/Label</td>
<td>Food Allergens</td>
<td>All finished product containers will be labeled with the correct market name of the fish</td>
</tr>
<tr>
<td>Finished Product Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time</td>
</tr>
</tbody>
</table>

---

**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:**
End Chapter 7: Principle 3

Establish Critical Limits
In this chapter, you will learn:

- Definition of monitoring,
- Purpose of monitoring,
- Design of a monitoring system,
- Methods and equipment for monitoring critical limits.
What is a Monitoring?

**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.

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

4 required parts for proper MONITORING
What will be monitored?
A *measurement* or *observation* to assess if the CCP is operating within the critical limit.
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 should be sufficient to ensure that the critical limit is met.
- Monitoring frequency can be \textit{non-continuous} or \textit{continuous}.
Who will monitor?
Person(s) trained to perform the specific monitoring activity and/or a continuous monitoring device.
Monitoring requires training

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.
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

Slide 11

Examples of monitoring equipment could include:
- thermometers
- recorder charts
- clocks
- pH meters
- water activity meters
- data loggers
- metal detectors
- salometer
## Monitoring for XYZ Seafood Company

### HACCP Plan Form for XYZ Seafood Company completed through monitoring

<table>
<thead>
<tr>
<th>Firm Name: <strong>XYZ Seafood Company</strong></th>
<th>HACCP Plan Form</th>
<th>Product: <strong>Fresh mahi-mahi fillets</strong></th>
</tr>
</thead>
</table>

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

### 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: ____________________________

### Date: ____________________________

### Print Name: ____________________________
End Chapter 8: Principle 4

MONITORING

QUESTIONS?
Principle 5: Corrective Actions

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

**Slide 2**
Definition:
Corrective Action: Procedures to be followed when a deviation occurs.

**Slide 3**
Predetermined corrective actions are recommended.
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.

- Identify involved product
- Assess safety and product disposition
- Correct the problem
- Restore control
Is the involved product safe?

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

Helpful Sources:
FDA Guide-Appendix 4
Is the involved product safe?

**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.

**Slide 7**

Corrective actions must identify the cause of the deviation and restore process control.
Using the FDA Guide for CA’s

Optional CA’s

**FDA Guide Example**
Chapter 7, page 143

**Tip**

In some cases, the final option to reject or destroy product is more logical than trying to produce evidence for other options.

---

**Establish Corrective Action Procedures.**

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action plan is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.
Corrective actions must be documented to indicate the safety status and consequences for the products and process involved.

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:
### Corrective action examples for species-related hazards

<table>
<thead>
<tr>
<th>Critical Control Point</th>
<th>Significant Hazard</th>
<th>Critical Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving aquacultured shrimp from the farm</td>
<td>Aquaculture drugs</td>
<td>Supplier certificate of origin (indicating proper drug treatment)</td>
</tr>
<tr>
<td>Receiving live oysters from the harvester</td>
<td>Natural toxins</td>
<td>All shellstock tagged with the date and place of harvest, type and quality of shellfish, and name and registration number of harvest vessel and harvester. All shellstock from which oysters are prepared shall be approved by State Shellfish Authority and be of commercial quality.</td>
</tr>
</tbody>
</table>

### Corrective action examples for process-related hazards

<table>
<thead>
<tr>
<th>Critical Control Point</th>
<th>Significant Hazard</th>
<th>Critical Limit</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batter application</td>
<td>Staphylococcus aureus growth and toxin formation</td>
<td>Hydrated batter does not exceed 50°F for more than 12 hrs. or 70°F for more than 3 hrs. cumulatively</td>
<td>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 product safety and adjust/repair refrigeration equipment for batter.</td>
</tr>
<tr>
<td>Metal detector (after packaging)</td>
<td>Metal inclusion</td>
<td>No detectable metal fragments in product</td>
<td>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.</td>
</tr>
<tr>
<td>Hot smoking (vacuum packaged)</td>
<td>Clostridium botulinum toxin formation (in finished product)</td>
<td>Internal fish temperature held at or above 145°F for at least 30 minutes</td>
<td>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.</td>
</tr>
</tbody>
</table>
Corrective Actions for XYZ Seafood Company

<table>
<thead>
<tr>
<th>Firm Name: XYZ Seafood Company</th>
<th>HACCP Plan Form</th>
<th>Product: Fresh mahi-mahi fillets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical Control Point (CCP)</strong></td>
<td><strong>Critical Limits for each Control Measure</strong></td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Receiving</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt.</td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time.</td>
</tr>
<tr>
<td>Weight/Pack/Label</td>
<td>Food Allergens</td>
<td>All finished product containers will be labeled with the correct market name of the fish.</td>
</tr>
</tbody>
</table>

see page 138-139
**Corrective Actions for XYZ Seafood Company**

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished Product Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time.</td>
<td>Adequacy of ice surrounding mahi-mahi fillets</td>
<td>Visual check of representative number of containers in cooler storage</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:** ____________________________
End Chapter 9: Principle 5

CORRECTIVE ACTIONS

QUESTIONS?
Principle 6: Establish Verification Procedures

Slide 1

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

**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.

**Slide 3**

“Trust what you can verify.”
Various types of Verifications

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)
Validation ‘before’ operations

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.

‘Will it work’
Before operations... ‘Validate the HACCP controls and plan will work’

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.
When to Validate

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
Verification ‘during’ operations

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

‘Is it working’

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

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

*NIST = National Institute of Standards and Technology*
Record Accuracy and Calibration

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

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
Verify through periodic testing

Periodic verification may also include targeted sampling and laboratory tests of in-process or finished products.
Must Review Monitoring and Corrective Action Records

**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.
Total HACCP Program Verification

Slide 15

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

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.

Requires a signature
Total HACCP Program Verification

**Slide 17**

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

**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
Ultimate Verification

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 Summary

#### Slide 20

Example of a company-established HACCP plan:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification activities scheduling</td>
<td>Yearly program</td>
</tr>
<tr>
<td>Initial validation of HACCP plan</td>
<td>Prior to implement</td>
</tr>
<tr>
<td>Reassessment of HACCP plan</td>
<td>Whenever changes change or changes needed for the system</td>
</tr>
<tr>
<td>Verification of CCP monitoring as described in the plan (e.g., monitoring of patty cooking temperature)</td>
<td>Annually (e.g., laboratory analysis)</td>
</tr>
<tr>
<td>Review of monitoring, corrective action records to show compliance with the plan</td>
<td>Weekly support systems training program</td>
</tr>
<tr>
<td>Comprehensive HACCP system verification</td>
<td>Yearly program</td>
</tr>
</tbody>
</table>

*May require additional technical expertise as well as laboratory testing.*

#### Slide 21

Examples of verification activities for specific critical limits:

<table>
<thead>
<tr>
<th>Significant Hazard</th>
<th>Critical Control Point</th>
<th>Critical Limits</th>
<th>Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquaculture drugs</td>
<td>Receiving (from farm)</td>
<td>Suppliers certificate on file (indicating proper drug use)</td>
<td>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.</td>
</tr>
<tr>
<td>Natural toxins</td>
<td>Receiving (from harvest)</td>
<td>All shellfish tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel; and all shellfish from waters approved by State Shellfish Authority; and all shellfish from a licensed harvester.</td>
<td>Review all monitoring and corrective action records once per week.</td>
</tr>
<tr>
<td>Histamine</td>
<td>Receiving (from suppliers)</td>
<td>Fish are completely surrounded by ice.</td>
<td>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.</td>
</tr>
<tr>
<td>C. botulinum toxin formation (in finished product)</td>
<td>Hot smoking</td>
<td>Internal fish temperature held at or above 145°F for at least 30 minutes.</td>
<td>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.</td>
</tr>
<tr>
<td>Pathogen growth</td>
<td>Cooler storage</td>
<td>Cooler temperature not to exceed 40°F.</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Verifications for XYZ Seafood Company

#### HACCP Plan Form

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt</td>
<td>Adequacy of ice surrounding mahi-mahi fillets at delivery</td>
<td>Visual check of adequacy of ice in a representative number of containers in each delivery</td>
<td>Every Delivery</td>
<td>Receiving Manager</td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time.</td>
<td>Adequacy of ice surrounding mahi-mahi fillets</td>
<td>Visual check of adequacy of ice in a representative number of containers in coolers to age</td>
<td>Every Delivery</td>
<td>Refrigeration Manager</td>
</tr>
</tbody>
</table>

### See page 155-156
### Critical Control Points (CCPs)

<table>
<thead>
<tr>
<th>CCP</th>
<th>Significant Hazards</th>
<th>Critical Limits for Each CCP Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>What</td>
<td>How</td>
<td>Frequency</td>
<td>Who</td>
</tr>
<tr>
<td>Weight/Pack Label</td>
<td>Food Allergens</td>
<td>All finished product containers will be labeled with the correct market name of the fish.</td>
<td>The market name on each container of finished product</td>
<td>Visual check of a representative number of containers and their label</td>
<td>Each container is properly labeled. Then is signed by the label manager.</td>
<td>Weekly review of Label 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 formulations occur, if appropriate.</td>
</tr>
<tr>
<td>Finished Product Refrigerated Storage</td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time.</td>
<td>Adequacy of ice surrounding mahi-mahi fillets</td>
<td>Visual check of representative number of containers in cooler storage</td>
<td>Product not have The mahi product evaluated at the chill level including testing prior to delivery, and if there is a problem in the cooler storage</td>
<td>Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check the internal temperature of fish quantity to ensure the ice maintains product temperature. Check the accuracy of the thermometer used to check internal temp.</td>
</tr>
</tbody>
</table>

---

**Firm Name:** XYZ Seafood Company  
**Firm Address:**  
238 Coastal Lane, Happy Beach, XX  
**Product:** Fresh mahi-mahi fillets  
**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:**
End Chapter 10: Principle 6

VERIFICATIONS

QUESTIONS?
Principle 7: Record-Keeping Procedures

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
Records support the HACCP Program

**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

**Slide 3**

1) The HACCP plan and its supporting documentation
## HACCP Plan

### Recommended and Required Records

### Hazard Analysis

#### RECOMMENDED

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving Fresh Birds</td>
<td>Histamine</td>
<td>Adequacy of ice surrounding margins on delivery.</td>
<td>Every Delivery</td>
<td>Receiving Manager</td>
<td>Weekly review of Receiving Log, Monitoring Records, and Corrective Action and Verification records.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### REQUIRED

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerated Storage</td>
<td>Histamine</td>
<td>Adequacy of ice surrounding margins on product.</td>
<td>At the beginning and end of the work day</td>
<td>Cooler Manager</td>
<td>Weekly review of Cooler Log, Monitoring Records, and Corrective Action and Verification records.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Example:**

- **Hazard Analysis:**
  - Significant Hazard: Histamine
  - Critical Limit: Adequacy of ice surrounding margins on delivery.

- **Monitoring:**
  - Every Delivery

- **Corrective Action:**
  - Receiving Manager

- **Verification:**
  - Weekly review of Receiving Log, Monitoring Records, and Corrective Action and Verification records.

**Records:**

- Cooler Log
- Monitoring Records
- Corrective Action and Verification records
Additional Record support for HACCP

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
CCP monitoring records are used to document that food safety hazards have been controlled at each CCP.

Required information on required records

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
## Example Monitoring Records

<table>
<thead>
<tr>
<th>Significant Hazard</th>
<th>Critical Control Point</th>
<th>Critical Limits</th>
<th>Monitoring Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquaculture drugs</td>
<td>Receiving (from farm)</td>
<td>Suppliers certificate on file (indicating proper drug use)</td>
<td>Suppliers certificate on file (indicating proper drug use)</td>
</tr>
<tr>
<td>Natural toxins</td>
<td>Receiving (from harvester)</td>
<td>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</td>
<td>Shellfish receiving log</td>
</tr>
<tr>
<td>Histamine</td>
<td>Receiving</td>
<td>Fish are completely surrounded by ice</td>
<td>Histamine fish receiving log</td>
</tr>
<tr>
<td><em>C. botulinum</em> toxin formation (in finished product)</td>
<td>Hot smoking</td>
<td>Internal fish temperature held at or above 145°F for at least 30 minutes</td>
<td>Smokehouse temperature record chart</td>
</tr>
<tr>
<td>Pathogen growth</td>
<td>Cooler storage</td>
<td>Cooler temperature not to exceed 40°F</td>
<td>Cooler storage log</td>
</tr>
</tbody>
</table>
Example Monitoring Records ...

Slide 8

Daily Cooker Temperature Log (Monitoring Record)

Form Title: Daily Cooker Temperature Log
Firm Name:
Critical Limits: ≥ 212°F for ≥ 3 minutes

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Line Number</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewer Signature:

Slide 9

Continuous Temperature Record with Periodic Monitoring.

Slide 10

Weigh/Pack/Label Log (Monitoring Record)

Form Title: Weigh/Pack/Label Log
Firm Name: XYZ Seafood Company
Product Identification: Fresh mahi-mahi fillets
Critical Limits: Proper label - seafood product market name and ingredients.

<table>
<thead>
<tr>
<th>Monitoring Activities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Firm Location: 238 Coastal Lane, Happy Beach, CA

XYZ Seafood Company
238 Coastal Lane
Happy Beach, XX
Temperature Chart
(cooker #1)
2/12 - 2/19/11
Reviewed By: __________
Review Date: __________
3) Corrective action records

Information for CA records

Pages 163-164
Slide 13

4) Verification records

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
### Additional Record Examples...

#### Slide 15

**Daily Thermometer Accuracy Log (Verification Record)**

- **Form Title:** Daily Thermometer Accuracy Log
- **Firm Name:**
- **Firm Location:**
- **Product Identification:**
- **Verification:**

#### Slide 21

**Annual HACCP Plan Verification Report (Verification Record)**

<table>
<thead>
<tr>
<th>Annual HACCP Plan Verification Checklist</th>
<th>Date Task Completed</th>
<th>Signature of Person who Completed the Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of HACCP Team with Individual Responsibilities Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of Seafood Products and Processes in Place at Facility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Flow Diagrams Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hazard Analysis Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP Plan Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Manufacturing Practice Plan Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanitation Standard Operating Practices Plan Updated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP Plan Implemented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviewer Signature:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Annual Review:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Do Not Forget Records for required SCP monitoring

Remember SCP records for the 8 Key Sanitation Conditions

<table>
<thead>
<tr>
<th>Sanitation Area</th>
<th>Decision</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Safety of water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Safe and sanitary source (S/U) (Annual)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No cross-connections in hard plumbing (S/U)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Condition and cleanliness of food contact surfaces</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Processing equipment and utensils in suitable condition (S/U)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Prevention of cross-contamination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Physical conditions of plant and layout equipment (S/U)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 = Satisfactory / U = Unsatisfactory Additional Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature or initials:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Do Not Forget Employee Training Records in GMP’s 117
Electronic or computerized monitoring records must be equivalent to paper records and handwritten signatures.

Computer Recordkeeping allowed ... IF

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.
# Records for XYZ Seafood Company

**Slide 31**

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazard(s)</th>
<th>Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receiving</strong></td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt.</td>
<td>Adequacy of ice surrounding fillets at delivery</td>
<td>Visual check of adequacy of ice in a representative number of containers in each delivery</td>
<td>Every Delivery</td>
<td>Receiving Manager</td>
</tr>
<tr>
<td><strong>Refrigerated Storage</strong></td>
<td>Histamine</td>
<td>Mahi-mahi fillets are completely surrounded with ice throughout storage time.</td>
<td>Adequacy of ice surrounding fillets</td>
<td>Visual check of adequacy of ice in a representative number of containers in cooler storage</td>
<td>At the beginning and end of the work cycle</td>
<td>Reception Log</td>
</tr>
</tbody>
</table>

See pages 179-180
### Records for XYZ Seafood Company

#### Slide 31 (cont.)

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>Significant Hazards</th>
<th>Critical Limits for each Control Measure</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight/Pack/Label</td>
<td>Food Allergens</td>
<td>All finished product containers will be labeled with the correct market name of the fish.</td>
<td>The market name on each container of finished product</td>
<td>Visual check of a representative number of containers and their label</td>
<td>Each customer order</td>
<td>Packing Manager</td>
</tr>
</tbody>
</table>

| 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 | 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 |

**Firm Name:** XYZ Seafood Company

**Firm Address:** 238 Coastal Lane, Happy Beach, XX

**Product:** Fresh mahi-mahi fillets

**Method of Storage and Distribution:** Refrigerated

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

**Signature:** John Doe

**Date:** 3/23/20

**Print Name:**

---

*See pages 179-180*
SPECIAL NOTE

The HACCP Plan form can be used in portrait format which can be more convenient.

XYZ Seafood Company

Pages 181-184

Blank forms are in Appendix 2

---

**HACCP Plan Form**

<table>
<thead>
<tr>
<th>Firm Name: XYZ Seafood Company</th>
<th>Product: Fresh mahi-mahi fillets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Address: 258 Coastal Lane, Happy Beach XX</td>
<td>Method of Storage &amp; Distribution: Stored and distributed in ice</td>
</tr>
<tr>
<td>Intended Use and Consumer: To be cooked and consumed by the general public</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Critical Control Point (CCP)</th>
<th>CCP 1: Receiving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Hazard(s)</td>
<td>Histamine</td>
</tr>
<tr>
<td>Critical Limits for each Control Measure</td>
<td>Mahi-mahi fillets are completely surrounded with ice at receipt.</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Adequacy of ice surrounding mahi-mahi fillets at delivery</td>
</tr>
<tr>
<td>How</td>
<td>Visual check of a representative number of containers and their label</td>
</tr>
<tr>
<td>When</td>
<td>Every Delivery</td>
</tr>
<tr>
<td>Who</td>
<td>Receiving Manager</td>
</tr>
<tr>
<td>Corrective Action</td>
<td>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.</td>
</tr>
<tr>
<td>Verification</td>
<td>Weekly review of Receiving Log (Monitoring record) and Corrective Action and Verification records</td>
</tr>
<tr>
<td>Records</td>
<td>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</td>
</tr>
</tbody>
</table>

Signature: John Doe
Date: 5/9/17
End Chapter 11: Principle 7

Record-Keeping

Are ya done!
Chapter 12

The Seafood HACCP Regulation

Slide 1

In this module, you will learn:
- The requirements of the regulation
- How to reference the specific requirements
Copies of the Official Published Regulation
21 CFR Part 123 Seafood HACCP Regulation

- SHA Training Manual
  - Appendix 1 (p. 205)

- FDA Guide
  - Appendix 8

Tip
Stay aware for periodic additions
Regulation Outlined in Parts

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
# Key Definitions in the Regulation

**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
Key Definitions in the Regulation

**Slide 4**

Regulatory terms “shall” and “should”

**Slide 5**

Products that are subject to the regulation:
- Fish
- Fishery Product
Who must comply?

Who must comply with the regulation:
- Importer 123.3 (g)
- Processor 123.3 (k) — domestic and foreign
Define Processing

What constitutes processing:
- Processing 123.3 (I)
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
Foundation for the Regulation

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

Copy of the current GMP’s Part 117

Appendix 3, Page 235
Determine hazards likely to occur...

Slide 10

Hazard Analysis 123.6(a)
Every processor shall conduct, or have conducted for it, a hazard analysis.

Slide 11

Determining those hazards that are “reasonably likely to occur:”
Those “for which a prudent processor would establish controls.”
Written HACCP plans ...

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.
HACCP plans ‘shall’ contain ...

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 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.
Special considerations for seafood canning operations ...
Sanitation or HACCP Controls?

Sanitation controls may be difficult to manage in a HACCP plan.
It is unlawful to process food under conditions that may render it injurious to health.
Processors ‘shall’ take ‘corrective actions’

Slide 18
Corrective Action 123.7
Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

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
Verifications are required ...

**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.

**Slide 21**

Ongoing verification:
- Review of consumer complaints
- Calibration of process-monitoring instruments
- Periodic end-product and in-process testing (processor’s option)
Required records ...

Slide 22

Records required by the regulation:
- HACCP plan(s)
- Monitoring records
- Corrective action records
- Verification records
- Sanitation control records
- Importer verification records
Information required on each record ...

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
Record Reviews and Retention ...

**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

**Slide 25**

Record retention:
- One year for refrigerated products
- Two years for frozen or preserved products
HACCP training to ...

Slide 26

The HACCP-trained individual shall:

- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- Review HACCP records.
SCP’s – Sanitation Control Procedures

Slide 27

- Processors should have written SCPs.
- Processor shall monitor and document sanitation control procedures.
- Processors shall correct sanitation deficiencies in a timely manner.
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.
HACCP with Imported Seafood

Slide 29
Importer Verification:
- Import from countries with a memorandum of understanding (MOU) or
- Implement verification procedures.

Slide 30
Importer Verification Procedures
Importers must have:
1) Written verification procedures
2) Product specifications
3) Affirmative steps
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
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.
HACCP with Raw Molluscan Shellfish

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.
HACCP with Raw Molluscan Shellfish

**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.
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

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
Resources for Preparing Seafood HACCP Plans

Recommended websites:

- FDA Seafood HACCP Regulations
- AFDO Seafood HACCP Alliance (Association of Food and Drug Officials)
- Numerous State based Sea Grant Programs via Seafood Safety and HACCP
- USDC/National Marine Fisheries Services via Seafood HACCP
- USDA Catfish HACCP