# Seafood HACCP Basic Training

Training Number:

Training Location:

Training Date:

AFDO Region:

Instructor:

Developed for the Seafood HACCP Alliance standardized training program. Version X xx/xx/xxxx

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:

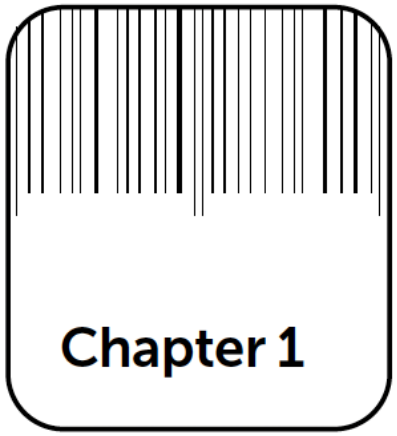

***Hazard Analysis and Critical Control Point Training Curriculum*** *(SGR 137; Blue Book) 7th edition August 2024*

***FDA Fish and Fishery Products Hazards and Controls Guidance*** *(Gold Book; SGR 129)*
*4th edition June 2022*

Program Introduction

# National Seafood HACCP Alliance for Training and Education

# Introduction to the Alliance Course and HACCP




**Slide 1**

In this chapter, you will learn the:

- Objective of the course
- Format of the course
- Expectations of the participants
- Meaning and importance of HACCP

## Slide 2

**Course Objective:**

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

## Slide 3

**Course Format:**

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

# Audience Role

**Slide 4**

Participants are encouraged to:

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

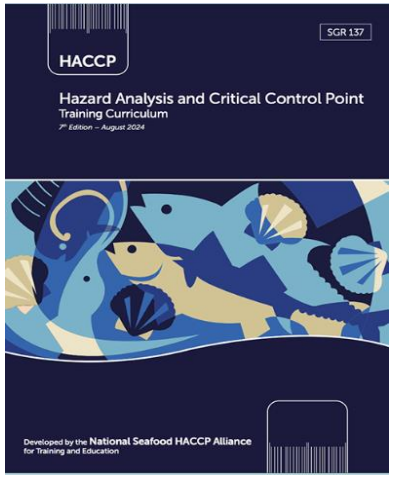
## Slide 5

The Seafood HACCP Training Manual (blue book) provides:

- Written content that describes each presentation in the course
- Reference information and forms to help you develop a HACCP Plan

The FDA Hazards Guide provides:

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



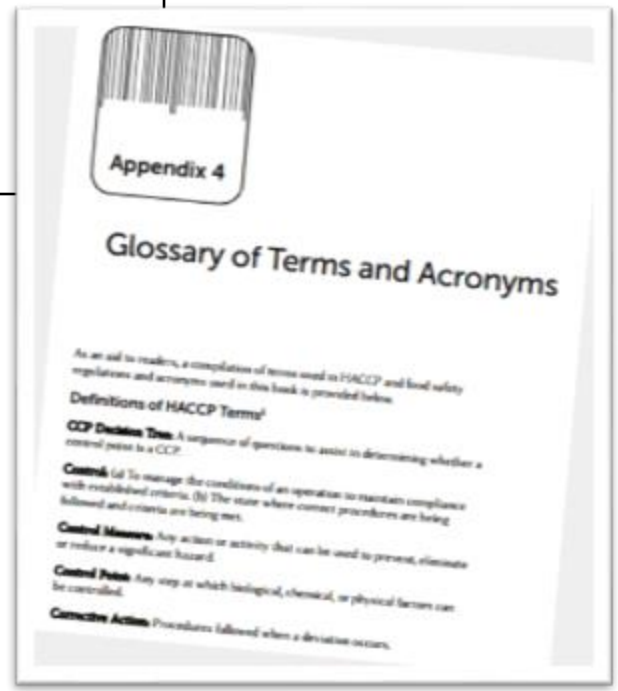

BLUE Book


GOLD Book

# Definitions and Terms

**Slide 6**

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[1]

**CCP Decision Tree.** A sequence of questions to assist in determining whether a control point is a CCP.

**Control.** (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met.

**Control Measure.** Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

**Control Point.** Any step at which biological, chemical, or physical factors can be controlled.

**Corrective Action.** Procedures followed when a deviation occurs.

Appendix 4
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## Slide 7

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

## Slide 8

**A HACCP system is**

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

## Slide 9

Origin of HACCP:

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

## Slide 10

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

NATIONAL ACADEMY OF SCIENCES

# 7 Principles of HACCP

Slide 11

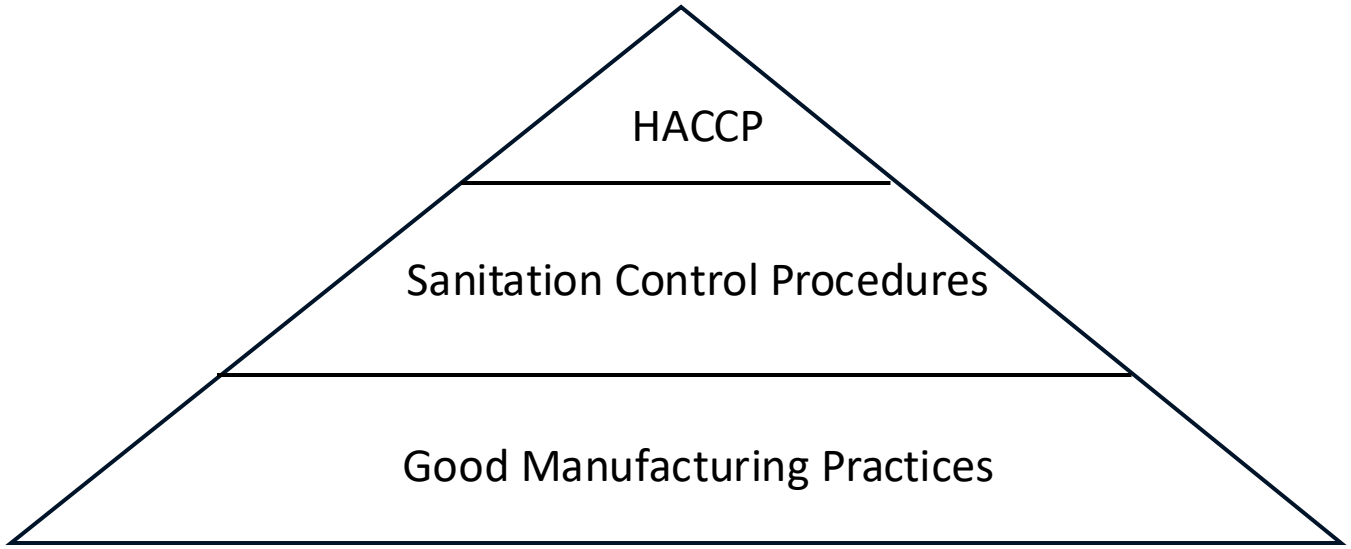
**Seven principles of HACCP:**

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

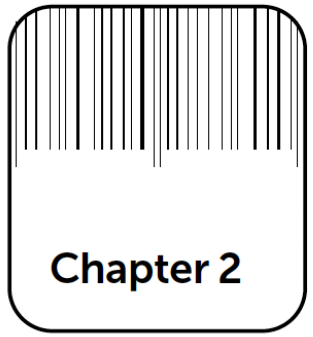
# Layers of Controls

Slide 12

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



# Prerequisite Programs and Sanitation Control Procedures




**Slide 1**

In this chapter you will learn:

- The importance of prerequisite programs for HACCP
- Good Manufacturing Practices (GMPs)
- Sanitation Control Procedures (SCPs)
- Examples of SCP monitoring

# Prerequisites

**Slide 2**

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

Slide 3

**Federal, State, or Local Requirements**

- Food Defense and Biosecurity Requirements
- Food Safety Modernization Act (FSMA) Requirements
  -Sanitary Transport
  -Food Traceability (some exemptions)
  -Mitigation for intentional adulteration
- 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
- Transportation Controls
- Recall 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

Slide 6

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

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

# Required Training Records

Page 13

Slide 7

Example of Training Records

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

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

# 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**

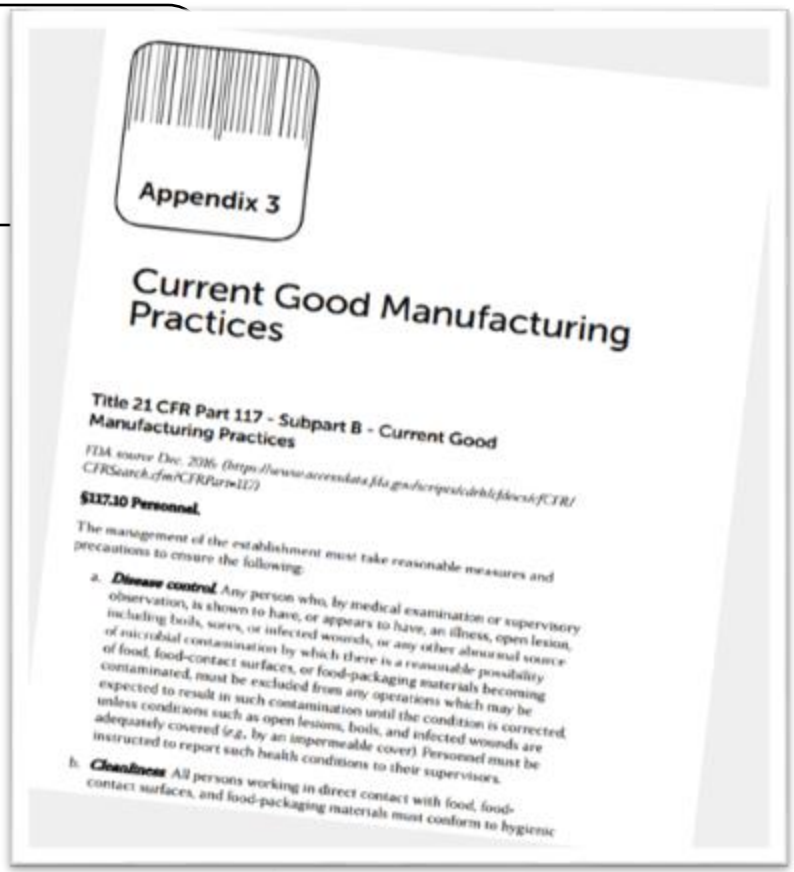
**Good Manufacturing Practices (21 CFR Part 117 Subpart B)**

- 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.

# GMP's 117

**Slide 10**

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



Appendix 3

Current Good Manufacturing Practices

Title 21 CFR Part 117 - Subpart B - Current Good Manufacturing Practices

FDA source Doc. 2016 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117)

§117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

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

b. *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic

Appendix 3 page 233

# Sanitation Control Procedures(SCPs)

**Slide 11**

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

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

# SSOP's- Written Procedures

Slide 12

**Sanitation Control Procedures:**

Recommended:

- Written Sanitation Standard Operating Procedures (SSOPs).

Required

- Monitoring
- Corrections
- Recordkeeping

# Example of Sanitation Control Procedures

Slide 13

**Examples of Sanitation Control Procedures**

**Control of bacterial cross contamination hazard**

- 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.

# 8 Key Areas of Sanitation

**Slide 14**

**Eight Key areas of sanitation:**

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

## Slide 15

**1) Safety of water**

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

## Slide 16

**2) Condition and cleanliness of food contact surfaces**

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

## Slide 17

**3) Prevention of cross-contamination**

- Employee hygiene practices
- Employee food handling practices
- Plant design and layout
- Physical separation of raw and ready-to-eat products

## Slide 18

**4) Maintenance of hand washing, hand sanitizing, and toilet facilities:**

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

Slide 19

**5) Protection from adulterants**

- Protect food, food contact surfaces, and food packaging material from contaminants.

Slide 20

**6) Labeling, storage and use of toxic compounds**

## Slide 21

**7) Employee health conditions:**

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

## Slide 22

**6) Exclusion of pests:**

- Pests must not be present in the food processing facility.

# SCPs in GMPs 117

Pages 21-22

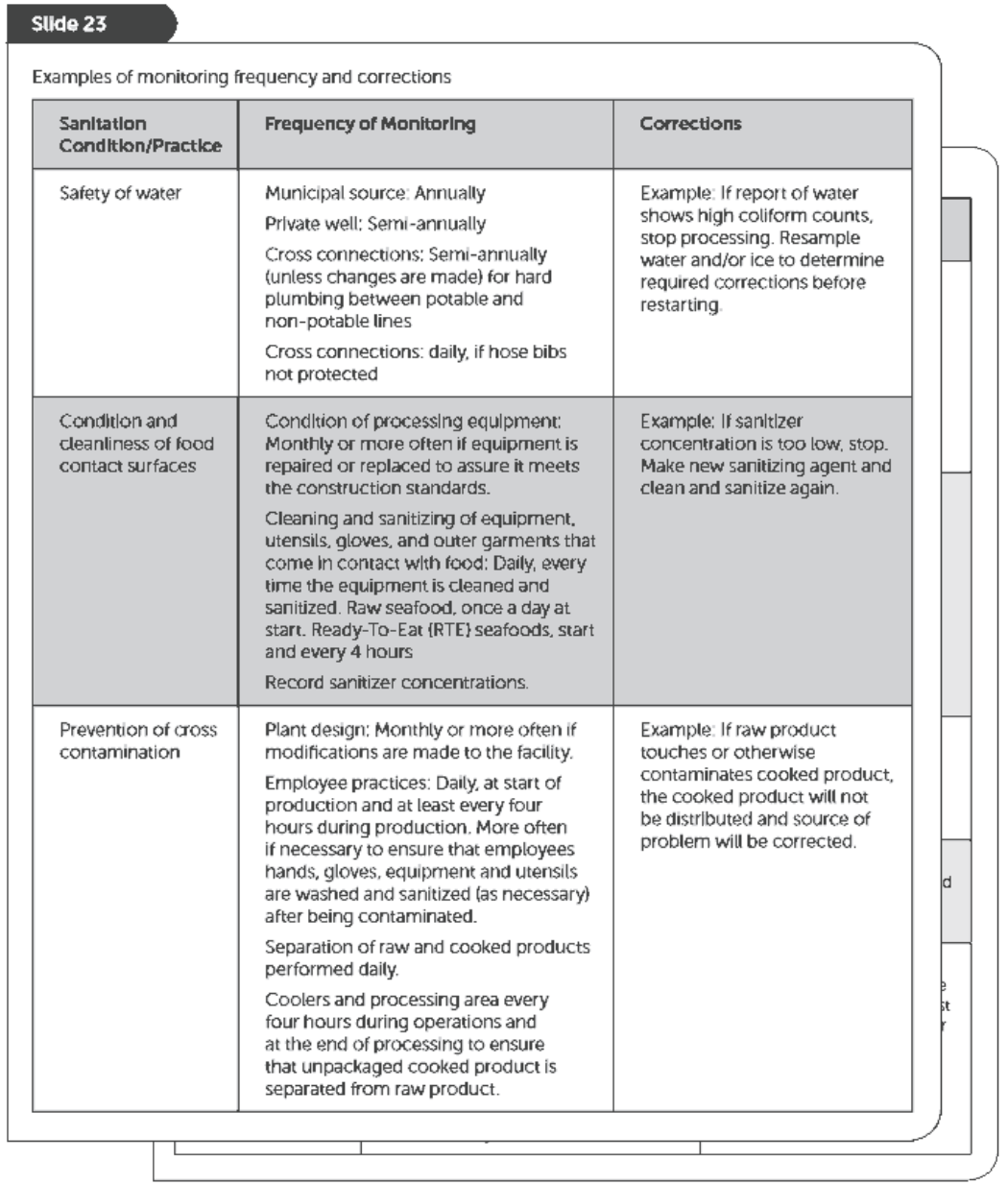
**Table 1**

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

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

# Monitoring SCPs

Pages 24-25



Slide 23

Examples of monitoring frequency and corrections

| Sanitation Condition/Practice | Frequency of Monitoring | Corrections |
|---|---|---|
| Safety of water | Municipal source: Annually<br>Private well: Semi-annually<br>Cross connections: Semi-annually (unless changes are made) for hard plumbing between potable and non-potable lines<br>Cross connections: daily, if hose bibs not protected | Example: If report of water shows high coliform counts, stop processing. Resample water and/or ice to determine required corrections before restarting. |
| Condition and cleanliness of food contact surfaces | Condition of processing equipment: Monthly or more often if equipment is repaired or replaced to assure it meets the construction standards.<br>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<br>Record sanitizer concentrations. | Example: If sanitizer concentration is too low, stop. Make new sanitizing agent and clean and sanitize again. |
| Prevention of cross contamination | Plant design: Monthly or more often if modifications are made to the facility.<br>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.<br>Separation of raw and cooked products performed daily.<br>Coolers and processing area every four hours during operations and at the end of processing to ensure that unpackaged cooked product is separated from raw product. | Example: If raw product touches or otherwise contaminates cooked product, the cooked product will not be distributed and source of problem will be corrected. |

# Monitoring SCPs

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

## Slide 25

A facility processes only chilled Atlantic Salmon and Pacific Cod fillets

- Does SCP concerning safety of water apply? How?
- Does SCP concerning protection from adulterants apply? How?

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

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

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# SCP Requirements

**Slide 26**

Sanitation in the Seafood HACCP Regulations:

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

# HACCP vs. SCP's

Slide 27

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

# Example SSOP 'written program' and accompanying records

Table 2

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

### Table 2. Model Sanitation Standard Operating Procedure

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

Controls and Monitoring:

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

Corrections:

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

Records:

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

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

Controls and Monitoring:

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

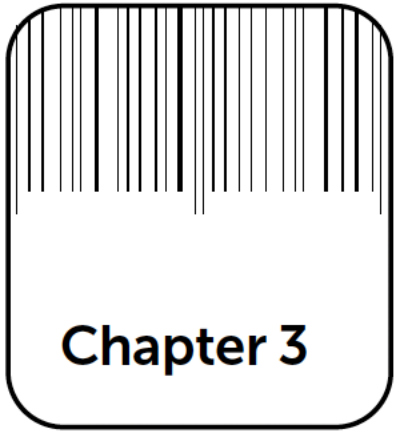
Form 1

Daily Sanitation Control Record with all 8 Key Sanitation Areas

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

Pages 30-39

# Seafood Safety Hazards




**Slide 1**

In this chapter you will learn:

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

## Slide 2

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

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

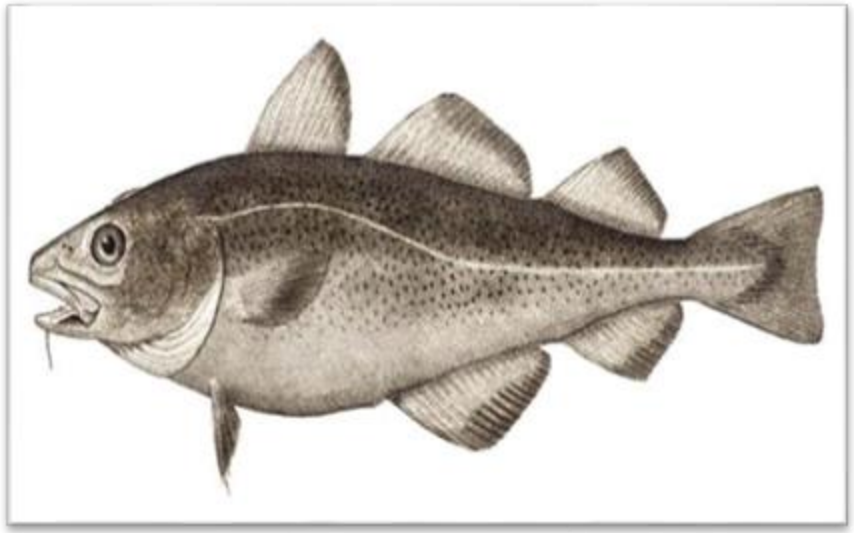
- Insects
- Hair
- Filth
- Spoilage
- Economic Fraud
- Violations of regulatory food safety standards not directly related to safety

# Categories for Seafood Safety Hazards

Slide 3

Potential seafood safety hazards can be grouped into two categories:

- Species-related hazards
- Process-related hazards



# Species- and Process-Related Hazards

Slide 4

**Species-Related Hazards**

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

**Process-Related Hazards**

- Pathogenic Bacteria Growth and Toxin Formation (Other than Clostridium botulinum) as a Result of Time and Temperature Abuse
- Clostridium botulinum Toxin Formation
- Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying
- Staphylococcus aureus Toxin Formation in Hydrated Batter Mixes
- Pathogenic Bacteria Survival Through Cooking or Pasteurization
- Introduction of Pathogenic Bacteria After Pasteurization and Specialized Cooking Processes
- Undeclared Major Food Allergens and Certain Food Intolerance Substances
- Metal and glass inclusion

# Pathogens in Seafood

**Slide 5**

Microorganisms that can be pathogenic and cause seafoodborne illnesses:

- Bacteria
- Viruses
- Protozoa
- Microscopic parasites

**Slide 6**

Bacterial Hazards:

- Foodborne infection
- Foodborne intoxication

# Pathogen Controls

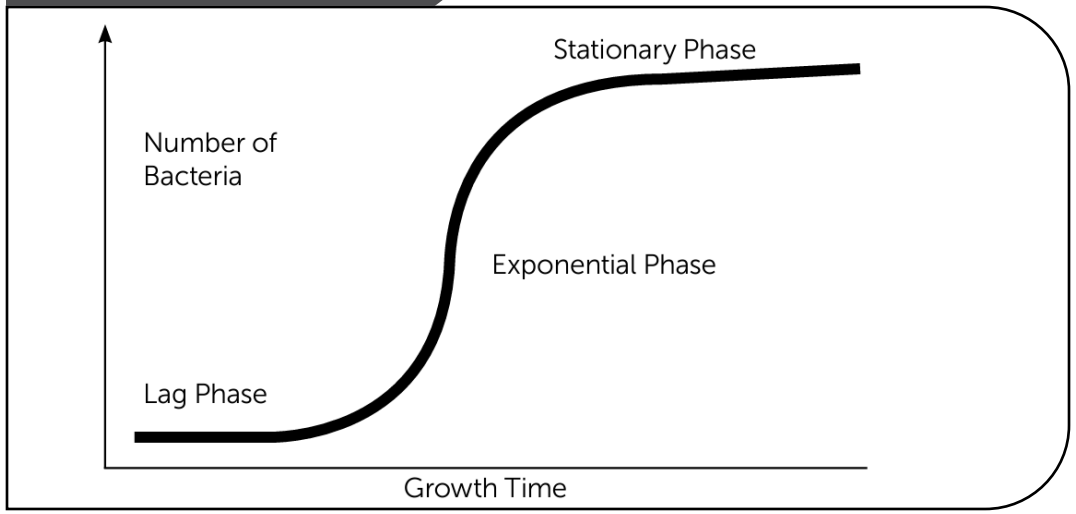
Slide 7

Control strategies for pathogens in seafood:

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

# Pathogens Growth

## Slide 8




## 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

Slide 10

Pathogens of Concern for Seafood Products:

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

# 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

**Slide 13**

Some controls for *Listeria monocytogenes in seafood*:

- Proper sanitation to prevent product contamination (product source, process facilities, and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

# Specific Pathogen Controls

**Slide 14**

Some controls for *Salmonella* spp. in seafood:

- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

# Specific Pathogen Controls

**Slide 15**

Some controls for *Staphylococcus aureus* in seafood:

- Proper sanitation to prevent product contamination (product source, process facilities and personnel)
- Proper refrigeration to prevent growth
- Proper cooking
- Prevent cross-contamination after cooking

# Specific Pathogen Controls

**Slide 16**

Some controls for *Vibrio cholerae, Vibrio parahaemolyticus and Vibrio vulnificus* in seafood:

- Product harvested from approved sources
- Proper refrigeration from harvest through processing
- Proper cooking
- Consumption advisories for more susceptible consumers

# 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

**Slide 18**

Viruses:

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

**Slide 19**

Some controls for viruses in seafood:

- Product from approved sources
- Thorough cooking

# Parasites

**Slide 20**

Parasites are organisms that need a host to survive.

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

**Slide 21**

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

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

# Parasites

**Slide 22**

Parasitic Worms:

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

**Slide 23**

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 Toxins 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 Toxins 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 gempyltoxin in seafood:

- Do not process certain potentially gempylotoxic fish

# Environmental Chemical Contaminants

Slide 30

**Controls for Environmental Chemical Contaminants (Pollutants)**

- Do not harvest or sell fish or shellfish from waters that have been closed by federal, state, or local authorities due to environmental pollution
- Properly locate and monitor aquaculture farming operations to prevent pond contamination from runoff, and previous or new human activities. Testing for chemical contaminants of concern

# Aquaculture Drugs: Illegal or Improper Use

Slide 31

Some controls for use of aquaculture drugs:

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

# Scombrotoxin(histamine poisoning)

Slide 32

Control for potential scombrotoxin in seafood:

- Temperature controls from the moment of harvest through processing, storage, and product distribution

# Process-Related Hazards

Slide 33

Other Process-Related Food Safety Hazards

- Food Intolerance Substances (FIS)
- Food Allergens
- Metal and Glass Inclusion

# Process-Related Hazards

**Slide 34**

Examples of Food and Color Additives

- Preservatives (e.g. nitrite, sulfites)
- Nutritional additives (e.g. vitamins)
- Color Additives (FD&C Yellow No. 5)

**Slide 35**

Controls for intentionally added ingredients in seafood:

- Use proper type and amount of ingredients
- Label product to inform consumers (e.g., sulfites and yellow #5)

# Food Allergens

**Slide 36**

Control for shellfish biotoxins in seafood:

- Only harvest approved shellfish products from approved waters

**Slide 37**

Control for ciguatera in seafood:

- Do not process certain fish harvested from waters that have been designated as potentially ciguatoxic

# Process-Related Hazards

Slide 33

Other Process-Related Food Safety Hazards

- Food Intolerance Substances (FIS)
- Food Allergens
- Metal and Glass Inclusion

# Physical Hazards

Slide 38

Physical Hazard:

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

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

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

# Physical Hazards Controls

**Slide 39**

Control for potential glass inclusion in seafood:

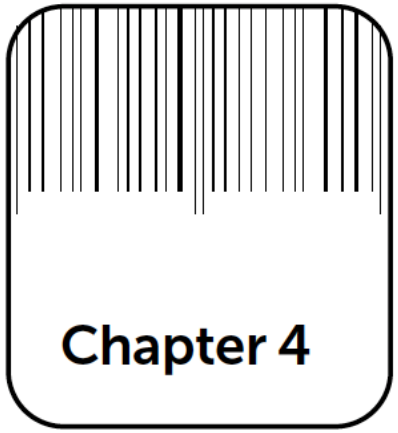
- Examination of glass containers for breakage

**Slide 40**

Controls for potential metal inclusion in seafood:

- Monitoring equipment for wear and breakage
- Screening products with metal detectors

# Preliminary Steps in Developing HACCP Plan




**Slide 1**

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 is involved?

# 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

# What is involved?

**Slide 3**

Product Description should include:

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

# What is involved?

Slide 4

Product Description Form for Fish and Shellfish Species

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

Useful Product Description Chart

Page 73

# Processing steps involved?

Slide 5

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

# Introduce XYZ Seafood Company
## (See pages 74-76)

Slide 6

XYZ Seafood Company Product Description Form for Fish and Shellfish Species

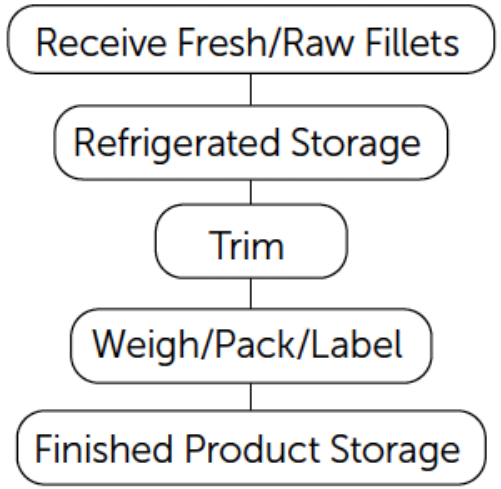
| Acceptable Market Name & Species | Where Product Is Purchased (Source) | | | How Product Is Received | | | | How Product Is Stored | | | | How Product Is Shipped | | | | How Product is Packaged | | Intended Use | | | Intended Consumer | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|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

# XYZ Processing Steps

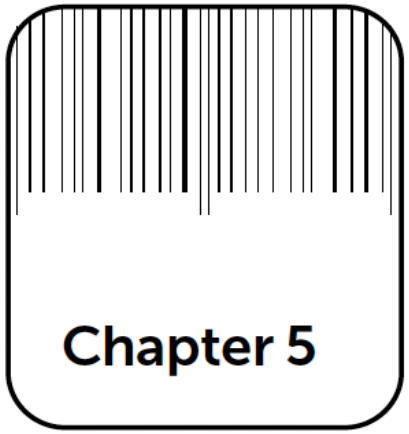
Slide7

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

**Process Flow Chart**



# Principle 1: Hazard Analysis




**Slide 1**

In this chapter you will learn how to:

- Conduct a hazard analysis
- Identify significant hazards
- Identify control measures

# Key Definitions

**Slide 2**

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

Food Safety Hazards

- Biological
- Chemical
- Physical

# Why conduct a Hazard Analysis?

**Slide 3**

The hazard analysis is conducted to identify:

- All **potential** food safety hazards,
- Which of these hazards are **significant**, and
- Measures to control the **significant** hazards.

# How to conduct a Hazard Analysis?

**Slide 4**

There are five steps in a hazard analysis:

1) List process steps
2) Identify **potential food safety hazards**
3) Determine if the hazard is **significant**
4) Justify the decision
5) Identify control measure(s)

# Use the Hazard Analysis Worksheet

Slide 5

Blank Hazard Analysis Worksheet

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

# **STEP 1**– Enter Processing Steps

Slide 6

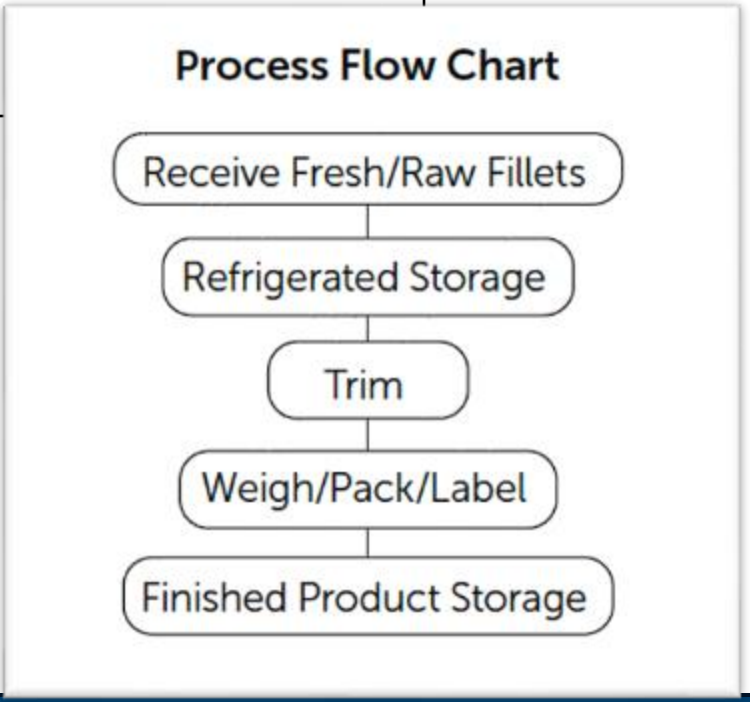
**Step 1: Enter each of the processing steps from the process flow chart in Column 1 of the hazard analysis worksheet.** Each step will have its own block on the worksheet and should be listed in the same order as on the process flow chart.

"Fresh Mahi-mahi Fillets"

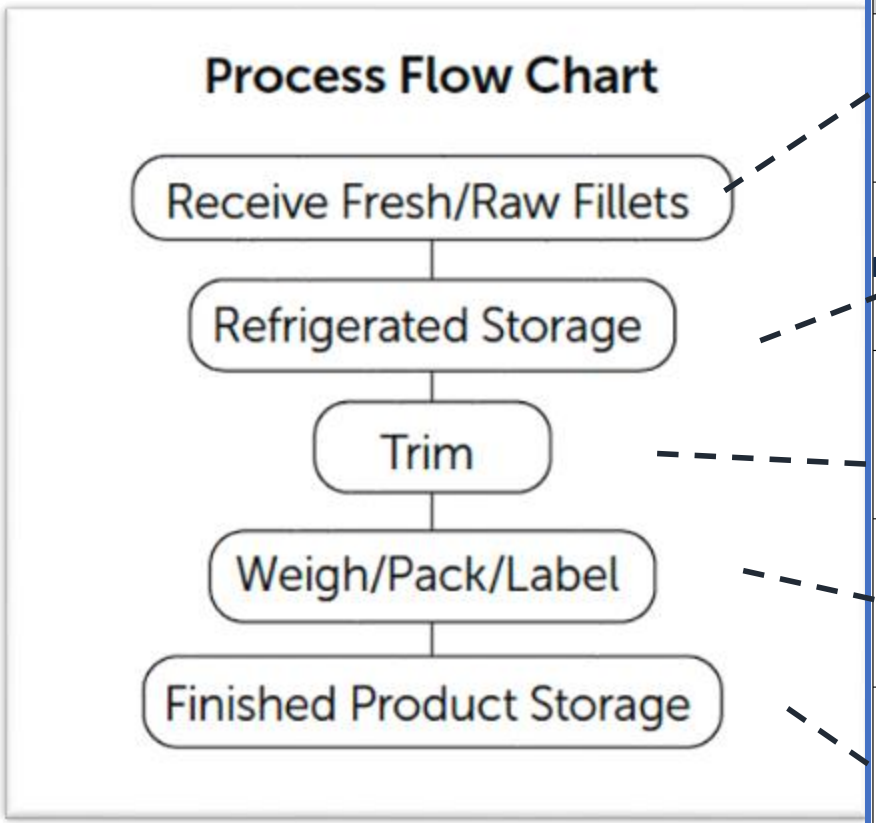
**Processing Steps**

Flow Diagram from

Chapter 4, Page 75



# List all Processing Steps




**Hazard Analysis Worksheet – Inclusive Method**

| | |
|---|---|
| **Firm Name:** | **Product Description:** |
| **Firm Address:** | **Method of Storage & Distribution:** |
| | **Intended Use & Consumer:** |

| (1) **Processing Step** | (2) List all potential **biological, chemical, and physical food safety hazards** that could be associated with this product and process. | (3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)** | (4) **Justify the decision** that you made in column 3 | (5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard? | (6) Is this step a **Critical Control Point? (Yes or No)** |
|---|---|---|---|---|---|
| Receiving Fresh/Raw Fillets | | | | | |
| Refrigerated Storage | | | | | |
| Trim | | | | | |
| Weigh/ Pack/Label | | | | | |
| Finish Product Refrig. Storage | | | | | |

**Column 1: List all of the processing steps from the Process Flow Chart**

# **STEP 2**– List Potential Food Safety Hazards

**Slide 7**

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

**Slide 8**

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

# Search for the potential hazards for the Fresh 'Wild' Mahi-mahi Fillets

Seafood HACCP Alliance

**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.)

| MARKET NAMES | LATIN NAMES | HAZARDS | | | | |
|---|---|---|---|---|---|---|
| | | Parasites[3] CHP 5 | Natural Toxins[13] CHP 6 | Scombrotoxin (Histamine) CHP 7 | Environmental Chemicals CHP 9 | Aquaculture Drugs CHP 11 |
| AHOLEHOLE | *Kuhlia* spp. | | | | | |
| ALEWIFE or RIVER HERRING | *Alosa pseudoharengus* | | | | | |
| ALFONSINO | *Beryx* spp. | | | | | |
| | *Centroberyx* spp. | | | | | |
| ALLIGATOR | *Alligator mississipiensis* | | | | | |
| | *Alligator sinensis* | | | | | |
| ALLIGATOR, aquacultured | *Alligator mississipiensis* | | | | | |
| | *Alligator sinensis* | | | | | |
| AMBERJACK | *Seriola dumerili* | | CFP | | | |
| | *S. rivoliana* | | CFP | | | |
| | *S.* spp. | | | | | |
| AMBERJACK or YELLOWTAIL | *Seriola lalandi* | | | | | |
| AMBERJACK or YELLOWTAIL, aquacultured | *Seriola lalandi* | ✓[4] | | | | |
| AMBERJACK or BURI, aquacultured | *Seriola quinqueradiata* | | | | | |
| ANCHOVY[12] | *Anchoa* spp. | ✓ | ASP | | | |
| ANGELFISH | *Pomacanthus* spp. | | | | | |

**TABLE 3-3**

**POTENTIAL INVERTEBRATE 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.)

| MARKET NAMES | LATIN NAMES | HAZARDS | | | | |
|---|---|---|---|---|---|---|
| | | Pathogens CHP 4 | Parasites CHP 5 | Natural Toxins CHP 6 | Environmental Chemicals CHP 9 | Aquaculture Drugs CHP 11 |
| ABALONE | *Haliotis laevigata* | | | ✓ | ✓ | |
| | *H. ruber* | | | | ✓ | |
| | *H.* spp. | | | | ✓ | |
| | *Marinauris roei* | | | | ✓ | |
| ARKSHELL | *Anadara* spp. | ✓ | | ✓ | ✓ | |
| | *Arca* spp. | ✓ | | ✓ | ✓ | |
| CLAM, BENTNOSE | *Macoma nasuta* | ✓ | | ✓ | ✓ | |
| CLAM BUTTER | *Saxidomus* spp. | ✓ | | ✓ | ✓ | |
| CLAM, CALICO | *Macrocallista maculata* | ✓ | | ✓ | ✓ | |
| CLAM, GEODUCK | *Panopea bitruncata* | ✓ | | ✓ | ✓ | |
| | *P.* spp. | ✓ | | ✓ | ✓ | |
| | | ✓ | | ✓ | ✓ | |
| | | ✓ | | ✓ | ✓ | |
| | | ✓ | | ✓ | ✓ | |
| | | ✓ | | ✓ | ✓ | |
| | *Protothaca thaca* | ✓ | | ✓ | ✓ | |
| CLAM, LITTLENECK | *Protothaca staminea* | ✓ | | ✓ | ✓ | |
| | *P. tenerrima* | ✓ | | ✓ | ✓ | |

Chapter 3: Potential Species-Related and Proces

3 - 3 (August 2019)

**Tables 3-2 and 3-3**
**Species-Related Hazards**

**TABLE 3-4**

**POTENTIAL PROCESS-RELATED HAZARDS**

| Package Type | Hazards | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Pathogenic Bacteria Growth - Temperature Abuse CHP 12 | *C. botulinum* Toxin CHP 13 | *S. aureus* Toxin - Drying CHP 14 | *S. aureus* Toxin - Batter CHP 15 | Pathogenic Bacteria Survival Through Cooking or Pasteurization CHP 16 | Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics CHP 17 | Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes CHP 18 | Allergens and Food Intolerance Substances[4] CHP 19 | Metal Inclusion CHP 20 | Glass Inclusion CHP 21 |
| Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed) | | ✓ | | ✓ | | | | ✓ | ✓ | |
| Other than reduced oxygen packaged | | | | ✓ | | | | ✓ | ✓ | |
| Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil) | ✓ | ✓ | | | ✓ | | | ✓ | ✓ | |
| Other than reduced oxygen packaged | | | | | | | | ✓ | ✓ | |
| All | | | | | | | | ✓ | ✓ | |

**Table 3-4**
**Process-Related Hazards**

Chapter 3: Potential Species-Related and Process-Related Hazards

3 - 52 (August 2019)

# 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.)

| MARKET NAMES | LATIN NAMES | HAZARDS | | | | |
|---|---|---|---|---|---|---|
| | | Parasites[3] CHP 5 | Natural Toxins[3] CHP 6 | Scombrotoxin (Histamine) CHP 7 | Environmental Chemicals CHP 9 | Aquaculture Drugs CHP 11 |
| MACKEREL, SPANISH or NARROW-BARRED | *Scomberomorus commerson* | | CFP | ✓ | | |
| MAHI-MAHI | *Coryphaena* spp. | | | ✓ | | |
| MAHI-MAHI, aquacultured | *Coryphaena* spp. | | | ✓ | | ✓ |
| MARLIN | *Makaira* spp. | | | ✓ | | |
| | *Tetrapturus* spp. | | | ✓ | | |

# Four Process-related hazard

Notice two hazards in Chapter 19

Seafood HACCP Alliance

## Table 3-4

| POTENTIAL PROCESS-RELATED HAZARDS | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Finished Product Food [1] | Package Type | Hazards | | | | | | | | | |
| | | Pathogenic Bacteria Growth - Temperature Abuse | *C. botulinum* Toxin | *S. aureus* Toxin - Drying | *S. aureus* Toxin - Batter | Pathogenic Bacteria Survival Through Cooking or Pasteurization | Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics | Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes | Allergens and Food Intolerance Substances[4] | Metal Inclusion | Glass Inclusion |
| | | CHP 12 | CHP 13 | CHP 14 | CHP 15 | CHP 16 | CHP 17 | CHP 18 | CHP 19 | CHP 20 | CHP 21 |
| Raw fish other than oysters, clams, and mussels (finfish and non-finfish) | Reduced oxygen packaged (e.g. mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil) | √ | √ | | | | | | √ | √ | |
| Raw fish other than oysters, clams, and mussels (finfish and non-finfish) | Other than reduced oxygen packaged | √ | | | | | | | √ | √ | |
| Raw oysters, clams, and mussels | Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil) | √ | √ | | | | √ | | | √ | √ |
| Raw oysters, clams, and mussels | Other than reduced oxygen packaged | √ | | | | | √ | | | √ | √ |

# Hazard Analysis for the XYZ Seafood Company should include 5 potential hazards:

## Species-related Hazards Table 3-2

1. Histamine formation (Chapter 7)

## Process-related Hazards Table 3-4

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

**Hazard Analysis Worksheet**

| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product Description:** Fresh/Raw Mahi-Mahi Fillets |
| **Firm Address:** 238 Coastal Lane, Happy Beach, XX | **Method of Storage & Distribution:** Stored and distributed on ice<br>**Intended Use & Consumer:** To be cooked and consumed by general public. |

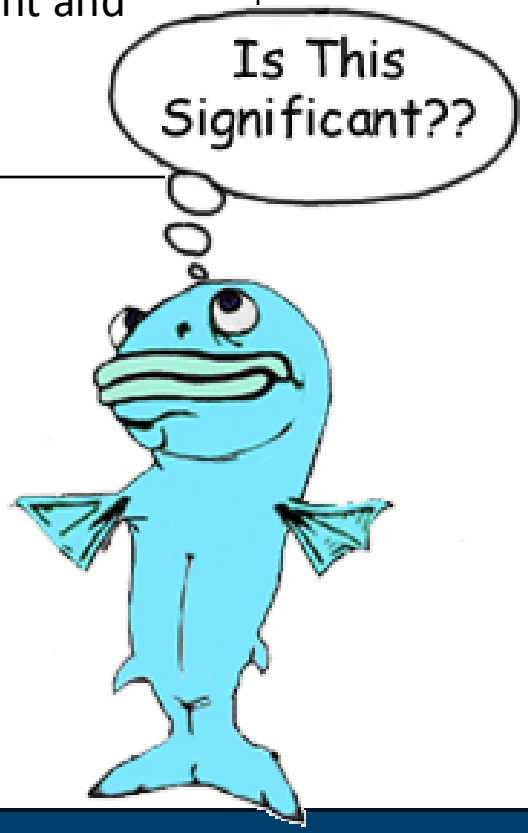
| (1) **Processing Step** | (2) List all potential **food safety hazards** that could be associated with this product and process. | (3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)** | (4) **Justify the decision** that you made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

**Column 2:**
**List <u>every</u> hazard that is reasonably likely to occur at <u>each</u> processing step**

# **STEPS 3 & 4** – Hazard Evaluation & Justification

**Slide 12**

**Steps 3 and 4: Hazard Evaluation and Justification.** Determinewhich hazards are significant and explain why.




## Simply answer the questions in the Hazard Analysis

# Exercise: Complete the Hazard Analysis Worksheet

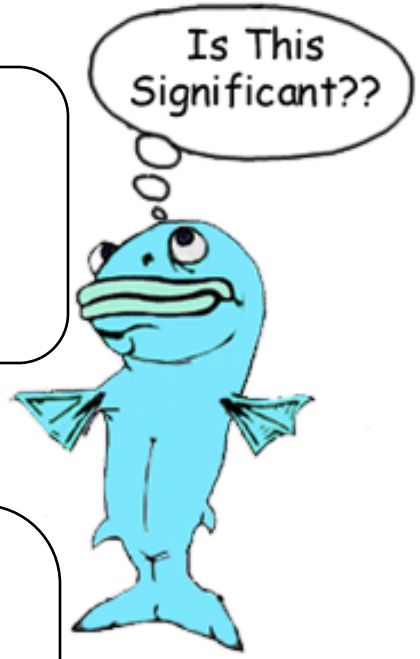
| (1) Processing Step | (2) List all potential **food safety hazards** that could be associated with this product and process | (3) Is the potential food safety hazard **significant** (introduced, enhanced, eliminated) at this step? **(Yes or No)** | (4) **Justify the decision** that you made in column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

**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**

## Slide 13

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




## Slide 14

**Example – Fresh/Raw 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

Slide 20

see page 93

XYZ Seafood Company – Fresh/Raw Mahi-Mahi Fillets

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

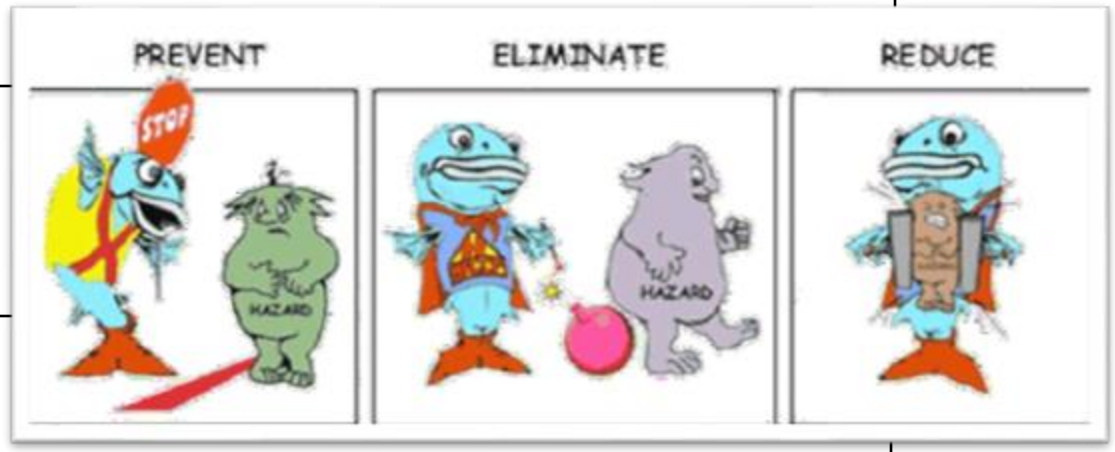
# BRIEF SUMMARY based on the FDA Guide that provides more recommended details

| Column 2<br>Potential Hazards<br>(Likely to Occur) | Columns 3 & 4<br>Is the hazard significant in this processing operation | |
|---|---|---|
| Histamine | YES | Mahi is potential scombrotoxic fish species subject to temperature abuse |
| Pathogen Growth -Temp. Abuse | NO | Mahi intended to be cooked before consumption |
| Undeclared Food Allergens | YES | Fish are food allergens |
| Food Intolerance Substances (FIS) | NO | No FIS or food additives used or added in this processing operation |
| Metal Inclusion | NO | Not likely to occur in processing steps |

# **STEPS 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

Slide 18

**Control Measures for Pathogenic Bacteria, Viruses, Parasites**

**Bacteria**

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

**Viruses**

1) Cooking
2) Source controls

**Parasites**

1) Cooking
2) Freezing

# Control Measures

Slide 19

**Control Measures for Chemical and Physical Hazards Chemical Hazards** (Natural toxins, pesticides, drug residues, unapproved food and color additives, histamine

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

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

1) Source controls
2) Production controls

# BRIEF SUMMARY based on the FDA Guide that provides more recommended details

| Column 2<br>Potential Hazards<br>(Likely to Occur) | Columns 3 & 4<br>Is the hazard significant in this processing operation | | Column 5<br>Necessary Controls |
|---|---|---|---|
| Histamine | YES | Mahi is potential scombrotoxic fish species subject to temperature abuse | Time and Temperature controls (Chapter 7) |
| Pathogen Growth<br>-Temp. Abuse | NO | Mahi intended to be cooked before consumption | Chapter 12 |
| Undeclared Food Allergens | YES | Fish are food allergens | Proper product labeling (Chapter 19) |
| Food Intolerance Substances (FIS) | NO | No FIS or food additives used or added in this processing operation | |
| Metal Inclusion | NO | Not likely to occur in processing steps | Chapter 20 (page 386) |

# Hazard Analysis Worksheet

Pages 95-97

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

Slide 22

XYZ Seafood Company – Fresh/Raw Mahi-Mahi Fillets

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

# Hazard Analysis Worksheet

Pages 95-97

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

Slide 22 (cont.)

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

# Hazard Analysis Worksheet

Pages 95-97

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

Slide 22 (cont.)

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


# Be sure to identify all potential FOOD SAFETY Hazards

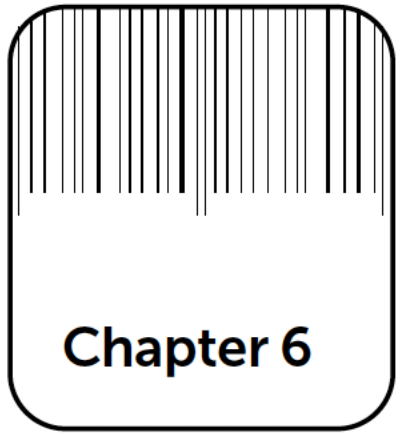
**Slide 21**

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

# Principle 2: Determine Critical Control Points




**Slide 1**

In this chapter you will learn:

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

# What's a Critical Control Points

**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.

# Hazard Prevention

Slide 4

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

| Control Measures | CCPs |
| --- | --- |
| Formulation | Mixing Step |
| Time/Temp Control | Refrigerated Storage Step |
| Supplier Certificates | Receiving Step |

# Hazard Elimination

Slide 5

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

| Control Measures | CCPs |
| --- | --- |
| Cooking | Cook Step |
| Use of Metal Detection | Metal Detector Step |
| Freezing Procedures | Freeze Step |

# Hazard Reduction

Slide 6

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

| Control Measure | CCP |
| --- | --- |
| Source Controls | Receiving Step |
| Time/Temp Control | Cook Step |

# More than one …

Slide 7

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

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

# Product & Process Specific …

**Slide 8**

CCP are product- and process-specific and impacted by:

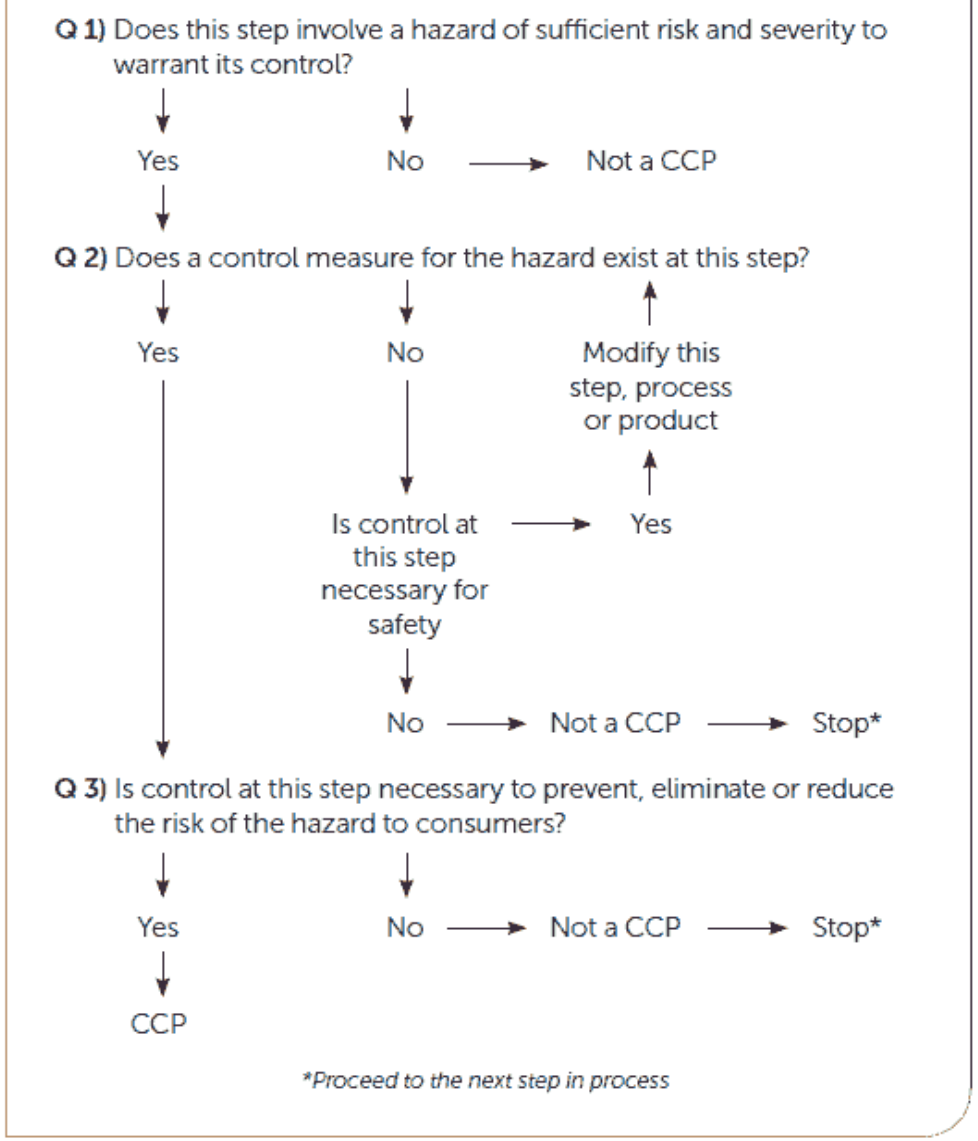
- Layout of the plant or processing line,
- Finished product formulation,
- Process flow or sequence of processing steps,
- Processing equipment,
- Ingredients,
- Sanitation or other support programs.

# CCP Decision Tree (optional tool)

Page 103

**Slide 9**

CCP Decision Tree



XYZ Seafood Company – Fresh/Raw Mahi-Mahi Fillets

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

CCP

Completed Hazard Analysis 105 - 107

**Every 'Yes' in column 3 requires a response in column 6**

Slide 10 (cont.)

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

CCP

Seafood HACCP Alliance

Completed Hazard Analysis 105 - 107

**Every 'Yes' in column 3 requires a response in column 6**

Slide 10 (cont.)

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

CCP

CCP

Seafood HACCP Alliance

Completed Hazard Analysis 105 - 107

**Every 'Yes' in column 3 requires a response in column 6**

# 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*"

Seafood HACCP Alliance

Slide 10

XYZ Seafood Company – Fresh/Raw Mahi-Mahi Fillets

**Hazard Analysis Worksheet**

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

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

**Hazard here**

**Every 'Yes' in column 3 requires a response in column 6**

Slide 10 (cont.)

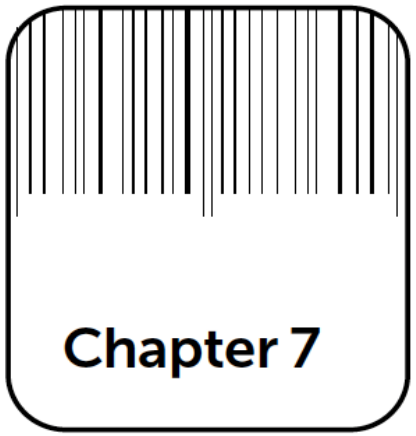
| (1) **Processing Steps** | (2) List all potential **food safety hazards** that could be associated with this product and process. | (3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)** | (4) **Justify the decision** that you made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

**CCP later**

# End Chapter 6: Principle 2

## Determine Critical Control Points

# Principle 3: Establish Critical Limits




**Slide 1**

In this chapter you will learn:

- Definition of critical limit.
- How to determine critical limits for a CCP.
- The relationship between critical limits and operating limits.
- Use of the HACCP plan form.

# What's is a Critical Limit?

Slide 2

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

# Sources & Examples …

Seafood HACCP Alliance

**Slide 3**

Sources of Informa

**Information Sou**

FDA

Regulations and

Experts

Scientific studies

Scientific informa

**Slide 4**

Examples of Critical Limits for species-related hazards

| Product | Significant Hazard | Critical Control Point | Critical Limits |
|---|---|---|---|
| Aquacultured shrimp | | | |
| Oysters (live) | | | |
| Raw Tuna | | | |

**Slide 5**

Examples of Critical Limits for process-related hazards

| Product | Significant Hazard | Critica Contr |
|---|---|---|
| Battered fish | *Staphylococcus aureus* growth and toxin formation | Batter |
| Imitation crabmeat | Metal inclusion | Metal (after p |
| Hot smoked fish, vacuum packaged | *Clostridium botulinum* toxin formation (in finished product) | Hot sn |
| Ready-to-eat seafood salad | Pathogen growth | Coole |

**Slide 6**

Examples of Critical Limits

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

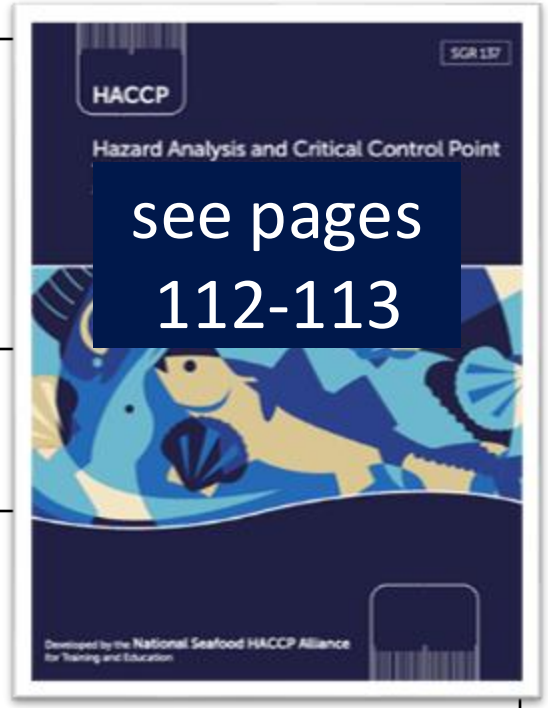
# Options and details…

**Slide 7**

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

**Slide 8**

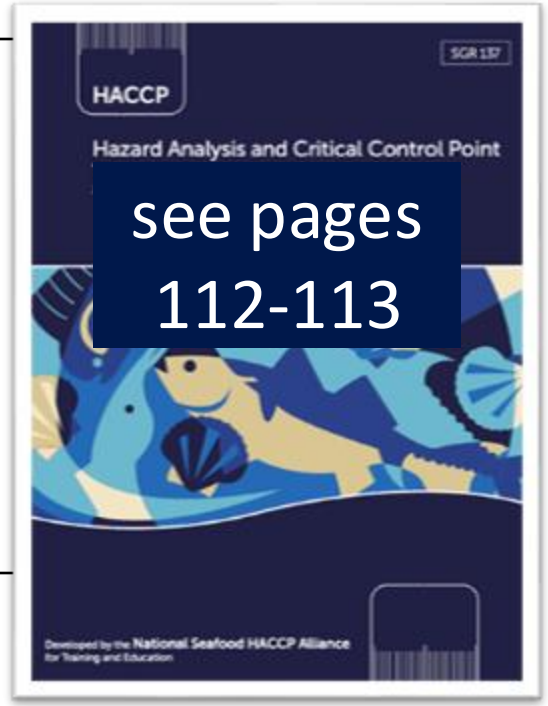
**Option No. 2**
Product: Fish cakes
Hazard — pathogen survival through cooking
CCP — fryer
Critical limit — minimum internal temperature of 165°F for 36 seconds



# Options and details…

Slide 7

**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



# Using Operating Limits

Slide 10

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

# Using ‘Lot’ Designations

Page 115

Slide 11

**Figure 1**

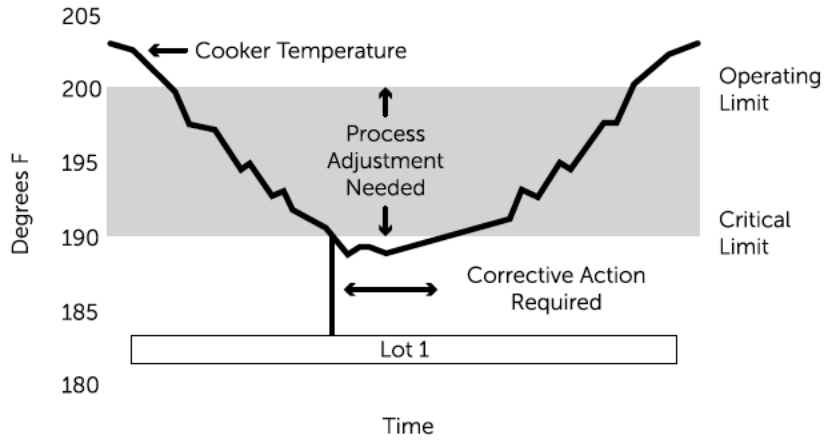
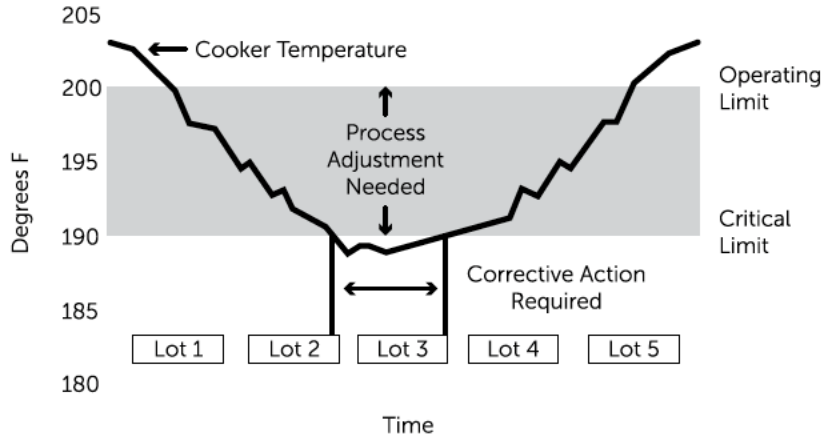



**Figure 2**



# Critical Limits should be specified in the written HACCP Plan

Slide 12

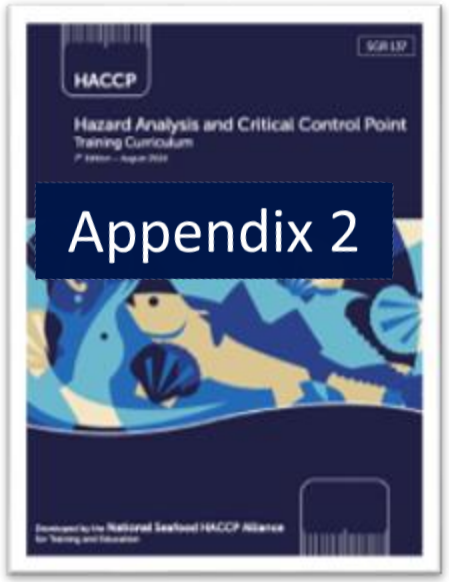
Blank HACCP Form

Firm Name: _____ HACCP Plan Form Product: _____

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

# Optional HACCP Plan Forms

## (both must contain same information)



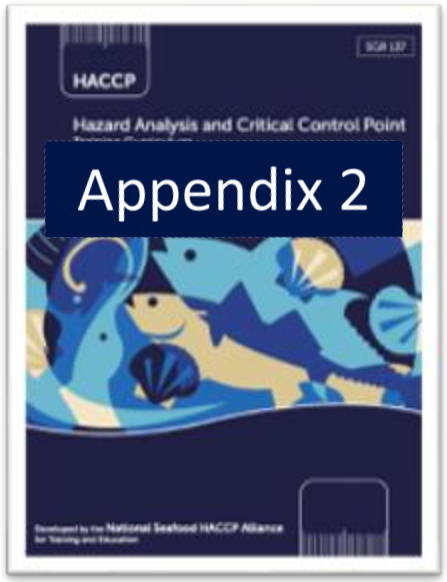

Landscape

| Firm Name:<br>Address: | | | | | | | Product Description: | | |
|---|---|---|---|---|---|---|---|---|---|
| Signature:<br>(printed name)<br>Date: | | | | | | | Method of Distribution & Storage:<br>Intended Use & Consumers: | | |
| (1) Critical Control Point (CCP) | (2) Significant Hazards | (3) Critical Limits for each Preventative Measure | (4) Monitoring | (5) | (6) | (7) | (8) Corrective Action(s) | (9) Verification | (10) Records |
| | | | What | How | Frequency | Who | | | |
| | | | | | | | | | |
| | | | | | | | | | |

Portrait

| Firm Name: XYZ Seafood Company | | Product: Fresh Mahi-Mahi Fillets |
|---|---|---|
| Address: 238 Coastal Lane, Happy Beach, XX | | Method Storage & Distribution: Stored and distributed on ice |
| Signature: Xxxxxxxxxxxx<br>Printed: Xxxxxxxxxx | | Intended Use: To be cooked and consumed by the general public<br>Date: (-*signed date*-) |
| | CCP number 1 | |
| Critical Control Point (CCP) | RECEIVING | |
| Significant Hazard | Histamine | |
| Critical Limits | | |
| Monitoring | What | |
| | How | |
| | When | |
| | Who | |
| Corrective Action | | |
| Verifications | | |
| Records | | |

# Expected Information in all HACCP Plans




| HACCP Plan Form | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Firm Name: | | | | | Product Description: | | | | |
| Firm Address: | | | | | Method of Storage and Distribution: | | | | |
| | | | | | Intended Use and Consumer: | | | | |
| (1) Critical Control Point(CCP) | (2) Significant Hazard(s) | (3) Critical Limits for each Control Measure | Monitoring | | | | (8) Corrective Action | (9) Verification | (10) Records |
| | | | (4) What | (5) How | (6) Frequency | (7) Who | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Signature: | | | | | | | Date: | | |

# Building a HACCP Plan Form for each CCP

## Hazard Analysis Worksheet

| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product Description:** Fresh/Raw 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 general public. |

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

XYZ Seafood Company

## HACCP Plan From

Fresh, V

| (1) Critical Control Point (CCP) | (2) Significant Hazards | (3) Critical Limits for each Preventative Measure | (4) Monitoring: What | (5) Monitoring: How | (6) Monitoring: Frequency | (7) Monitoring: Who | (8) Corrective Action(s) |
|---|---|---|---|---|---|---|---|
| RECEIVING | Histamine | | | | | | |
| REFRIGERATED STORAGE | Histamine | | | | | | |

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

# Recommended Critical Limits

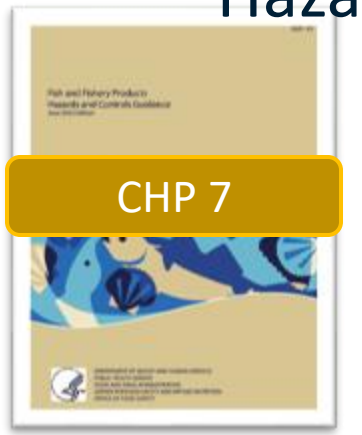
Tip

- REMINDER: The FDA Guide contains control strategies  with recommended CL's
- Processors may select alternative CL's 'however' equivalent effectiveness MUST be demonstrated and documented

# Select a Control Strategy

**CONTROL STRATEGY** selected from the FDA Guide

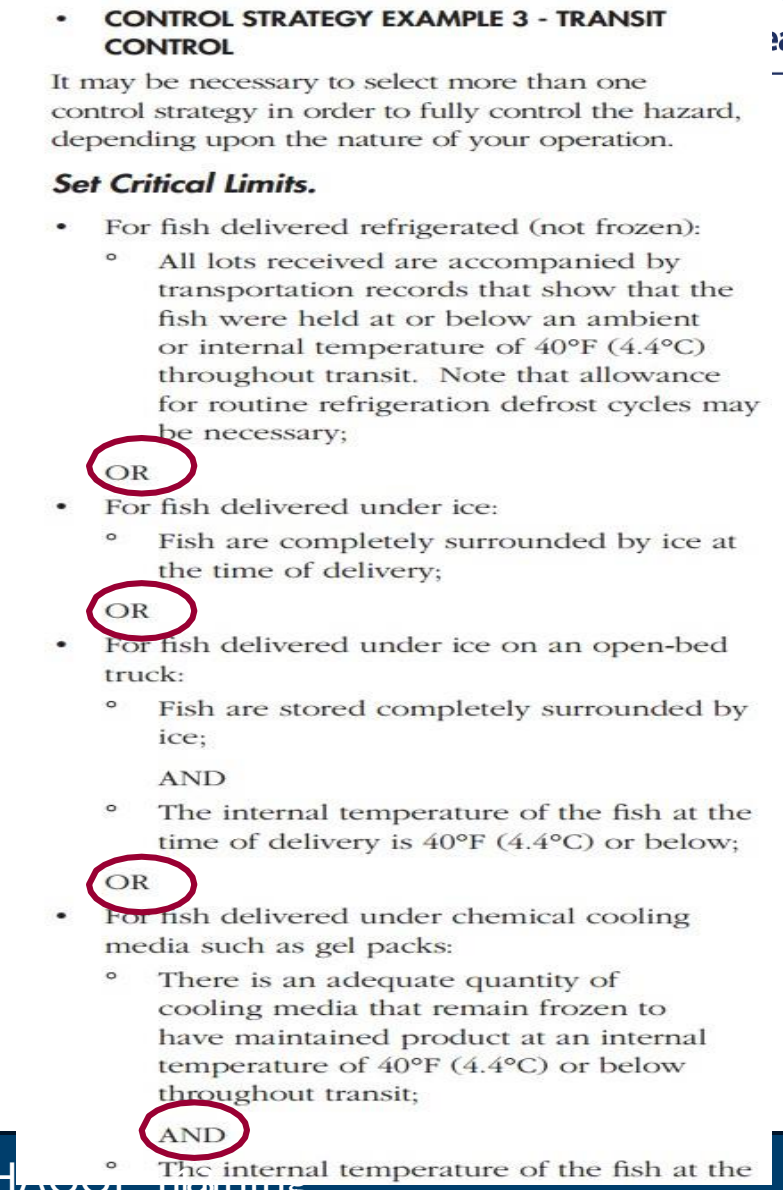
CCP – Receiving
Hazard - Histamine




| CONTROL STRATEGY | MAY APPLY TO PRIMARY PROCESSOR | MAY APPLY TO SECONDARY PROCESSOR |
|---|---|---|
| Harvest vessel control | ✓ | |
| Histamine testing | ✓ | |
| Transit control | ✓ | ✓ |
| Processing control | ✓ | ✓ |
| Storage Control | ✓ | ✓ |

# 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**



- **CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

***Set Critical Limits.***

- For fish delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the fish were held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

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;

AND

  - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

OR

- For fish delivered under chemical cooling media such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained product at an internal temperature of 40°F (4.4°C) or below throughout transit;

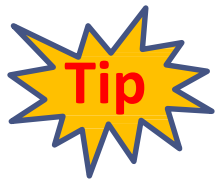
AND

  - The internal temperature of the fish at the

# Select the best control to situation and assure effective control for the potential hazard

- **TRANSIT CONTROL CRITICAL LIMITS**

1. Transit temperature records, **or**
2. Completely surrounded by ice on delivery, **or**
3. Use of ice; **AND** internal fish temperature, **or**
4. Frozen gel-packs; **AND** internal fish temperature, **or**
5. Transit time (< 4 hours); **AND** internal fish temperature




**Notice *'ORs & ANDs'***

# HACCP Plan for XYZ Seafood Company

Firm Name: *XYZ Seafood Company* HACCP Plan Form Product: *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | |
|---|---|---|---|---|---|
| | | | What | How | Frequenc |
| Receiving | Histamine | Tub or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | | | |
| Refrigerated Storage | Histamine | | | | |
| Weigh/Pack/ Label | Food Allergens | | | | |
| Finished Product Refrigerated Storage | Histamine | | | | |

**FDA Guide, Chapter 7**

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;

  AND
  - 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

Slide 13

Firm Name: *XYZ Seafood Company*

**HACCP Plan Form**

Product: *Fresh/Raw Mahi-Mahi Fillets*

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

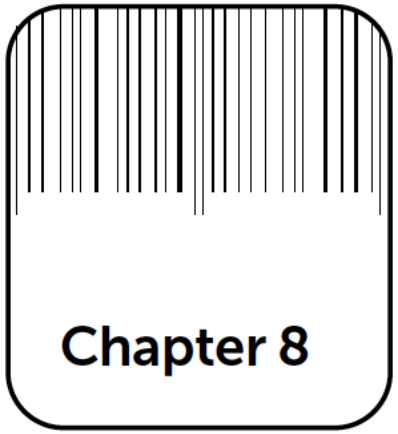
**Critical Limits based on recommendations in the FDA Hazards Guide**

| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product:** Fresh/Raw 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

# Principle 4: Critical Control Point Monitoring




**Slide 1**

In this chapter you will learn:

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

# 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

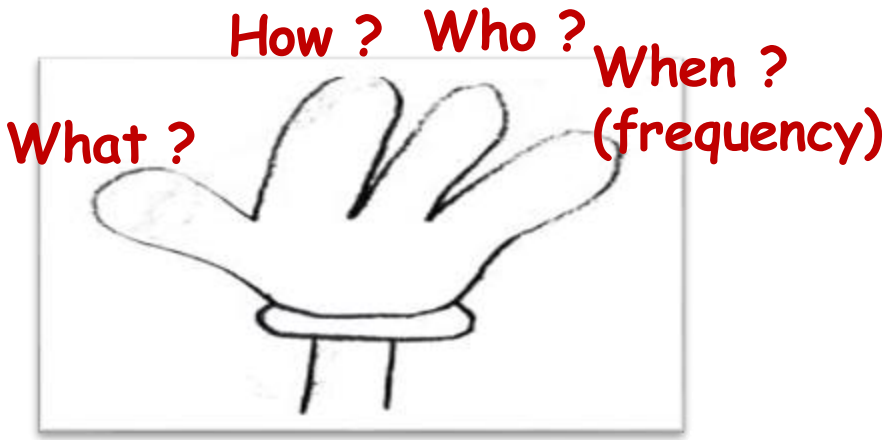
- To ensure that a critical limit is met,
- To provide documentation that critical limits have been met,
- To identify when there is loss of control (a deviation occurs at a CCP).

# 4 required parts for proper MONITORING

Slide 4

Elements of Monitoring

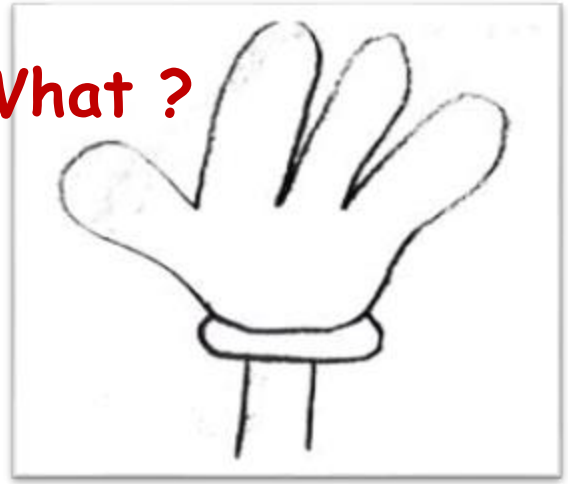
- What will be monitored?
- How will monitoring be performed?
- What is the frequency of monitoring?
- Who will conduct the monitoring?



# What?

**Slide 5**

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

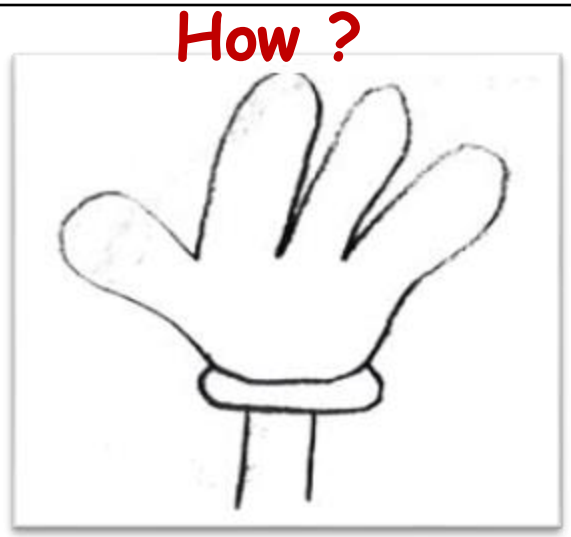


# How?

Slide6

How will monitoring be performed?

- Measurements (quantitative critical limits) or observations (qualitative critical limits).
- Needs to be real-time and accurate.

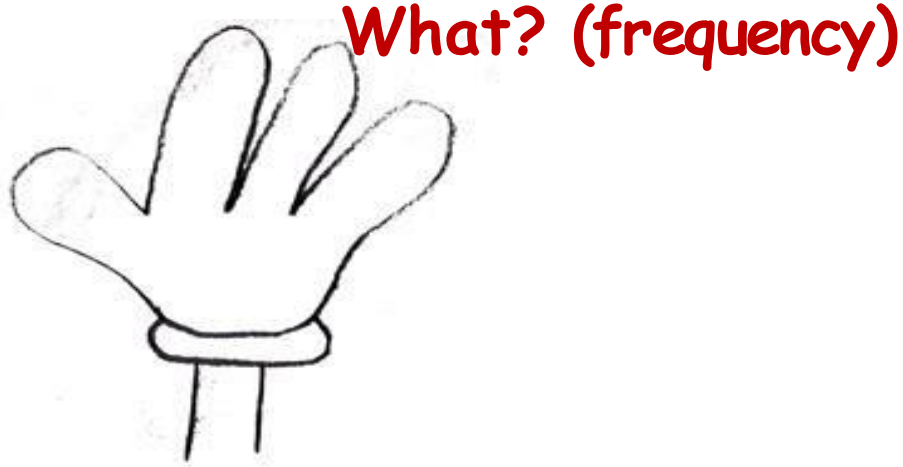


# When?(frequency)

Slide 7

What is the frequency of monitoring?

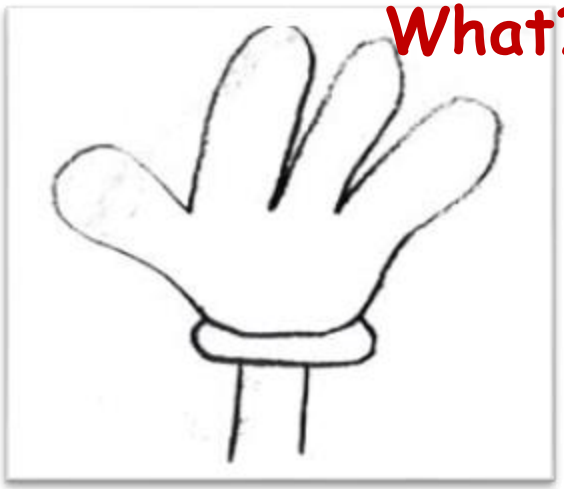
- Monitoring frequency should be sufficient to ensure that the critical limit is met.
- Monitoring frequency can be **non-continuous** or **continuous.**



# Who?

**Slide 8**

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



What? (frequency)

# Monitoring requires training

Slide 9

Those responsible for monitoring a CCP should

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

# Monitoring examples

**Slide 10**

Monitoring Example:

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

# Monitoring equipment examples

**Slide 11**

Examples of monitoring equipment

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

# Monitoring for XYZ Seafood Company

Slide 12

HACCP plan form for XYZ Seafood Company completed through monitoring

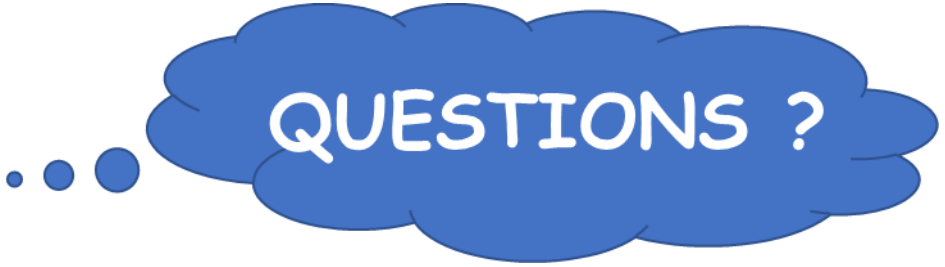
**Firm Name:** *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets at delivery | Visual check of adequacy of ice in a representative number of containers in each delivery | Every Delivery | Receiving Manager | | | |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | At the beginning and end of the work day | Cooler Manager | | | |
| Weigh/Pack/ Label | Food Allergens | All finished product containers will be labeled with the correct market name | The market name on each container of finished product | Visual comparison of the label against the product specification for accuracy | At the start of the production lot AND at least every 2 hours OR when new containers of labels are opened or rolls of labels are changed. | Packing Manager | | | |
| Finished Product Refrigerated Storage | Histamine | Containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding containers of mahi-mahi fillets | Visual check of representative number of containers in cooler storage | At the beginning and end of the work day | Cooler Manager | | | |

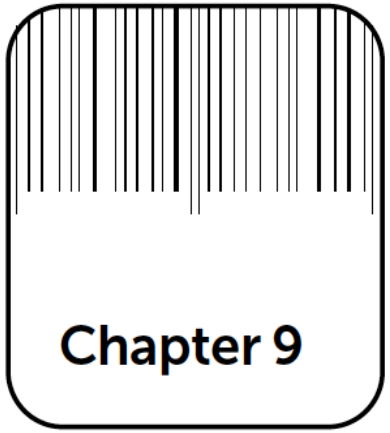
| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product:** Fresh/Raw Mahi-Mahi Fillets |
| **Firm Address:** 238 Coastal Lane, Happy Beach, XX | **Method of Storage and Distribution:** Stored and distributed buried in ice |
| | **Intended Use and Consumer:** To be cooked and consumed by the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

# End Chapter 8:Principle 4

## Monitoring



# Principle 5: Corrective Actions




**Slide 1**

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

Slide 4

Corrective action components:

1)identify the product that was produced during the process deviation, evaluate its safety and determine its disposition.

2)Correct and eliminate the cause of the deviation and restore process control.

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

# Is the involved product safe?

Seafood HACCP Alliance

**Slide 5**

Tools to help evaluate product safety:

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

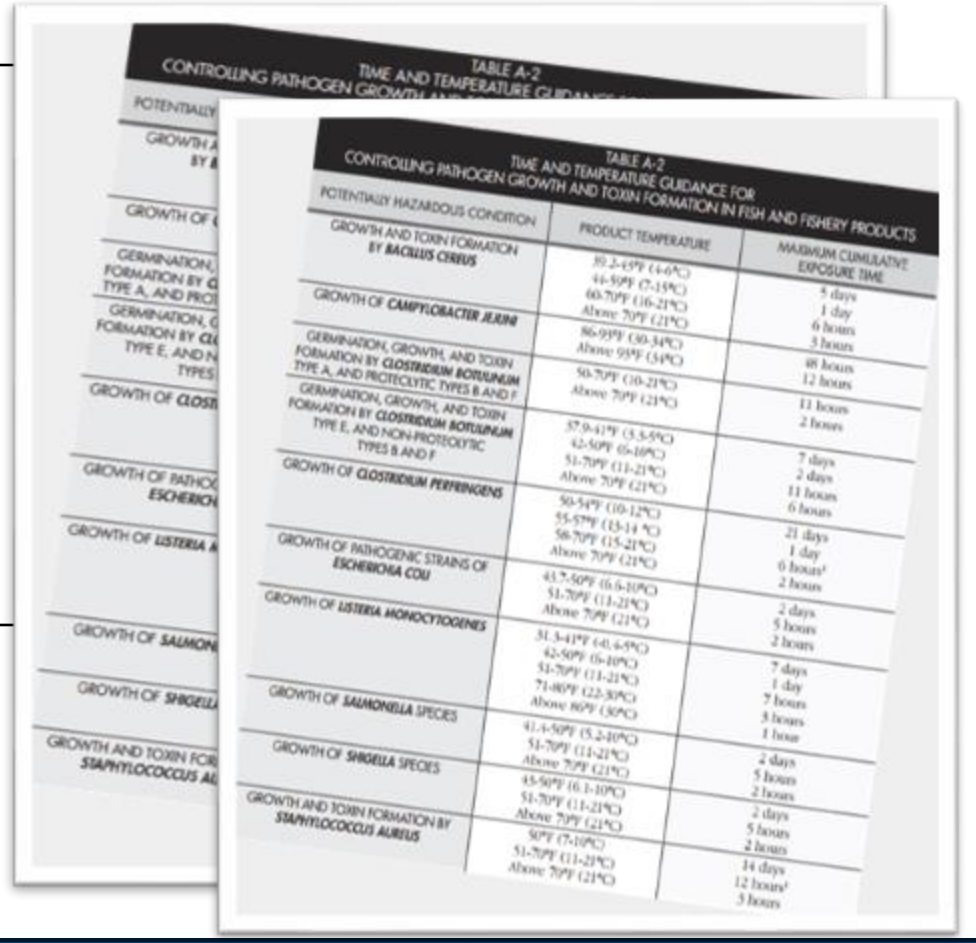


TABLE A-2
TIME AND TEMPERATURE GUIDANCE FOR CONTROLLING PATHOGEN GROWTH AND TOXIN FORMATION IN FISH AND FISHERY PRODUCTS

| POTENTIALLY HAZARDOUS CONDITION | PRODUCT TEMPERATURE | MAXIMUM CUMULATIVE EXPOSURE TIME |
|---|---|---|
| GROWTH AND TOXIN FORMATION BY *BACILLUS CEREUS* | 32-45°F (0-7°C)<br>46-50°F (7-10°C)<br>51-70°F (10-21°C)<br>Above 70°F (21°C) | 4 days<br>1 day<br>6 hours<br>3 hours |
| GROWTH OF *CAMPYLOBACTER JEJUNI* | 86-93°F (30-34°C)<br>Above 93°F (34°C) | 48 hours<br>12 hours |
| GERMINATION, GROWTH, AND TOXIN FORMATION BY *CLOSTRIDIUM BOTULINUM* TYPE A, AND PROTEOLYTIC TYPES B AND F | 50-70°F (10-21°C)<br>Above 70°F (21°C) | 11 hours<br>2 hours |
| GERMINATION, GROWTH, AND TOXIN FORMATION BY *CLOSTRIDIUM BOTULINUM* TYPE E, AND NON-PROTEOLYTIC TYPES B AND F | 37.9-41°F (3.3-5°C)<br>42-50°F (6-10°C)<br>51-70°F (11-21°C)<br>Above 70°F (21°C) | 7 days<br>2 days<br>11 hours<br>6 hours |
| GROWTH OF *CLOSTRIDIUM PERFRINGENS* | 50-54°F (10-12°C)<br>55-57°F (13-14 °C)<br>58-70°F (15-21°C)<br>Above 70°F (21°C) | 21 days<br>1 day<br>6 hours[1]<br>2 hours |
| GROWTH OF PATHOGENIC STRAINS OF *ESCHERICHIA COLI* | 43.7-50°F (6.6-10°C)<br>51-70°F (11-21°C)<br>Above 70°F (21°C) | 2 days<br>5 hours<br>2 hours |
| GROWTH OF *LISTERIA MONOCYTOGENES* | 31.3-41°F (-0.4-5°C)<br>42-50°F (6-10°C)<br>51-70°F (11-21°C)<br>71-80°F (22-30°C)<br>Above 80°F (30°C) | 7 days<br>1 day<br>7 hours<br>3 hours<br>1 hour |
| GROWTH OF *SALMONELLA* SPECIES | 41.4-50°F (5.2-10°C)<br>51-70°F (11-21°C)<br>Above 70°F (21°C) | 2 days<br>5 hours<br>2 hours |
| GROWTH OF *SHIGELLA* SPECIES | 45-50°F (6.1-10°C)<br>51-70°F (11-21°C)<br>Above 70°F (21°C) | 2 days<br>5 hours<br>2 hours |
| GROWTH AND TOXIN FORMATION BY *STAPHYLOCOCCUS AUREUS* | 50°F (7-10°C)<br>51-70°F (11-21°C)<br>Above 70°F (21°C) | 14 days<br>12 hours[1]<br>3 hours |

Helpful Sources:
FDA Guide-Appendix 4

# Is the involved product safe?

**Slide 6**

Steps to determine the disposition of the 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:
c)Reworked/reprocessed, or
d)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

Tip

## Optional CA's

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

**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.

# Information for documenting Corrective Actions

**Slide 8**

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

Page 133

**Slide 9**

Sample Corrective Action Report

| | |
|---|---|
| Company Name: | Street Address, City Name, State: |
| Product Identification: | |
| Date: | Code or Lot Number: |
| Date and Time of Deviation: | |
| Description of Deviation: | |
| What Actions were taken to Restore Order to the Process: | |
| Person (name and signature) of Person Taking Action: | |
| Amount of Product Involved in Deviation: | |
| Evaluation of Product involved with Deviation: | |
| Final Disposition of Product: | |
| Reviewed by (Name and Signature): | Date: |

# Example Corrective Actions

## See pages 134 & 135

Seafood HACCP Alliance

**Slide 10**

Corrective action examples for species-related hazards

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

**Slide 11**

Corrective action examples for process-related hazards

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

# Corrective Actions for XYZ Seafood Company

Slide 12

HACCP plan form for XYZ Seafood Company completed through corrective action

**Firm Name:** *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets at delivery | Visual check of adequacy of ice in a representative number of containers in each delivery | Every Delivery | Receiving Manager | **If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected. | | |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | At the beginning and end of the work day | Cooler Manager | **If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process. | | |

# Corrective Actions for XYZ Seafood Company

Slide 12 (cont.)

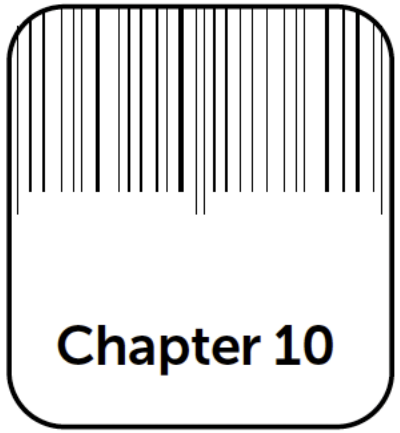
| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Weigh/Pack/ Label | Food Allergens | All finished product containers will be labeled with the correct market name of the fish. | The market name on each container of finished product | Visual comparison of the label against the product specification for accuracy | At the start of the production lot AND at least every 2 hours OR when new containers of labels are opened or rolls of labels are changed. | Packing Manager | **If:** A) container is improperly labeled, **Then:** Hold and isolate labeled product since the last acceptable inspection of labels; Inspect 100% of affected product and relabel mislabeled products; Inspect remaining labels staged for use and remove inaccurate labels from processing area; Review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate; Discontinue use of label supplier; Modify label procedures, as appropriate. | | |

see page 138-139

# End Chapter 9:Principle 5

## Corrective Actions

# Principle 6: Establish Verification Procedure




**Slide 1**

In this chapter 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 s

Slide 4

**Types of Verification Procedures:**

1)Validation (before the HACCP plan is implemented)

2)CCP verification (regularly scheduled activities):

- Calibration of process-monitoring devices,
- Record review,
- Targeted sampling and testing.

3)HACCP system verification (periodic activity):

- HACCP plan reassessment
- Microbiological end-product testing and third party audits

4)Regulatory verification (periodic activity)

# Validation ‘before’ operations

Slide5

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*’

Slide 6

Validation involves establishing the scientific basis for the HACCP plan.
Strategies that can be used to validate the HACCP plan include:

- using scientific principles and data,
- relying on expert opinion, or
- conducting in-plant observations or tests

# When to Validate

Slide 7

Validation frequency:

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

# Verification ‘during’ operations

**Slide 8**

CCP verification activities:

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

*‘Is it working’*

**Slide 9**

Accuracy checks and calibrations are performed:

- On equipment and instruments used in the HACCP plan
- At a frequency that ensures accuracy of measurements

# *'Is it working'* ... see page 146

Slide 10

Examples of calibration and accuracy activities

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

*NIST = National Institute of Standards and Technology

# 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 the device is used

**Slide 12**

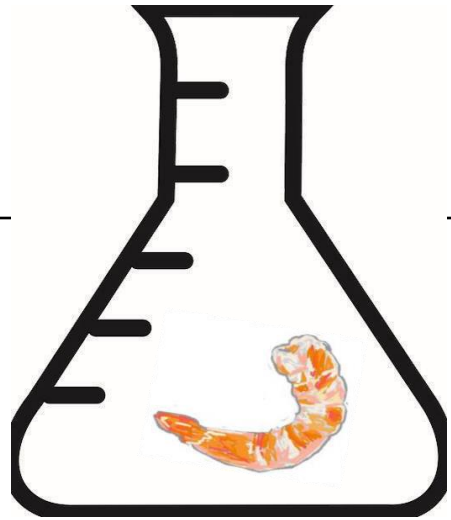
Accuracy checks and calibration records must:

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

Slide 13

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



# Must Review Monitoring and Corrective Action Records

Slide 14

**Verification through Record Reviews:**

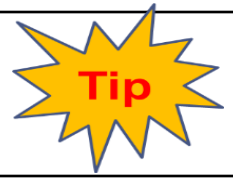
- All monitoring and correction action records
- Records must be reviewed within one week from time they were made by an individual who meets the training requirements of the FDA seafood HACCP regulation.

# 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.

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**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.

# 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...

Pages 152-153

Seafood HACCP Alliance

Slide 20

Example of a company-established HACCP verification schedule

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

Slide 21

Examples of verification activities for specific critical limits

| Significant Hazard | Critical Control Point | Critical Limits | Verification |
|---|---|---|---|
| Aquaculture drugs | Receiving (from farm) | Supplier's certificate for each incoming lot declaring proper drug use. | Analyze a representative number of samples of fish from each farm for drug residues that are reasonably likely to be present, and verify the adequacy of the testing methods and equipment by periodically sending samples to a third-party laboratory.<br>All records will be reviewed by a HACCP trained person once per week. |
| Natural toxins | Receiving (from harvester) | All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel; and all shellstock from waters approved by State Shellfish Authority; and all shellstock from a licensed harvester. | Review all monitoring and corrective action records once per week. |
| Histamine | Receiving (from supplier) | Fish are completely surrounded by ice. | Check the accuracy of new thermometers before they are used and daily thereafter and calibrate thermometers once per year; and<br>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<br>All records will be reviewed by a trained person once per week. |
| *C. botulinum* toxin formation (in finished product) | Hot smoking | Internal fish temperature held at or above 145°F for at least 30 minutes. | Check the accuracy of the smokehouse temperature sensor before it is used and daily thereafter and calibrate at least once per year; and<br>All records will be reviewed by a trained person once per week. |
| Pathogen growth | Cooler storage | Cooler temperature not to exceed 40°F. | Check the accuracy of the cooler temperature sensor before it is used and daily thereafter and calibrate at least once per year; and<br>All records will be reviewed by a trained person once per week. |

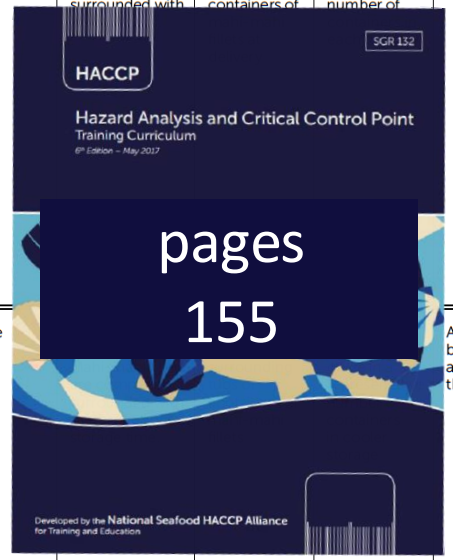
# Verifications for XYZ Seafood Company

Slide 22

HACCP plan form for XYZ Seafood Company completed through corrective action

**Firm Name:** *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with | Adequacy of ice surrounding tubs or containers of | Visual check of adequacy of ice in a representative number of | Every Delivery | Receiving Manager | **If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected. | Weekly review of Receiving Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | |
| Refrigerated Storage | Histamine | | | | At the beginning and end of the work day | Cooler Manager | **If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process. | Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | |

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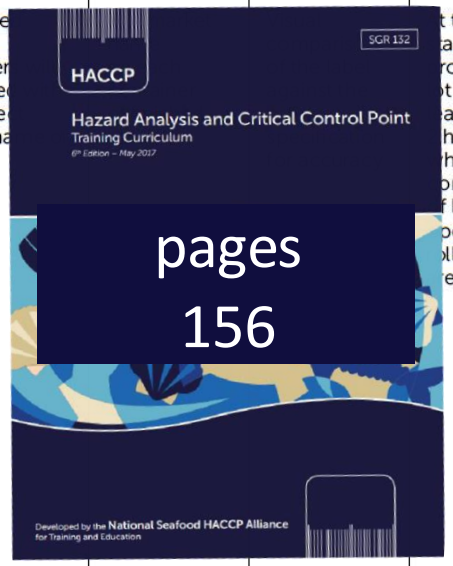
# Verifications for XYZ Seafood Company

Slide 22 (cont.)

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Weigh/Pack/ Label | Food Allergens | All finishe product containe be labele the corre market na the fish. | | | t the art of the roduction t AND at ast every hours OR hen new ontainers f labels are pened or lls of labels e changed. | Packing Manager | **If:** a container is improperly labeled, **Then:** Hold and isolate labeled product since the last acceptable inspection of labels; Inspect 100% of affected product and relabel mislabeled products; Inspect remaining labels staged for use and remove inaccurate labels from processing area; Review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate; Discontinue use of label supplier; Modify label procedures, as appropriate. | Weekly review of Packing Room Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate. | |

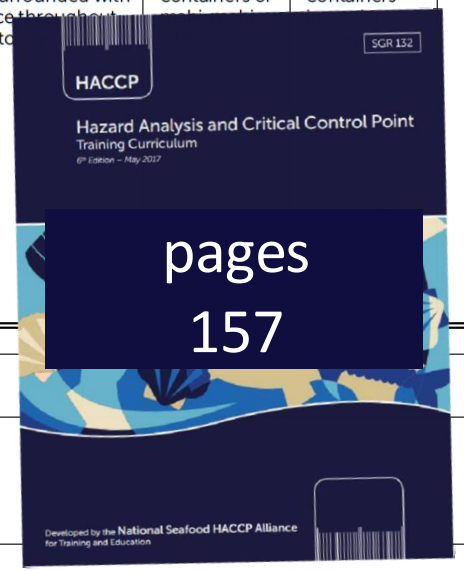



pages
156

# Verifications for XYZ Seafood Company

Slide 22 (cont.)

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Finished Product Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout sto | Adequacy of ice surrounding tubs or containers of | Visual check of representative number of containers | At the beginning and end of the work day | Cooler Manager | **If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it. | Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | |



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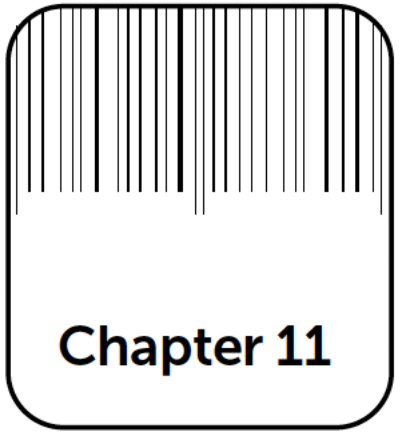
| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product:** Fresh/Raw Mahi-Mahi Fillets |
| **Firm Address:** 238 Coastal Lane, Happy Beach, XX | **Method of Storage and Distribution:** Stored and distributed buried in ice |
| | **Intended Use and Consumer:** To be cooked and consumed by the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

# End Chapter 10:Principle 6

VERIFICATIONS

# Principle 7: Record Keeping Procedures




**Slide 1**

In this chapter you will learn:

- What records are needed
- How to develop appropriate records
- How to conduct a record review
- How computerized records may be used

# 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

Required Records

**Slide 3**

1) The HACCP plan and its supporting documentation

# Recommended and Required Records

## Hazard Analysis

XYZ Seafood Company –

**Hazard Analysis Worksheet**

| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product Description:** Fresh/Raw 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 |

RECOMMENDED

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

## HACCP Plan

HACCP plan form for XYZ Seafood Company completed through corrective action

**Firm Name:** XYZ Seafood Company — **HACCP Plan Form** — **Product:** Fresh/Raw Mahi-Mahi Fillets

REQUIRED

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring: What | Monitoring: How | Monitoring: Frequency | Monitoring: Who | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets at delivery | Visual check of adequacy of ice in a representative number of containers in each delivery | Every Delivery | Receiving Manager | **If:** the amount of ice is not adequate; **Then:** reject product, and call supplier so as them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected. | Weekly review of Receiving Log (Monitoring records) and Corrective Action Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice. Corrective Action records Verification Record • Accuracy Check Log • Calibration Log |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | As the beginning and end of the work day | Cooler Manager | **If:** the amount of ice is not adequate; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and add ice and make adjustments to the ice application process. | Weekly review of Cooler Ice Log (Monitoring records) and Corrective Action Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration Log |

# Additional Record Support for HACCP

Slide 4

Examples of HACCP Plan Support Documents:

- Data from published scientific studies
- Data from in-plant studies conducted by processing authorities
- Data from equipment manufacturers or other authorities
- Data gathered in the Preliminary Steps
- Pre-requisite programs including sanitation control procedures
- Written hazard analysis worksheets

# Records support the HACCP Program

**Slide 5**

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

**Slide 6**

Information required on CCP monitoring records:

- Title of record (e.g. Shellfish Receiving Log)
- Firm name and location
- Product identification (if applicable)
- Date and time of monitoring observation
- Actual measurement or observation taken
- Signature or initials of the person performing the monitoring activity
- Signature of the trained person reviewing the monitoring record and the date of review

Required information on required records

# Example Monitoring Records

Slide 7

| Significant Hazard | Critical Control Point | Critical Limits | Monitoring Record |
|---|---|---|---|
| Aquaculture drugs | Receiving (from farm) | Suppliers certificate accompanying all incoming lots (indicating proper drug use) | Suppliers certificate (indicating proper drug use) |
| Natural toxins | Receiving (from harvester) | All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel AND<br>All shellstock from waters approved by State Shellfish Authority AND<br>All shellstock from a licensed harvester | Shellfish receiving log |
| Histamine | Receiving | Fish are completed surrounded by ice | Histamine fish receiving log |
| *C. botulinum* toxin formation (in finished product) | Hot smoking | Internal fish temperature held at or above 145°F for at least 30 minutes | Smokehouse temperature recording log |
| Pathogen growth | Cooler storage | Cooler temperature not to exceed 40°F | Cooler temperature |

# Example Monitoring Records …

Pages 163-165

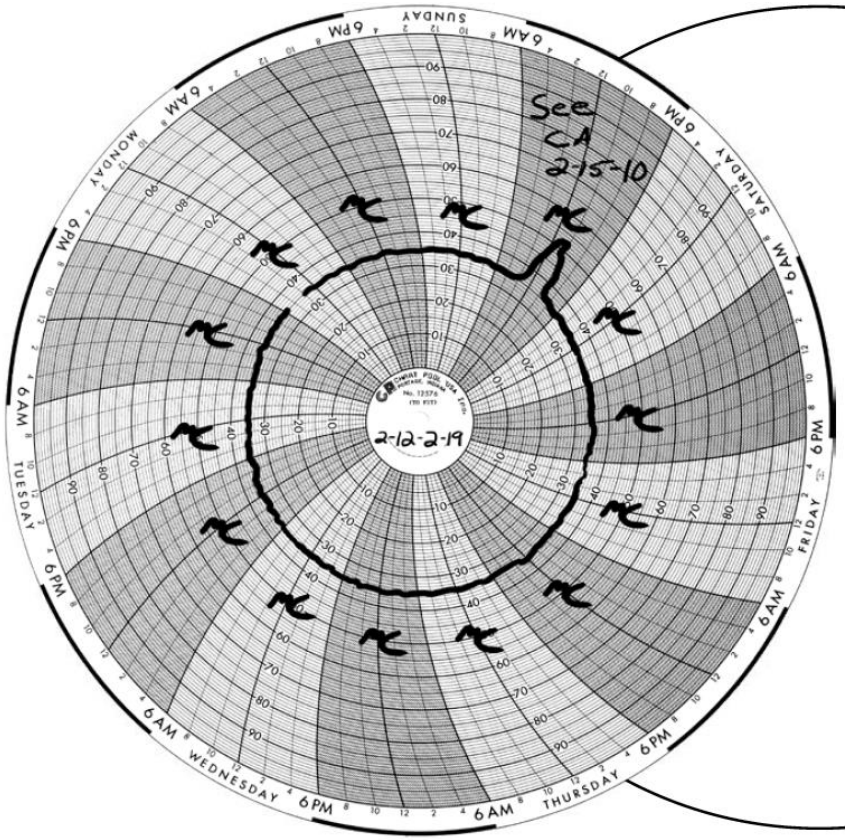
Slide 8

**Daily Cooker Tempe**

| | |
|---|---|
| **Form Title:** Daily Cooker | |
| **Firm Name:** | |
| **Product Identification:** | |
| **Critical Limits:** ≥ 212°F f | |
| **Date** | |
| | |
| | |
| | |
| | |
| | |
| **Reviewer Signature:** | |

Slide 9

**Continuous Temperature Record with Periodic Monitoring.**




XYZ Seafood Company
238 Coastal Lane
Happy Beach, XX
Temperature Chart
(cooler #1)
2/12 - 2/19/11
Reviewed By:_____
Review Date:_____

238 Coastal Lane, Happy Beach, CA

tivities:

| d | Label Type (description) | Line Operator (Initials) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

:

Slide 11

3) Corrective action records

# Information for CA records

… Pages 165-166

Slide 12

**Corrective Action Report (Corrective Action Record)**

| | | | |
|---|---|---|---|
| **Form Title:** Corrective Action Report Form | | | |
| **Firm Name:** | | **Firm Location:** | |
| **Product Description:** | | | |
| **Date:** | **Line Number:** | **Lot Number:** | **Code Number:** |
| Date and time of process deviation: | | | |
| Describe the process deviation and what happened to the product? | | | |
| What action(s) was taken to restore order to the process? | | | |
| Name and signature of person reporting deviation and responsible for taking the correction action: | | | |
| Amount of product affected by the process deviation: | | | |
| Evaluation of product involved by the process deviation: | | | |
| Final disposition of the affected product: | | | |
| **Reviewer Signature:** | | **Date of Review:** | |

## Slide 13

4) Verification records

## Slide 14

Verification records document the results of

- Accuracy and checks and calibration of process-monitoring instruments
- Record Reviews
- Laboratory test results
- In-plant studies or challenge test
- Audits and inspections

# Additional Record Examples …

Pages 168-171

Slide 15

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

| | |
|---|---|
| **Form Title:** Daily Thermometer Accura | |
| **Firm Name:** | |
| **Product Identification:** | |
| **Verification:** | |
| **Date** | **Time** |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| **Reviewer Signature:** | |

Slide 21

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

| Annual HACCP Plan Verification Checklist | Date Task Completed: | Signature of Person who Completed the Task |
|---|---|---|
| List of HACCP Team with Individual Responsibilities Updated. | | |
| List of Seafood Products and Processes in Place at Facility. | | |
| Product Flow Diagrams Updated | | |
| Hazard Analysis Updated | | |
| HACCP Plan Updated | | |
| Good Manufacturing Practice Plan Updated | | |
| Sanitation Standard Operating Practices Plan Updated | | |
| HACCP Plan Implemented | | |
| **Reviewer Signature:** | **Date of Annual Review:** | |

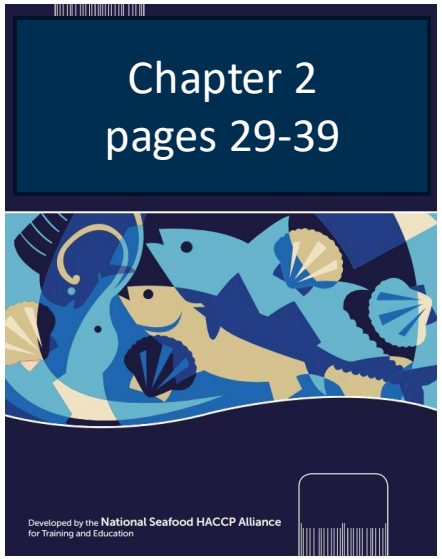
# Do Not Forget Records for required SCP monitoring

Form 2

Monthly Sanitation Control Record

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

**Remember SCP records for the 8 Key Sanitation Conditions**



# Do Not Forget Employee Training Records in GMP's 117

Page 173

Slide 22

Example of Training Report (Pre-requisite Document)

| Employee Training Record | | | |
|---|---|---|---|
| **Employee:** *Anybody Jones* | | **Position/Duty:** Processing belt for shrimp cooker | |
| **Firm Name:** *XYZ Seafood Company* | | **Firm Location:** *238 Coastal Lane, Happy Beach, XX* | |
| **COURSES** | **LOCATION** | **DATE COMPLETED** | **SIGNED** |
| Basic Sanitation Course (Seafood HACCP Alliance) | Headquarters | Nov 01, 2015 | *Ben Smith* |
| GMP's 117 | Plant Unit 3 | Jan 15, 2017 | *BS* |
| SCP Monitoring | Plant Unit 3 | Jan 15, 2017 | *BS* |
| Basic Sanitation Review | Headquarters | Feb 01, 2017 | *S Otwell* |

| Group Employee Training Record | |
|---|---|
| **Firm Name:** *XYZ Seafood Company* | **Firm Location:** *238 Coastal Lane, Happy Beach, XX* |
| **Course:** Personnel Hygiene and Food Safety Level 1 | **Location:** *Headquarters* |
| **DATE COMPLETED**: April 15, 2017 | **SIGNED** *Ben Smith, Supv. No. 1* |
| **EMPLOYEES** | |
| *Nancy Dolittle – Packing and Labeling* | |
| *Anyone Jones – Shrimp cooker belt* | |
| *Wei Not – Recv Dock* | |
| *Bettie Done – Thawing* | |

**Slide 23**

Electronic or computerized monitoring records must be equivalent to paper records and and written signature

# Computer Recordkeeping allowed… IF

**Slide 24**

An effective electronic record-keeping system must:

- Be authentic, accurate and protected;
- Provide accurate and complete copies of records;
- Protect records for later retrieval;
- Limit Access to authorized individuals;
- Provide a secure record audit train ; and
- Be reviewed by HACCP trained individual.

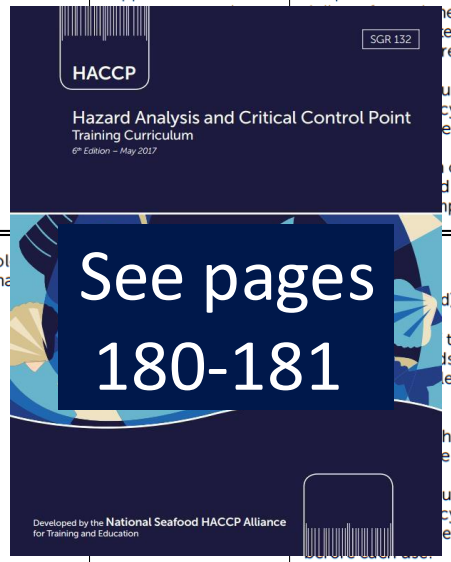
# Records for XYZ Seafood Company

Slide 31

HACCP plan form for XYZ Seafood Company completed through corrective action

**Firm Name:** *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets at delivery | Visual check of adequacy of ice in a representative number of containers in each delivery | Every Delivery | Receiving Manager | **If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their | Weekly review of Receiving Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at | 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.<br>Corrective Action records<br>Verification Record<br>• Accuracy Check Log<br>• Calibration Log |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | At the beginning and end of the work day | Cool Mana | | Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice.<br>Corrective Action records<br>Verification Records<br>• Accuracy Check Record<br>• Annual Calibration Log |




See pages 180-181

# Records for XYZ Seafood Company

Slide 31

HACCP plan form for XYZ Seafood Company completed through corrective action

**Firm Name:** *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Receiving | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets at delivery | Visual check of adequacy of ice in a representative number of containers in each delivery | Every Delivery | Receiving Manager | **If:** the amount of ice is not adequate; **Then:** reject product, and | Weekly review of Receiving Log (Monitoring record) | Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice.<br>Corrective Action records<br>Verification Record<br>• Accuracy Check Log<br>• Calibration Log |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | At the beginning and end of the work day | Cooler Manager | and add ice and make adjustments to the ice application process. | quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice.<br>Corrective Action records<br>Verification Records<br>• Accuracy Check Record<br>• Annual Calibration Log |

# Records for XYZ Seafood Company

Slide 31 (cont.)

| Critical Control Point (CCP) | Significant Hazard(s) | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| Finished Product Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of representative number of containers in cooler storage | At the beginning and end of the work day | Cooler Manager | **If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total | Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable | 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.<br>Corrective Action records<br>Verification Records<br>• Accuracy Check Record<br>• Annual Calibration Log |


| | |
|---|---|
| **Firm Name:** XYZ Seafood Company | **Product:** Fresh/F |
| **Firm Address:** 238 Coastal Lane, Happy Beach, XX | **Method of Stora** ice<br>**Intended Use an** neral public |
| Signature:_____<br>Print name:_____ | Date:_____ |

# SPECIAL NOTE

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

XYZ Seafood Company

Pages 184-187

Blank forms are in Appendix 2

Slide 32

**HACCP Plan Form**

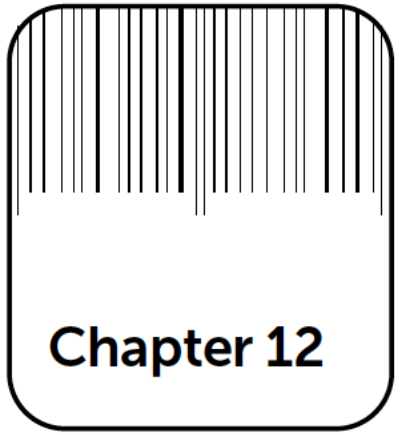
| | | |
|---|---|---|
| **Firm Name: XYZ Seafood Company** | | **Product: Fresh/Raw Mahi-Mahi Fillets** |
| **Firm Address: 238 Coastal Lane, Happy Beach XX** | | **Method of Storage & Distribution: Stored and distributed buried in ice** |
| | | **Intended Use and Consumer: To be cooked and consumed by the general public** |
| **Critical Control Point (CCP)** | | **CCP 1: Receiving** |
| Significant Hazard(s) | | Histamine |
| Critical Limits for each Control Measure | | Tubs or container of Mahi-mahi fillets are completely surrounded with ice at receipt. |
| Monitoring | What | Adequacy of ice surrounding tubs or container of mahi-mahi fillets at delivery |
| | How | Visual check of adequacy of ice in a representative number of containers in each delivery |
| | When | Every Delivery |
| | Who | Receiving Manager |
| Corrective Action | | **If:** the amount of ice is not adequate; **Then:** reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected. |
| Verification | | Weekly review of Receiving Log (Monitoring record) and Corrective Action and Verification records. Review of the Verification records within a reasonable time frame.<br>Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature<br>Check the accuracy of the thermometer before each use.<br>Annual calibration of thermometer used to check internal temp. |
| Records | | Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice.<br>Corrective Action records<br>Verification Records<br>• Accuracy Check Log<br>• Calibration Log |
| Signature: *John Doe* | | Date: *2/29/20* |

Page _ of _

# End Chapter11: Principle 7

## Record-Keeping

# The Seafood HACCP Regulation



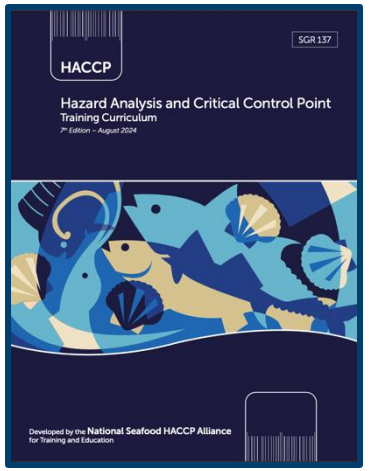

**Slide 1**

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
- **Addendum 1**

Tip

Stay aware for periodic additions and updates

# Regulation Outlined in Parts

Slide 2

Regulation Format

Subpart A — General provision

- 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 control

Subpart C — Raw molluscan shellfish

- 123.20 General
- 123.28 Source controls

# Key Definition 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**

Ongoing verification:

- Review of consumer complaints
- Calibration of process-monitoring instruments
- Periodic end-product and in-process testing (processor’s option)

# Who must comply?

Slide 6

Products that are subject to regulation:

- Importer 123.3 (g)
- Processor 123.3 (k) — domestic and foreign

# Define Processing

**Slide 7**

What constitutes processing:

- Processing 123.1(l)

# Regulation does not apply to:

Slide 8

This Regulation doe 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

Slide 9

Current Good Manufacturing Practices:

- Regulations found in Title 21, Part 117 of the Code of Federal Regulations
- Proper practices for the safe and sanitary handling of all foods


## Copy of the current GMP's Part 117

Appendix 3, Page 233

# Determine hazards likely to occur…

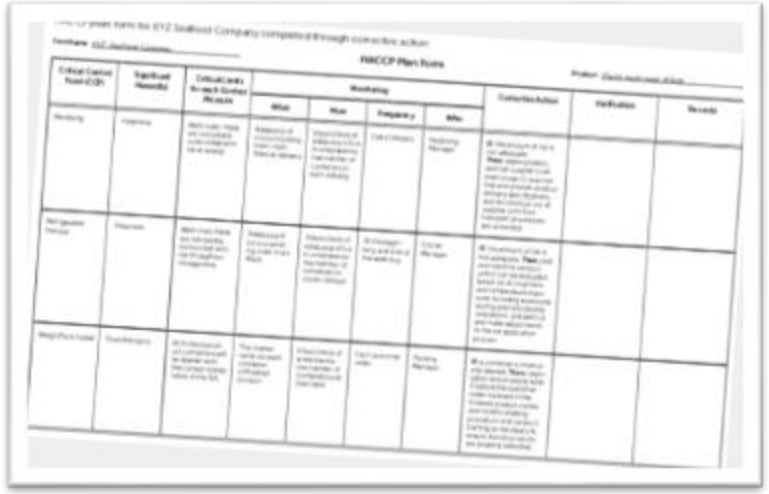
**Slide 10**

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.”

# Witten 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 …

**Slide 13**

The HACCP plan shall list:

- the food-safety hazards that are reasonably likely to occur.
- the CCPs.
- the critical limits.
- the monitoring procedures.
- predetermined corrective action plans.*
- the verification measures.
- records that will be maintained

# HACCP plans ‘shall’ be signed and dated …

Slide 14

The HACCP plan shall be signed and dated

- By the most responsible individual at the processing facility or a higher level official.

-Signed and dated:

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

*This is a verification

# Special considerations for seafood canning operations

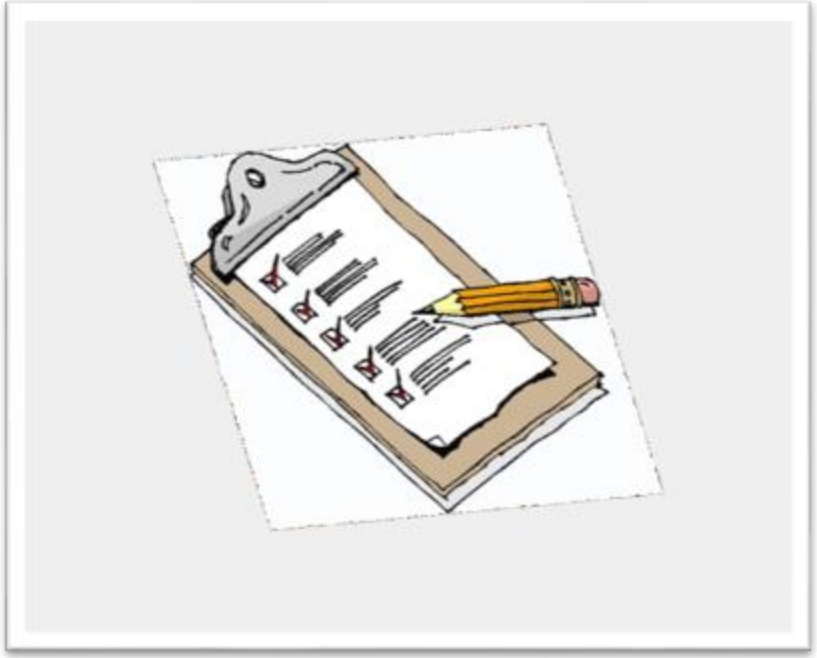
Slide 15

Processors of acidified or low acid canned foods do not need to include controls for C. botulinum in their HACCP plan.

# Sanitation or HACCP Controls?

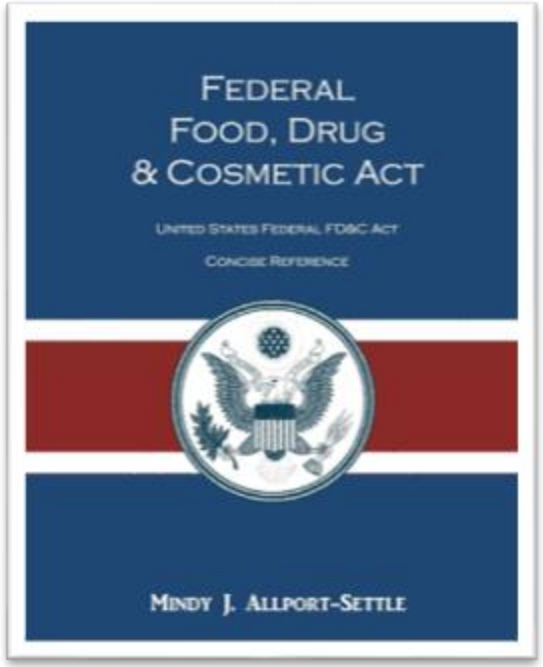
Slide 16

Sanitation controls may be difficult to manage in a HACCP plan.



## Slide 17

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:

3)Predetermined
4)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)

# 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

# Required record…

Slide 23

Records required by the regulation:

- HACCP plan(s)
- Monitoring records
- Corrective action records
- Verification records
- Sanitation control records
- Importer verification records

# 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.

# 8 Key Sanitation Control Areas

Slide 28

Eight key sanitation areas:

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

# HACCP with Imported Seafood

Seafood HACCP Alliance

**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

# HACCP with Imported Seafood

Slide 31

Affirmative steps may include any of the following:

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

# HACCP with Smoked Seafood

Slide 32

Smoked and Smoke-Flavored Fishery Products

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

# HACCP with Imported Seafood

Slide 32

Smoked and Smoke-Flavored Fishery Products

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

# HACCP with Raw Molluscan Shellfish

Slide 33

Raw Molluscan Shellfish 123.20

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

# 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**

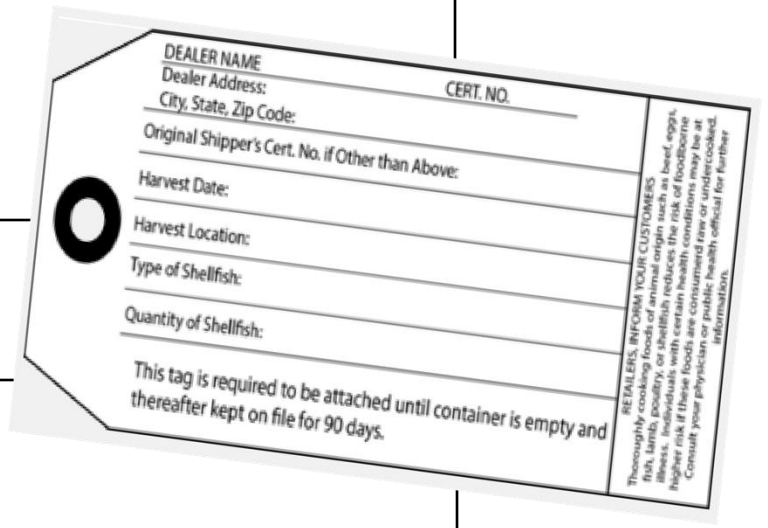
Raw Molluscan Shellfish 123.28
Shellstock Receiving:

- 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.

## Slide 36

Raw Molluscan Shellfish 1240.60 (b)
Required information on tag:

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




## Slide 37

Raw Molluscan Shellfish 123.28
Records for shellstock receiving must document:
Date of harvest

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

## Slide 38

Raw Molluscan Shellfish 123.28
Shucked molluscan shellfish containers must bear a label that contains:

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

## Slide 39

Raw Molluscan Shellfish 1240.60 (c)
Records for shucked product must document:

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

# Resources for Preparing Seafood HACCP Plans

Resources are available through FL Sea Grant Website:

https://www.flseagrant.org/wp-content/uploads/2024/10/Seafood-and-HACCP-Resources-For-Insturctors_Updated-9-2024-2.pdf

# Course Closeout

- Certificates are sent via email within two weeks of AFDO receiving course closeout paperwork.
- Make sure you can receive emails from haccp@afdo.org.
- If certificate is not received, first check your junk folder, then contact your instructor.
- Confirm certificate information is accurate upon receipt.


**NOTE:** there is a $15 fee to have certificates re-issued or revised more than 3 months after it was issued.

# Training Evaluation

Complete your training evaluation online using the url or QR code below.

**bit.ly/SHAEvaluation**

Contact Dr. Razieh Farzad with any questions or comments about these slides.

Email:rfarzad@ufl.edu
Phone number: (352)-2945-3902