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:

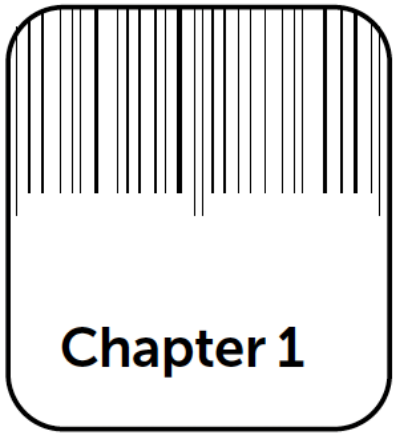
Hazard Analysis and Critical Control Point Training Curriculum *(SGR 137; Blue Book) 7th edition August 2024*

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

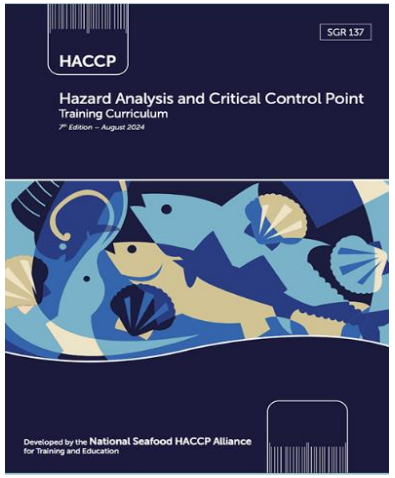
Slide 5

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



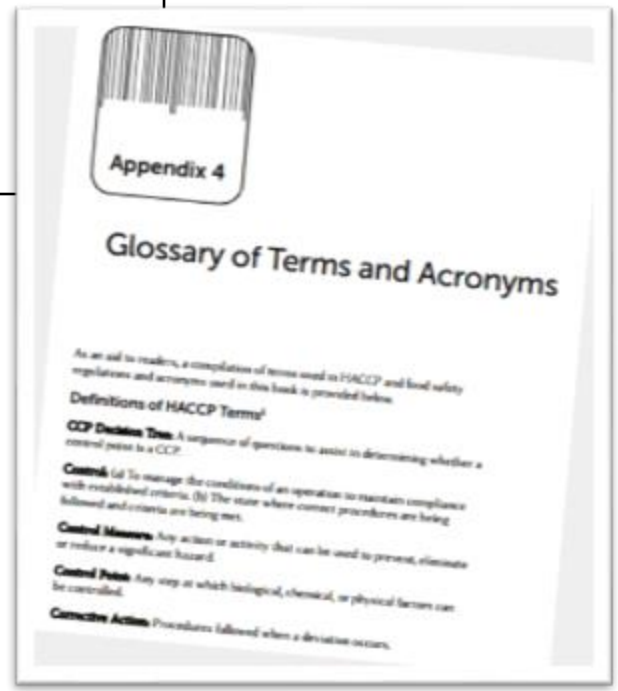
BLUE Book

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

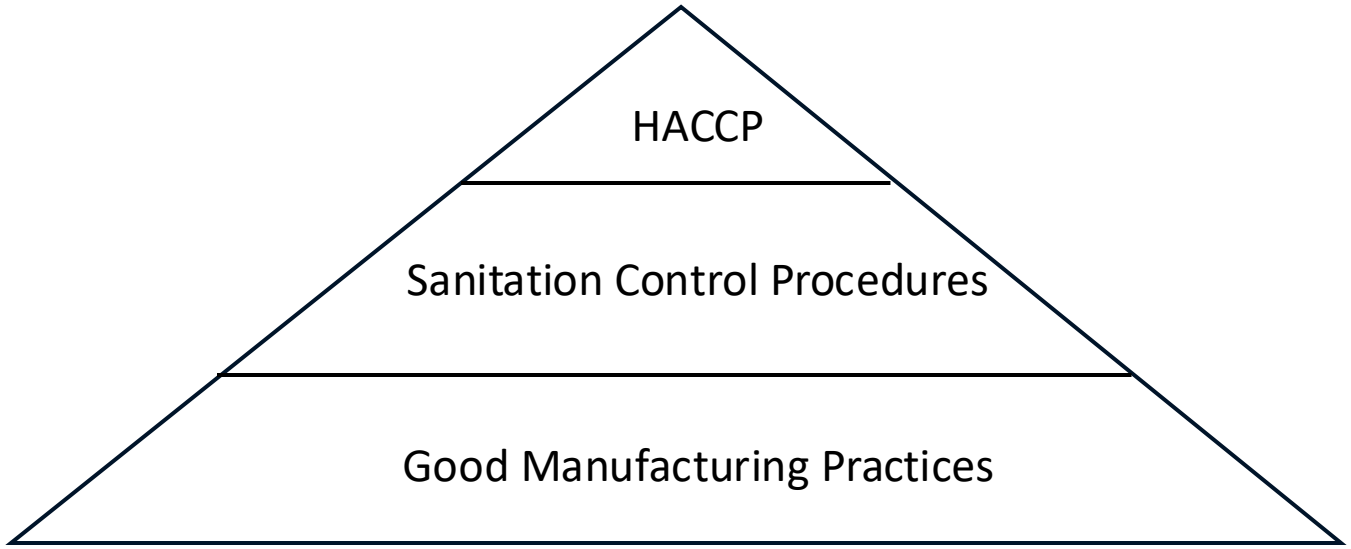
Seven principles of HACCP:

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

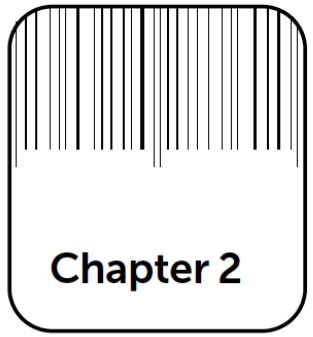
Layers of Controls

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

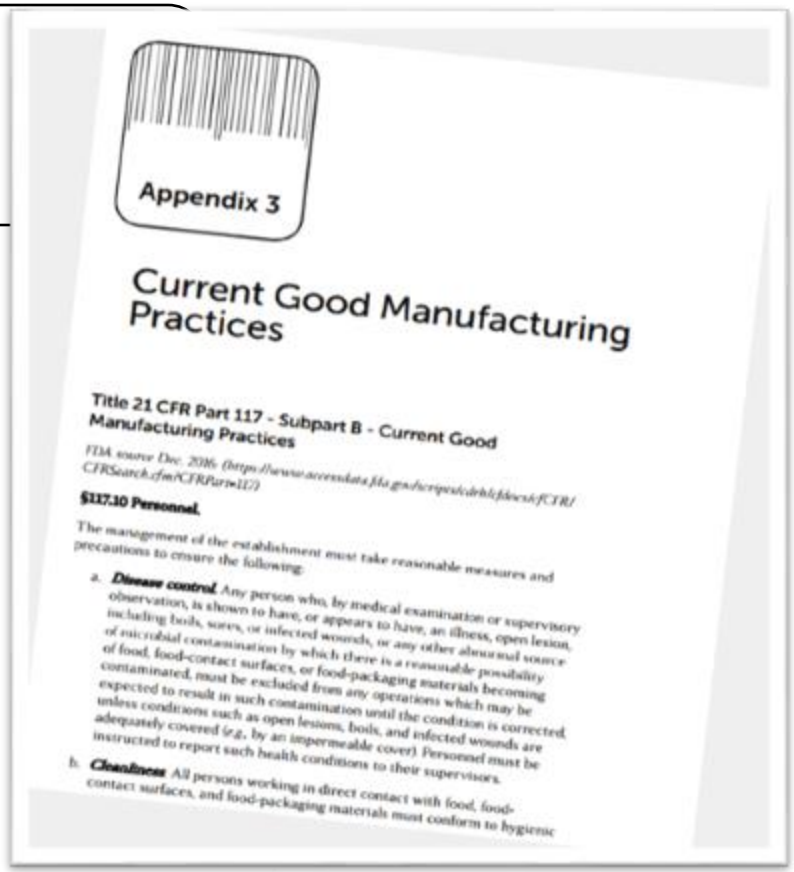
Good Manufacturing Practices (21 CFR Part 117 Subpart B)

- 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

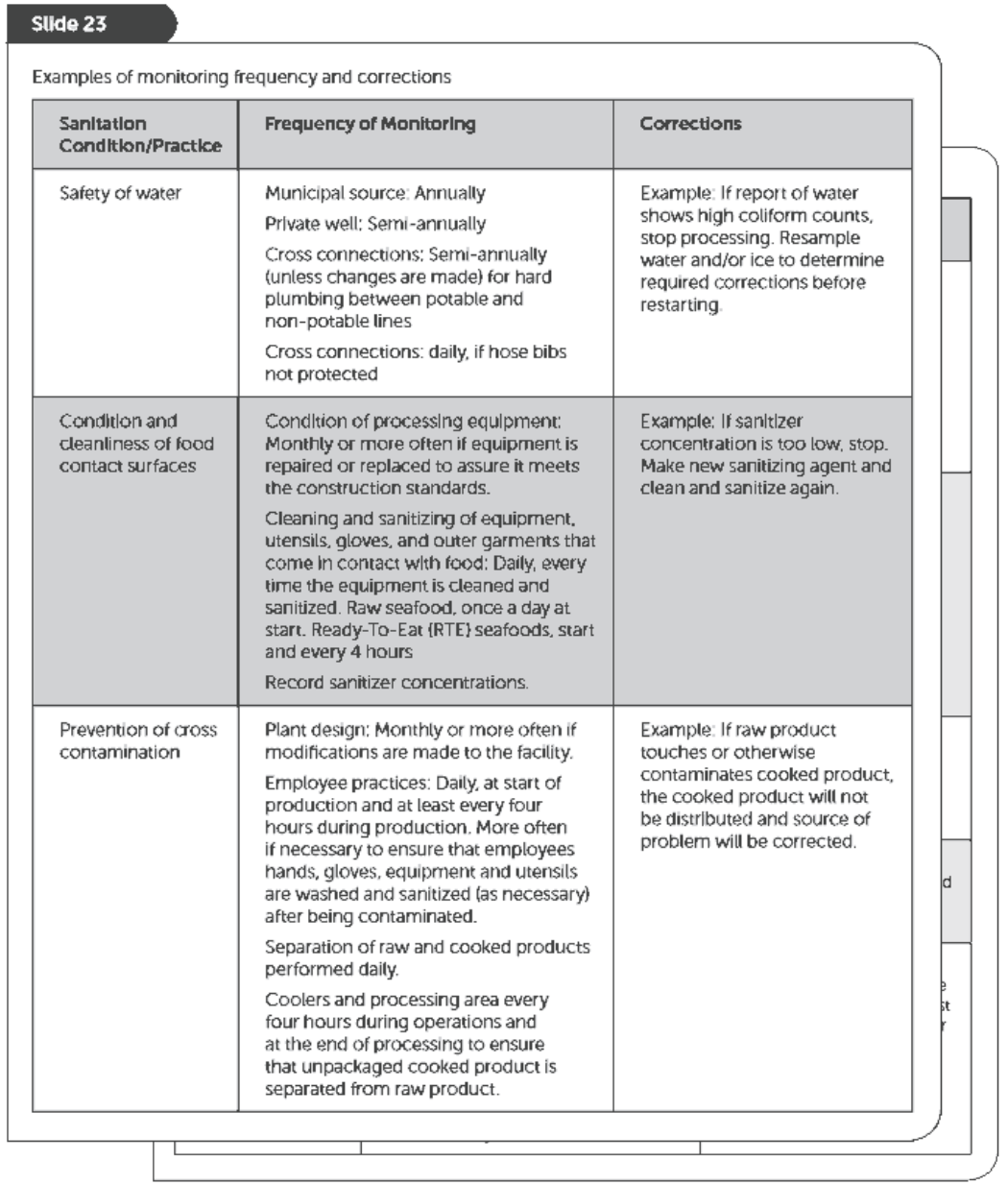
Table 1

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

Monitoring SCPs

Pages 24-25



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Examples of monitoring frequency and corrections

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

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) Line 2: Ready-to-eat					Firm Address:	
Sanitation Area and Goal	Pre-Op Time	Start Time	4 Hour Time	8 Hour Time	Post-Op Time	Comments and Corrections
1) Safety of water (See Monthly Sanitation Control Record) • Back Siphonage – Hose (S/U)*						
2) Condition and cleanliness of food contact surfaces (See Monthly Sanitation Control Record) • Equipment cleaned and sanitized						
Line 1: (S/U)						
Line 2: (S/U)						
• Sanitizer Strength Sanitizer Type _____ Strength _____ ppm						
Line 1: (ppm)						
Line 2: (ppm)						
• Allergen cross-contact controls performed during each production changeover (S/U)						
• Gloves and aprons clean and in good repair						
Line 1: (S/U)						
Line 2: (S/U)						
*S = Satisfactory / U = Unsatisfactory						

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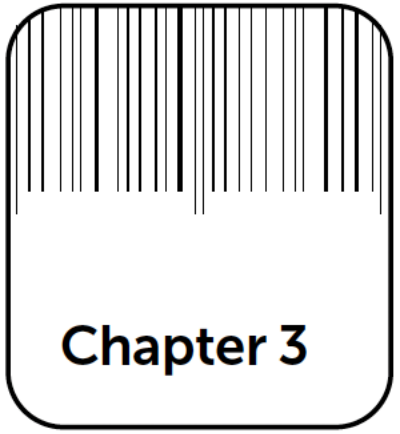
Seafood Safety Hazards



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:

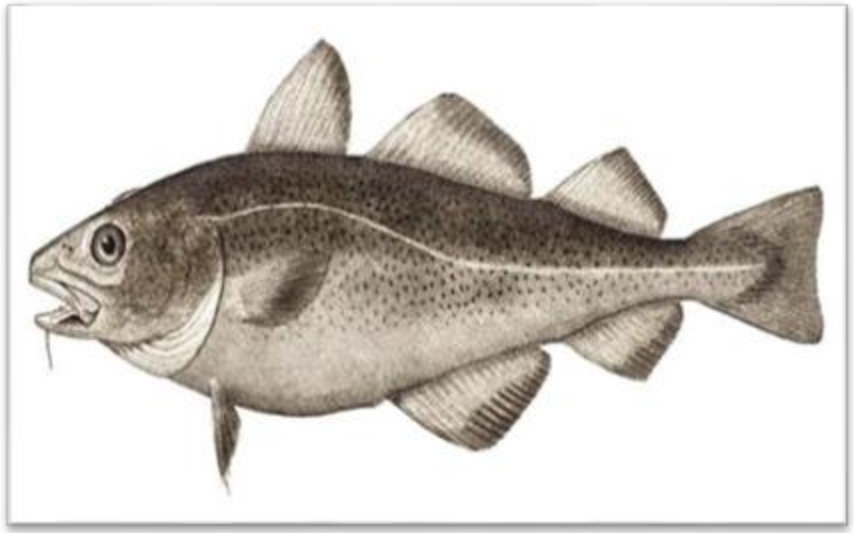
- Insects
- Hair
- Filth
- Spoilage
- Economic Fraud
- Violations of regulatory food safety standards not directly related to safety

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

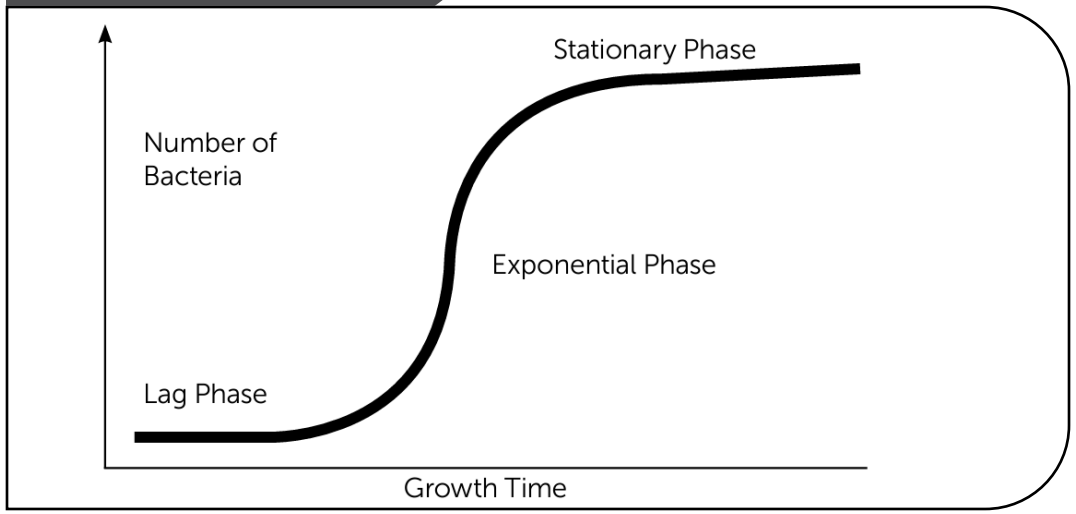
Slide 7

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

Pathogens of Concern for Seafood Products:

- Sporeforming bacteria
  - *Clostridium botulinum*
  - *Bacillus cereus*
  - *Clostridium perfringens*
- Non-Sporeforming bacteria
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  - Others (*Campylobacter jejuni*, *Yersina enterocolitica*, *Shigella* spp. and *Escherichia coli*)

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:

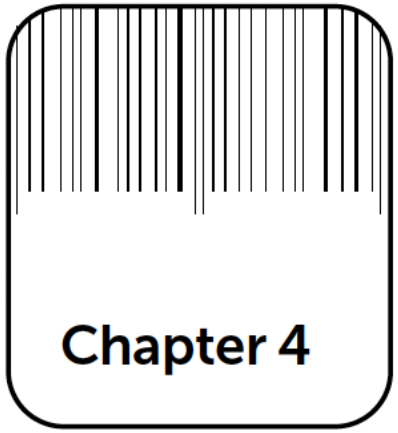
- Examination of glass containers for breakage

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

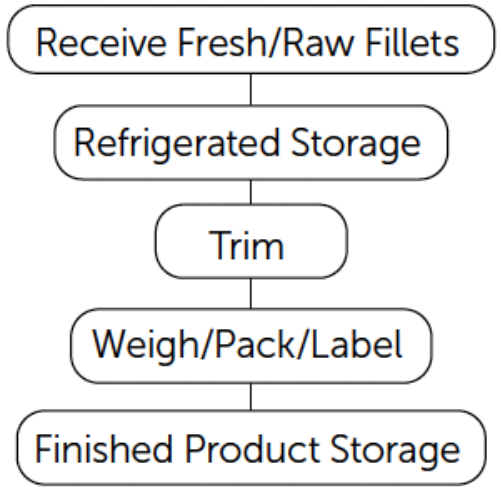
Acceptable Market Name & Species	Where Product Is Purchased (Source)			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/ Dealer	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	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

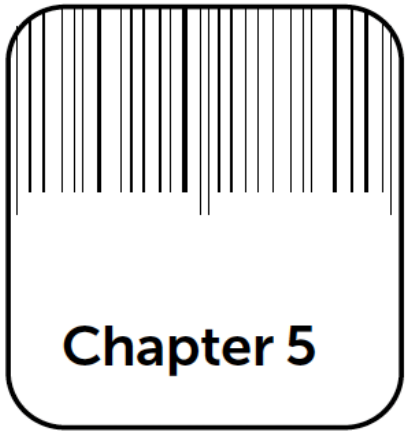
Slide7

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

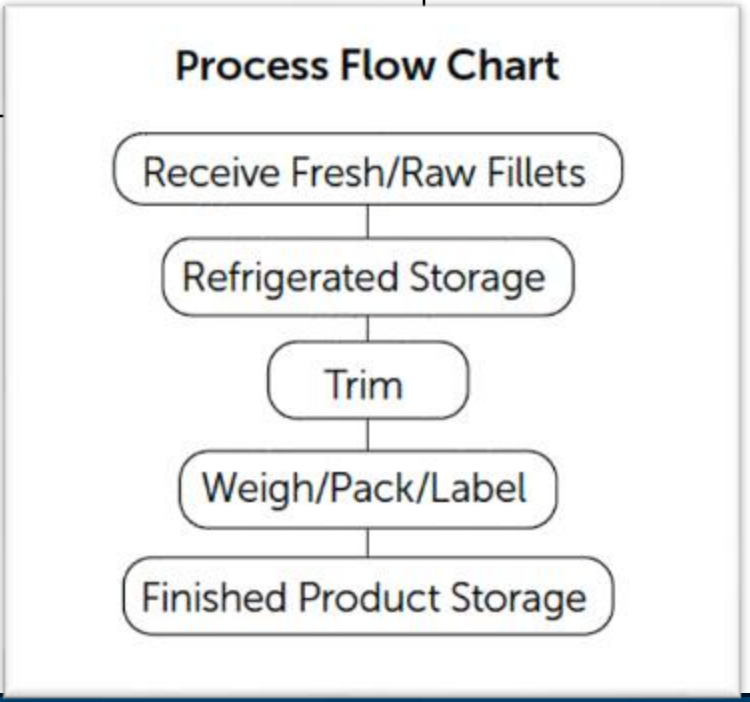
Step 1: Enter each of the processing steps from the process flow chart in Column 1 of the hazard analysis worksheet. Each step will have its own block on the worksheet and should be listed in the same order as on the process flow chart.

"Fresh Mahi-mahi Fillets"

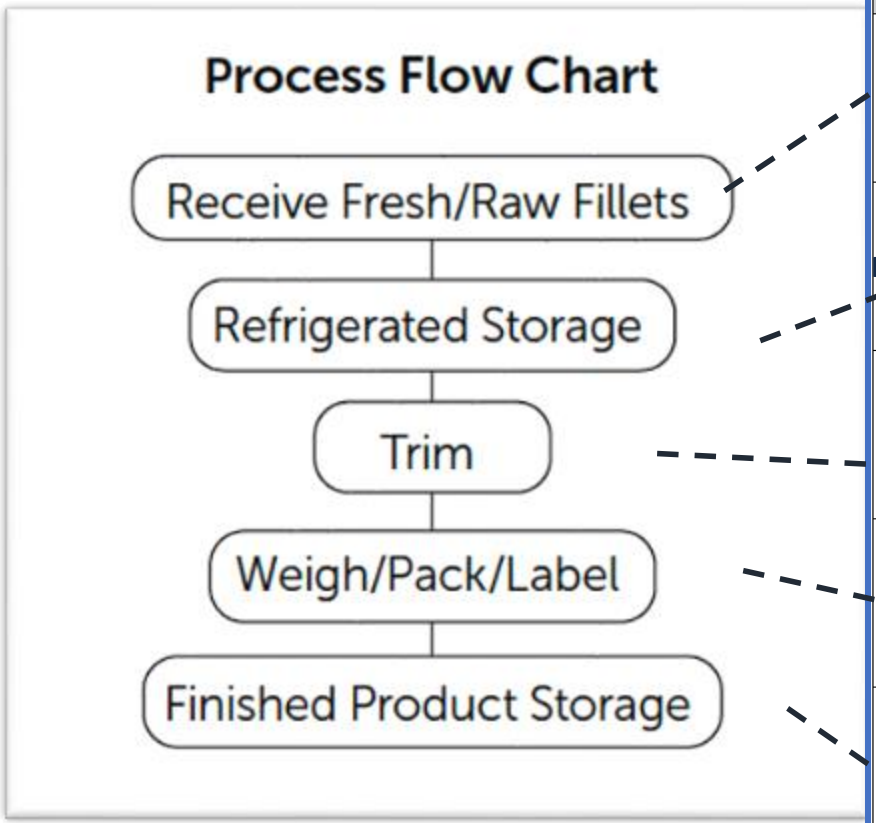
Processing Steps

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

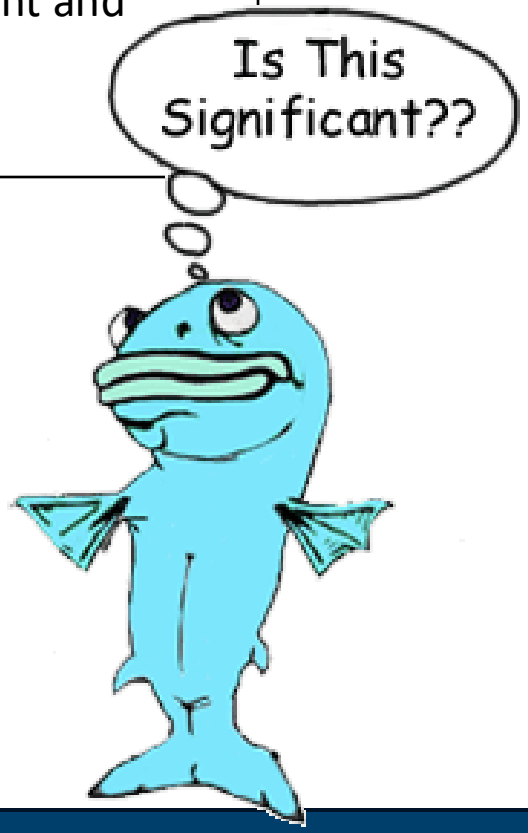
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 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

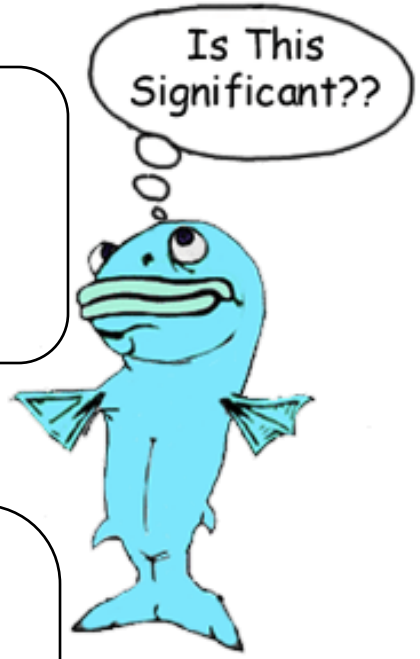
(1) Processing Step	(2) List all potential **food safety hazards** that could be associated with this product and process	(3) Is the potential food safety hazard **significant** (introduced, enhanced, eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) 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		

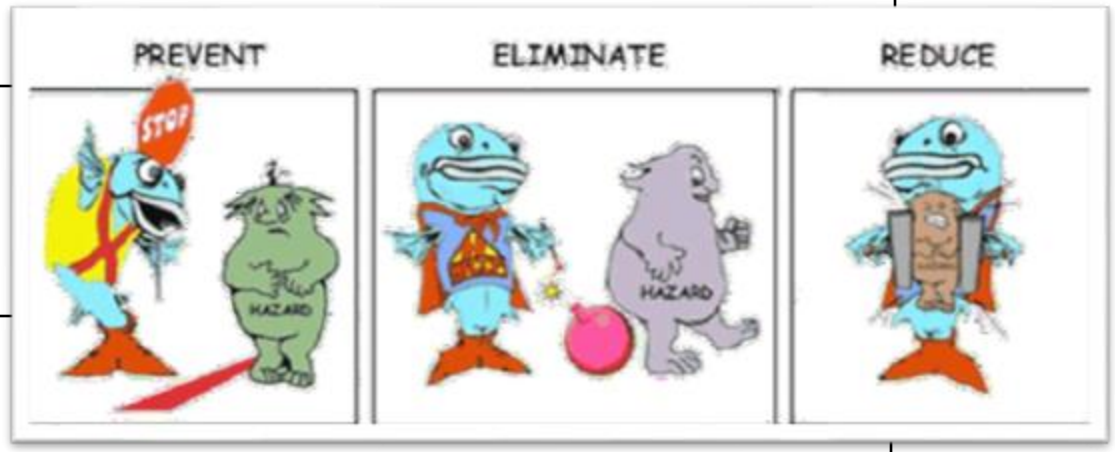
BRIEF SUMMARY based on the FDA Guide that provides more recommended details

Column 2 Potential Hazards (Likely to Occur)	Columns 3 & 4 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 Potential Hazards (Likely to Occur)	Columns 3 & 4 Is the hazard significant in this processing operation		Column 5 Necessary Controls
Histamine	YES	Mahi is potential scombrotoxic fish species subject to temperature abuse	Time and Temperature controls (Chapter 7)
Pathogen Growth -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

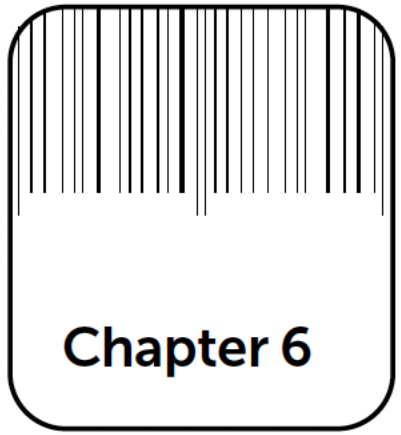
Slide 21

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:

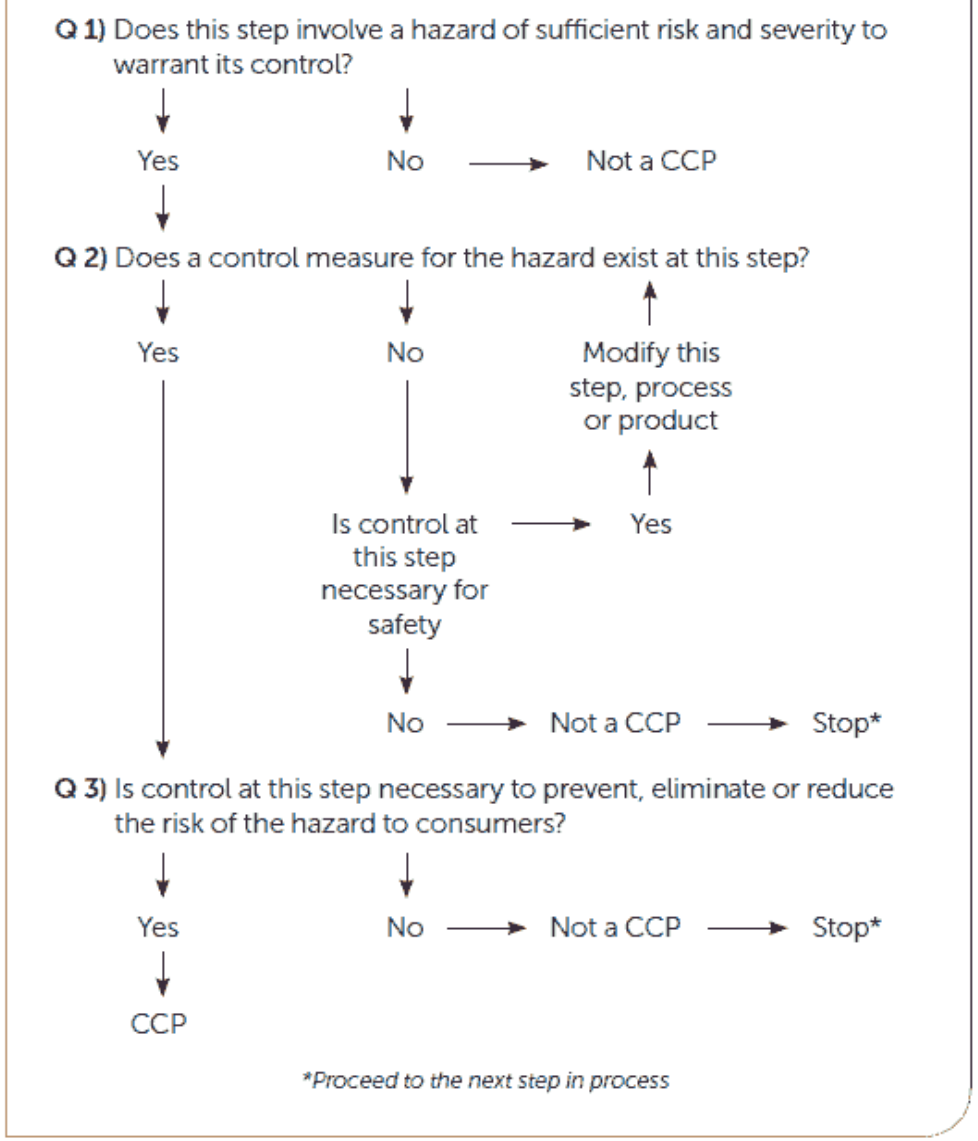
- Layout of the plant or processing line,
- Finished product formulation,
- Process flow or sequence of processing steps,
- Processing equipment,
- Ingredients,
- Sanitation or other support programs.

CCP Decision Tree (optional tool)

Page 103

Slide 9

CCP Decision Tree



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	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

(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

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

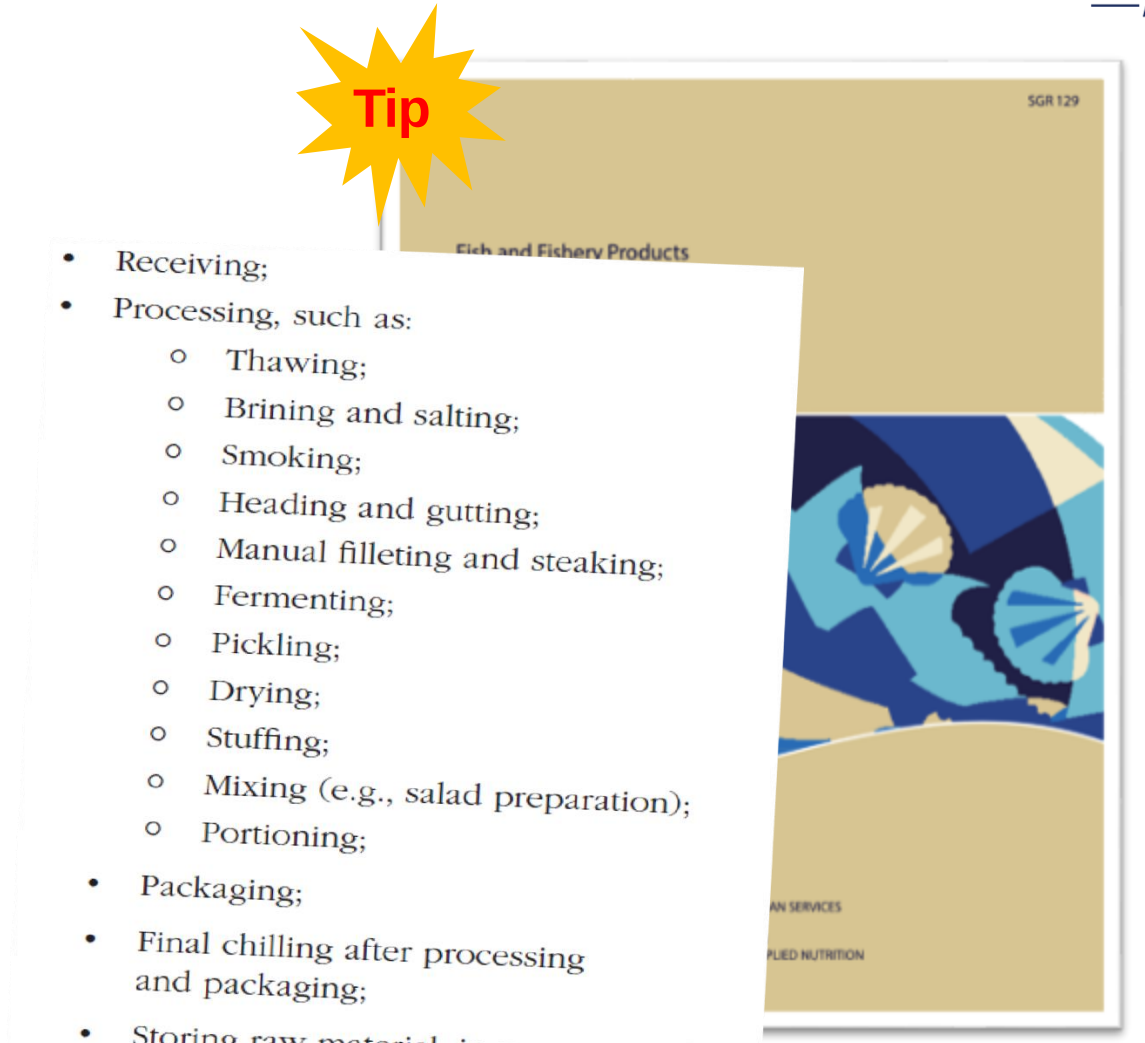
- Undeclared food allergen is a significant food safety hazard and there is one CCP for this hazard:

  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

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

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

Slide 10 (cont.)

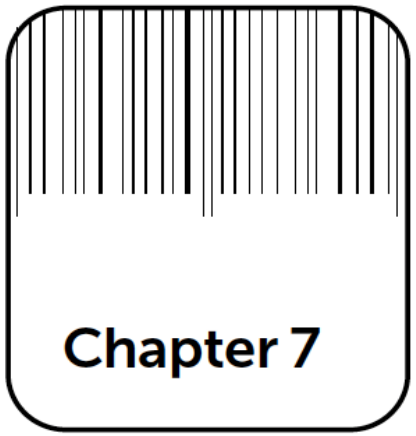
(1) **Processing Steps**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 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)

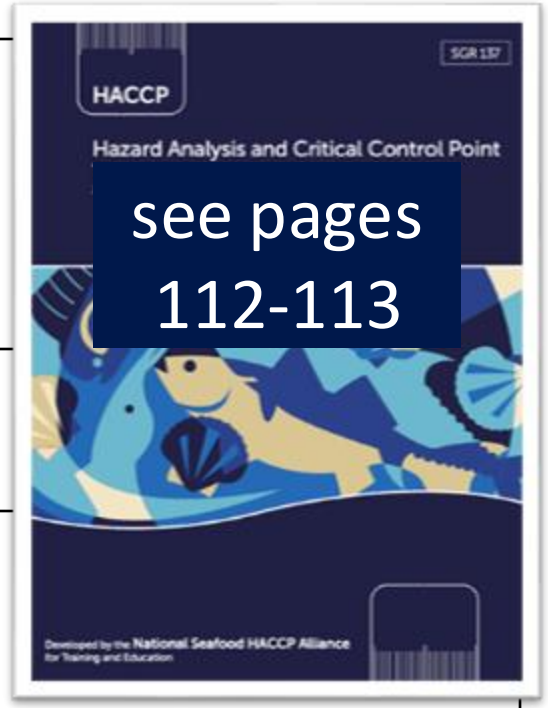
Options and details…

Slide 7

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

Slide 8

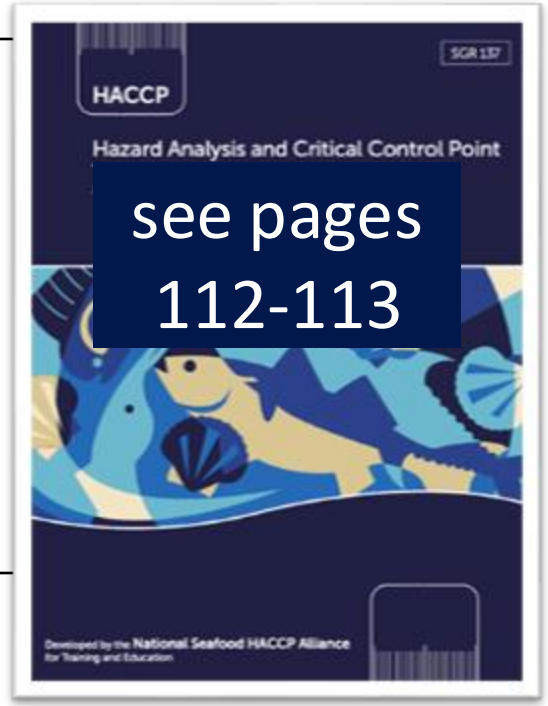
Option No. 2
Product: Fish cakes
Hazard — pathogen survival through cooking
CCP — fryer
Critical limit — minimum internal temperature of 165°F for 36 seconds



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

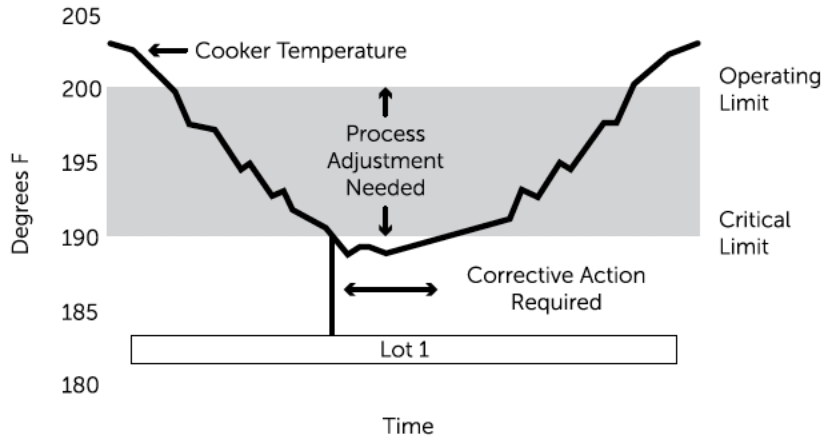
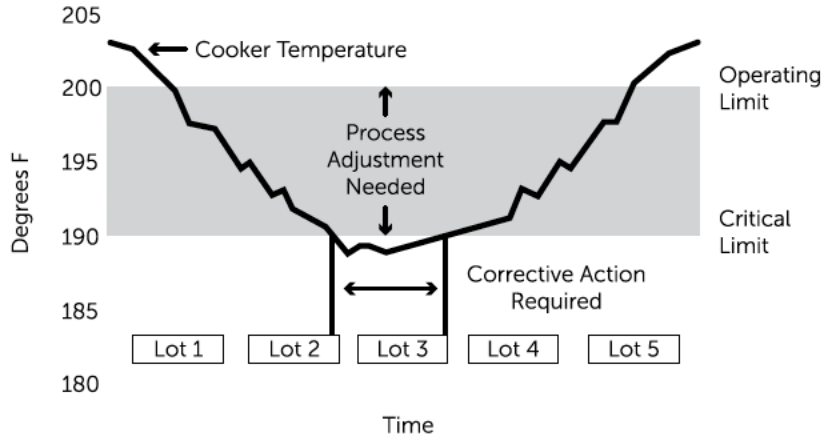


Figure 2



Critical Limits should be specified in the written HACCP Plan

Slide 12

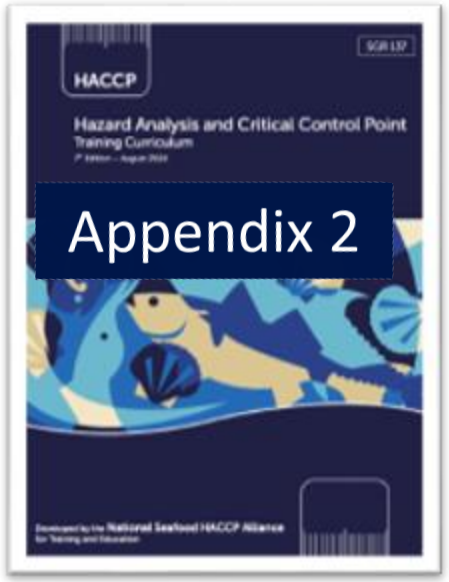
Blank HACCP Form

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)



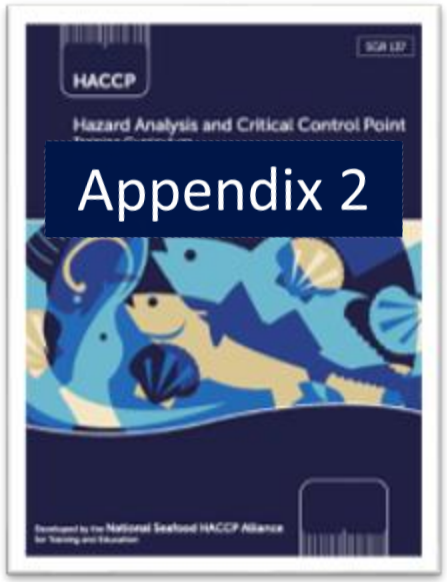
Landscape

Firm Name: Address:							Product Description:		
Signature: (printed name) Date:							Method of Distribution & Storage: 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 Printed: Xxxxxxxxxx		Intended Use: To be cooked and consumed by the general public 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

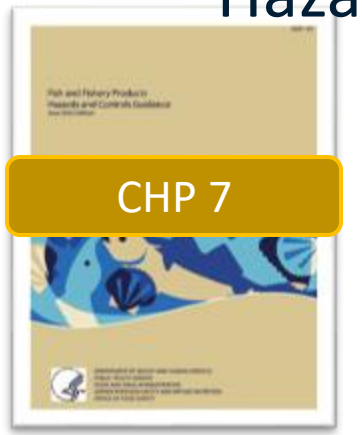
Tip

- 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

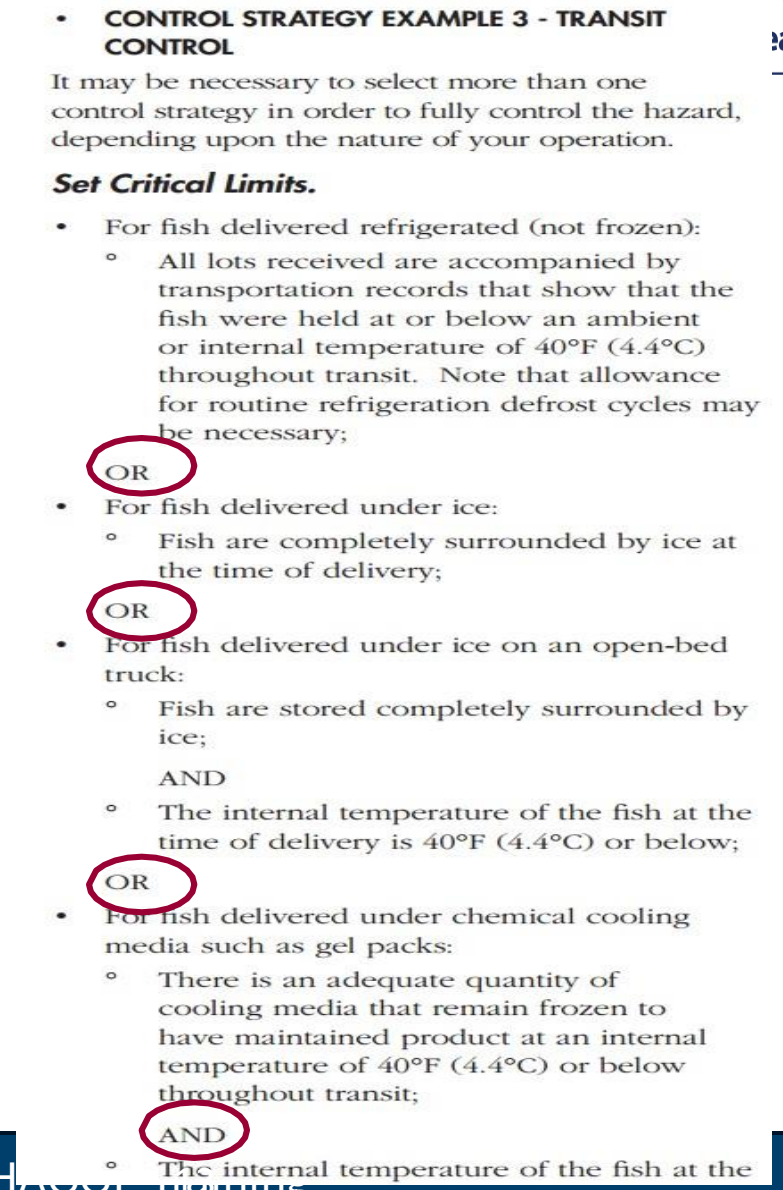
CCP – Receiving
Hazard - Histamine



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;

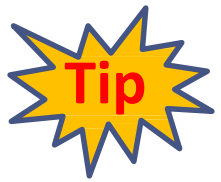
AND

  - 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.							

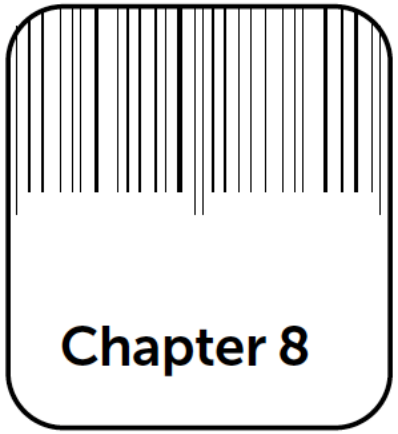
Critical Limits based on recommendations in the FDA Hazards Guide

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

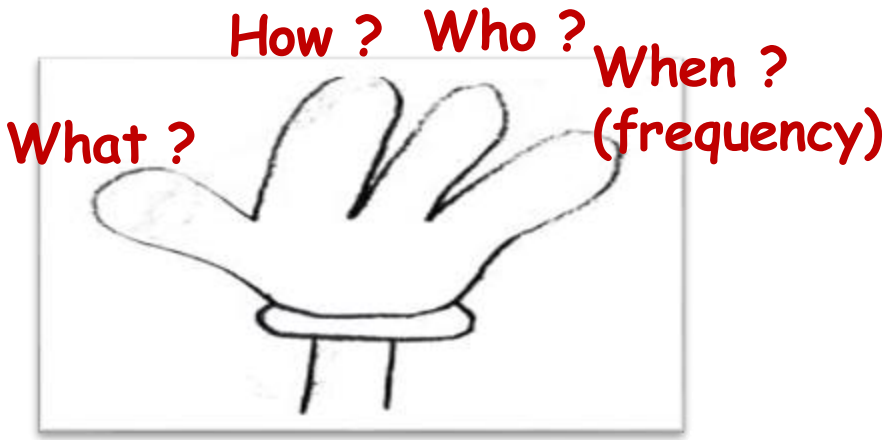
- To ensure that a critical limit is met,
- To provide documentation that critical limits have been met,
- To identify when there is loss of control (a deviation occurs at a CCP).

4 required parts for proper MONITORING

Slide 4

Elements of Monitoring

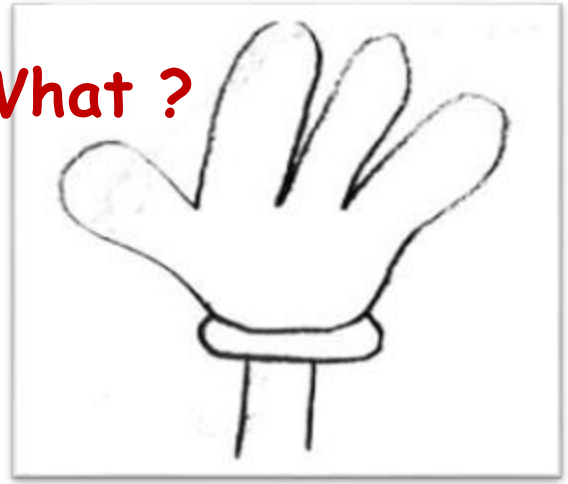
- What will be monitored?
- How will monitoring be performed?
- What is the frequency of monitoring?
- Who will conduct the monitoring?



What?

Slide 5

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

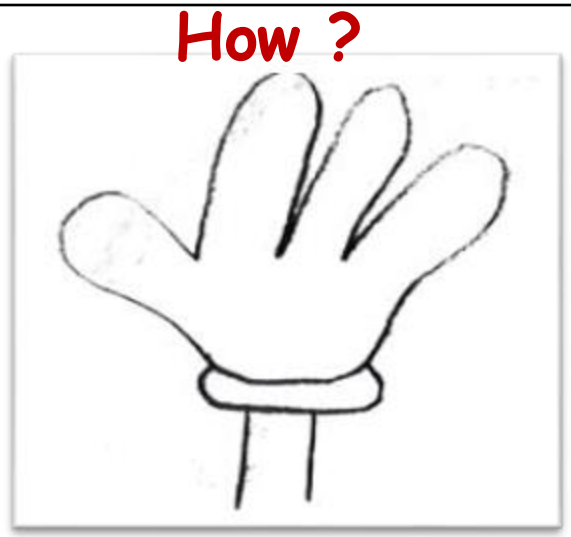


How?

Slide6

How will monitoring be performed?

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

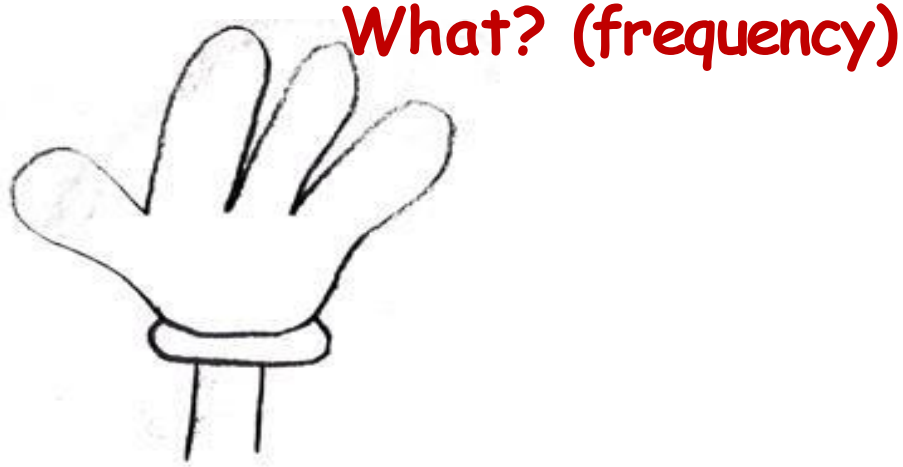


When?(frequency)

Slide 7

What is the frequency of monitoring?

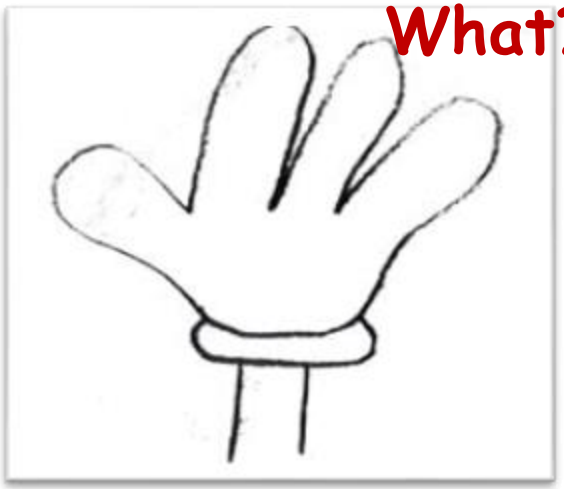
- Monitoring frequency should be sufficient to ensure that the critical limit is met.
- Monitoring frequency can be **non-continuous** or **continuous.**



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

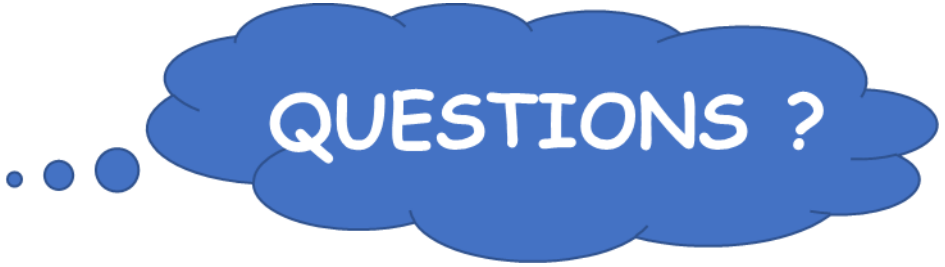
Firm Name: *XYZ Seafood Company* **HACCP Plan Form** **Product:** *Fresh/Raw Mahi-Mahi Fillets*

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			

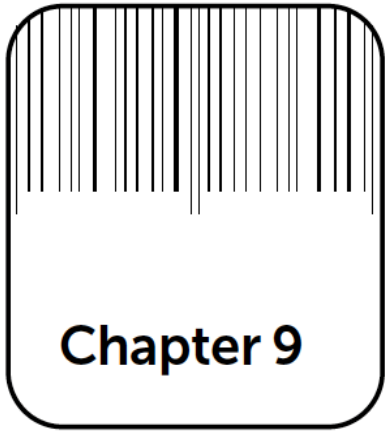
Firm Name: XYZ Seafood Company	**Product:** Fresh/Raw Mahi-Mahi Fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Storage and Distribution:** Stored and distributed buried in ice
	Intended Use and Consumer: To be cooked and consumed by the general public
Signature:_____ Print name:_____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

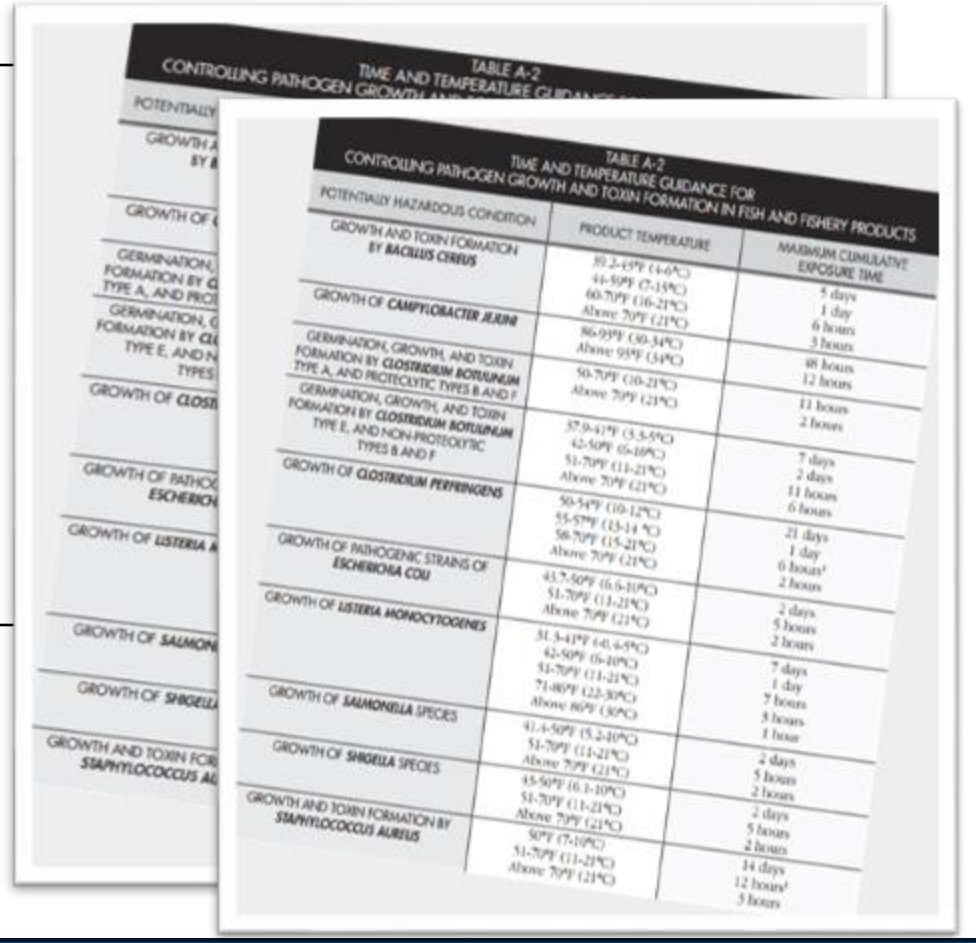


TABLE A-2
TIME AND TEMPERATURE GUIDANCE FOR CONTROLLING PATHOGEN GROWTH AND TOXIN FORMATION IN FISH AND FISHERY PRODUCTS

POTENTIALLY HAZARDOUS CONDITION	PRODUCT TEMPERATURE	MAXIMUM CUMULATIVE EXPOSURE TIME
GROWTH AND TOXIN FORMATION BY *BACILLUS CEREUS*	32-45°F (0-7°C) 46-50°F (7-10°C) 51-70°F (10-21°C) Above 70°F (21°C)	4 days 1 day 6 hours 3 hours
GROWTH OF *CAMPYLOBACTER JEJUNI*	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY *CLOSTRIDIUM BOTULINUM* TYPE A, AND PROTEOLYTIC TYPES B AND F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 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) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
GROWTH OF *CLOSTRIDIUM PERFRINGENS*	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours[1] 2 hours
GROWTH OF PATHOGENIC STRAINS OF *ESCHERICHIA COLI*	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF *LISTERIA MONOCYTOGENES*	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-80°F (22-30°C) Above 80°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
GROWTH OF *SALMONELLA* SPECIES	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF *SHIGELLA* SPECIES	45-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH AND TOXIN FORMATION BY *STAPHYLOCOCCUS AUREUS*	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 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; **Then:** reject lot and discontinue using supplier until appropriate, accurate certificate obtained.
Receiving live oysters from the harvester	Natural toxins	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel and All shellstock from waters approved by State Shellfish Authority and All shellstock from a licensed harvester.	**If:** shellstock tags are missing and/or do not have required information; **Then:** reject shellstock. **If:** harvester not licensed or harvest waters are not approved; **Then:** reject shellstock and discontinue purchasing from harvester until properly licensed.

Slide 11

Corrective action examples for process-related hazards

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

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.)

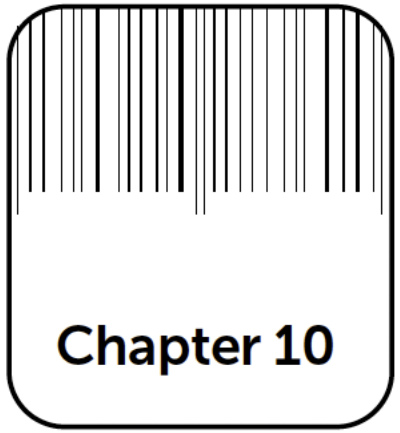
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Weigh/Pack/ Label	Food Allergens	All finished product containers will be labeled with the correct market name of the fish.	The 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 Verifications

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

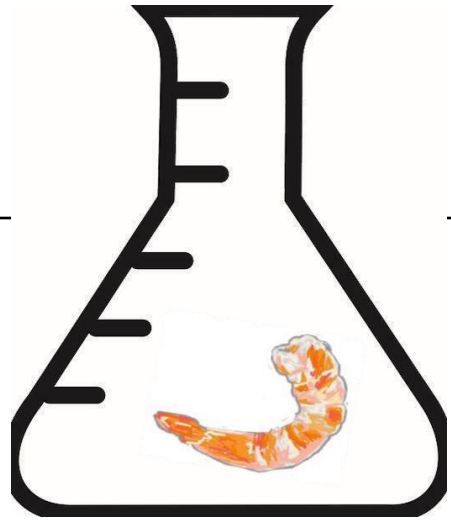
Accuracy checks and calibration records must:

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:

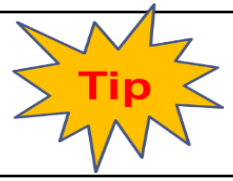
- All monitoring and correction action records
- Records must be reviewed within one week from time they were made by an individual who meets the training requirements of the FDA seafood HACCP regulation.

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.



Requires a signature

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. All records will be reviewed by a HACCP trained person once per week.
Natural toxins	Receiving (from harvester)	All shellstock tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of harvest vessel; and all shellstock from waters approved by State Shellfish Authority; and all shellstock from a licensed harvester.	Review all monitoring and corrective action records once per week.
Histamine	Receiving (from supplier)	Fish are completely surrounded by ice.	Check the accuracy of new thermometers before they are used and daily thereafter and calibrate thermometers once per year; and Check internal temperature of iced fish at receipt before accepting fish from new suppliers and quarterly for existing suppliers to verify adequacy of ice; and All records will be reviewed by a trained person once per week.
C. botulinum toxin formation (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes.	Check the accuracy of the smokehouse temperature sensor before it is used and daily thereafter and calibrate at least once per year; and All records will be reviewed by a trained person once per week.
Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F.	Check the accuracy of the cooler temperature sensor before it is used and daily thereafter and calibrate at least once per year; and All records will be reviewed by a trained person once per week.

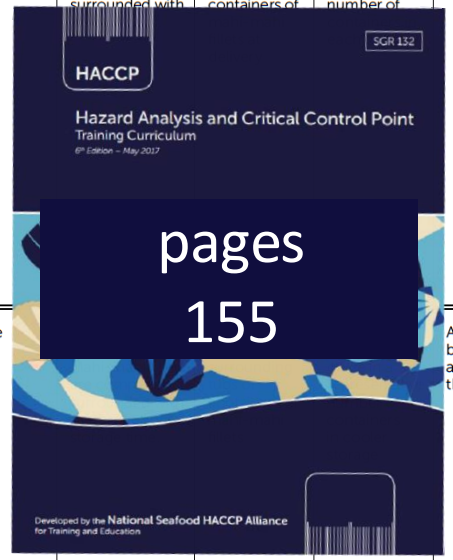
Verifications for XYZ Seafood Company

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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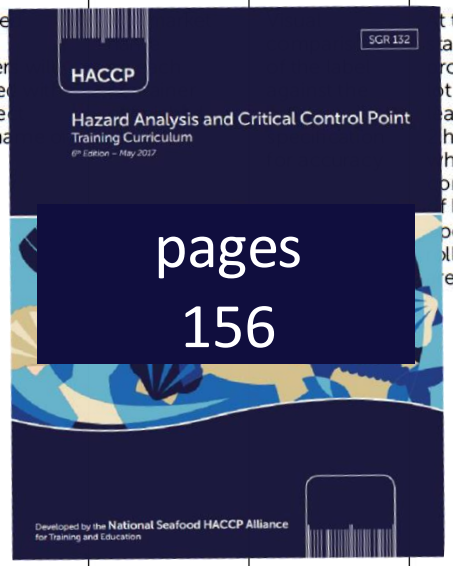
Verifications for XYZ Seafood Company

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.	



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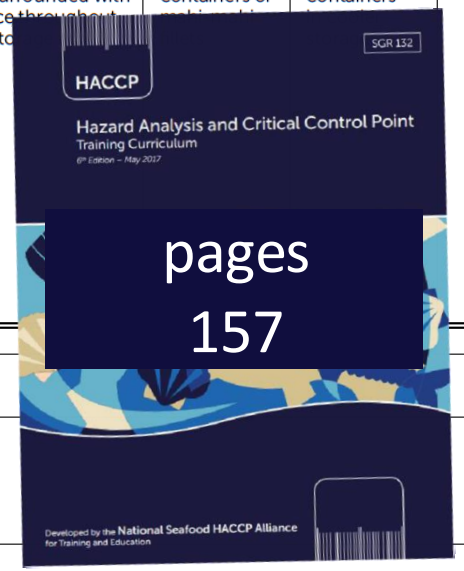
Verifications for XYZ Seafood Company

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			
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.	



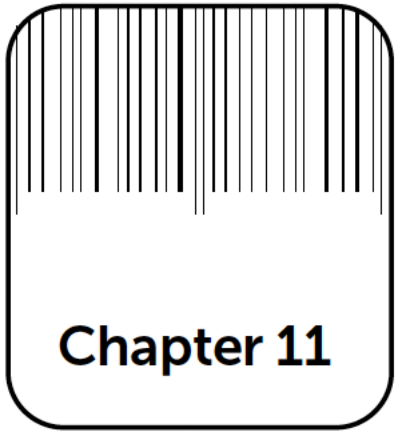
pages
157

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	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 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 All shellstock from waters approved by State Shellfish Authority AND All shellstock from a licensed harvester	Shellfish receiving log
Histamine	Receiving	Fish are completed surrounded by ice	Histamine fish receiving log
C. botulinum toxin formation (in finished product)	Hot smoking	Internal fish temperature held at or above 145°F for at least 30 minutes	Smokehouse temperature recording log
Pathogen growth	Cooler storage	Cooler temperature not to exceed 40°F	Cooler temperature

Example Monitoring Records …

Pages 163-165

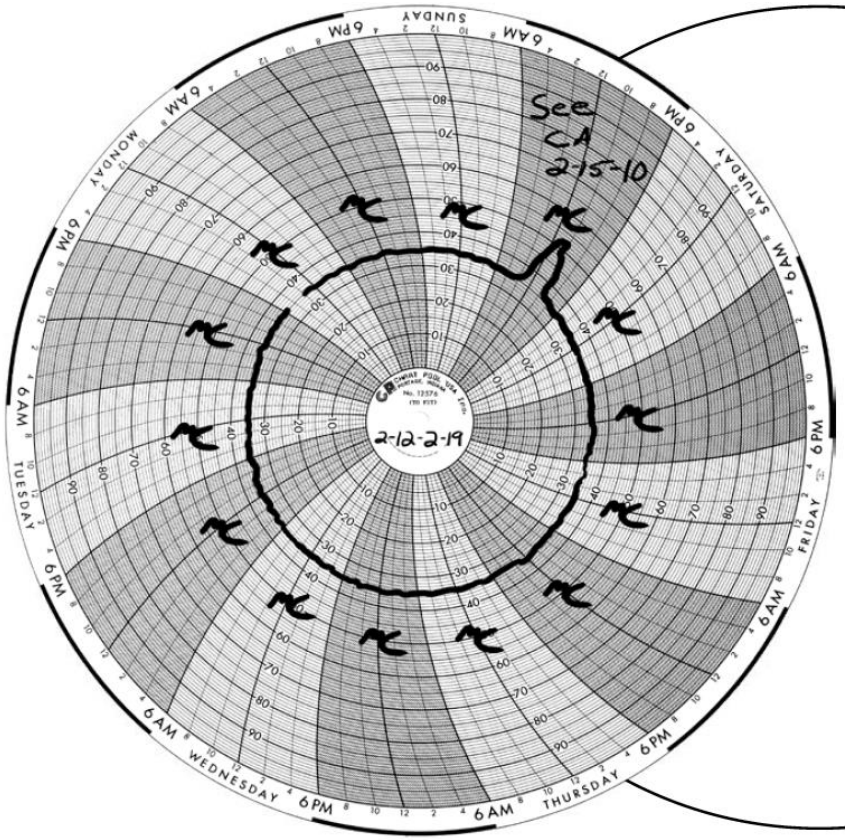
Slide 8

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:**	

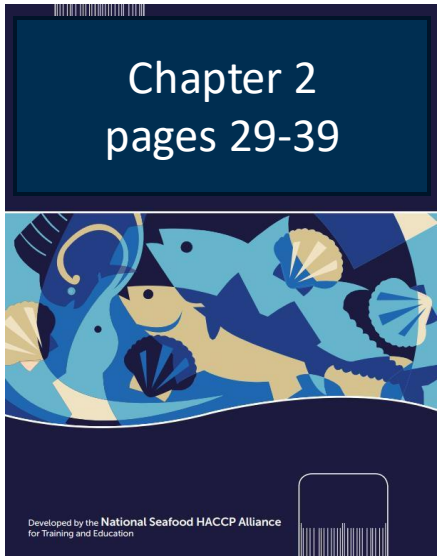
Do Not Forget Records for required SCP monitoring

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 Additional Comments: 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.

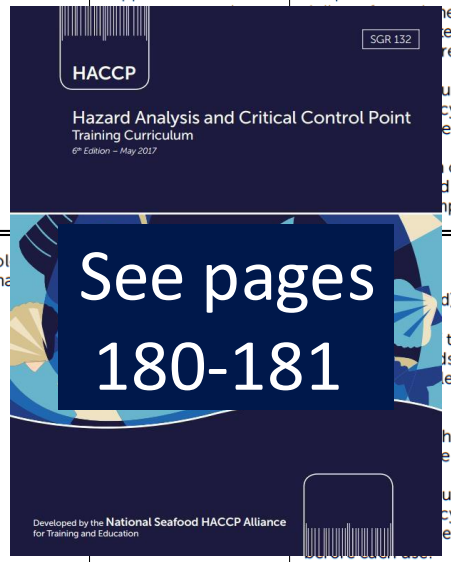
Records for XYZ Seafood Company

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. 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	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. Corrective Action records Verification Records • Accuracy Check Record • 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. 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	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. Corrective Action records Verification Records • Accuracy Check Record • 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. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration Log

Firm Name: XYZ Seafood Company	**Product:** Fresh/F
Firm Address: 238 Coastal Lane, Happy Beach, XX	**Method of Stora** ice **Intended Use an** neral public
Signature:_____ 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

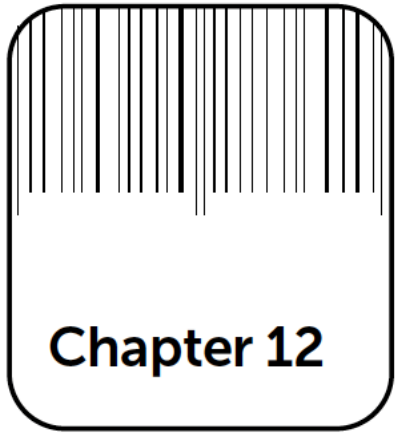
Firm Name: XYZ Seafood Company		**Product: Fresh/Raw Mahi-Mahi Fillets**
Firm Address: 238 Coastal Lane, Happy Beach XX		**Method of Storage & Distribution: Stored and distributed buried in ice**
		Intended Use and Consumer: To be cooked and consumed by the general public
Critical Control Point (CCP)		**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. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.
Records		Receiving Log that documents: the number of containers examined; the number of containers in each delivery; and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Log • Calibration Log
Signature: *John Doe*		Date: *2/29/20*

Page _ of _

End Chapter11: Principle 7

Record-Keeping

The Seafood HACCP Regulation



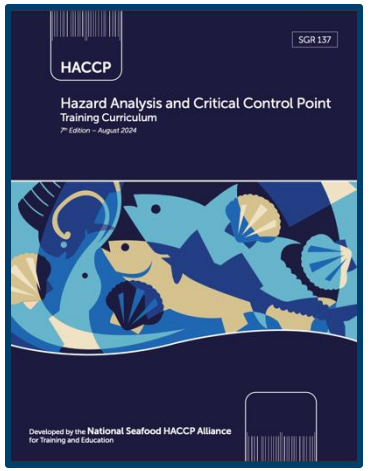
Slide 1

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…

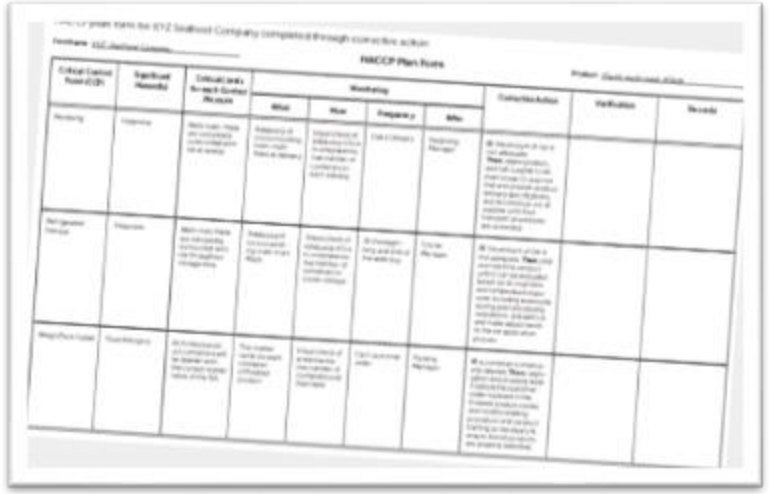
Slide 10

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

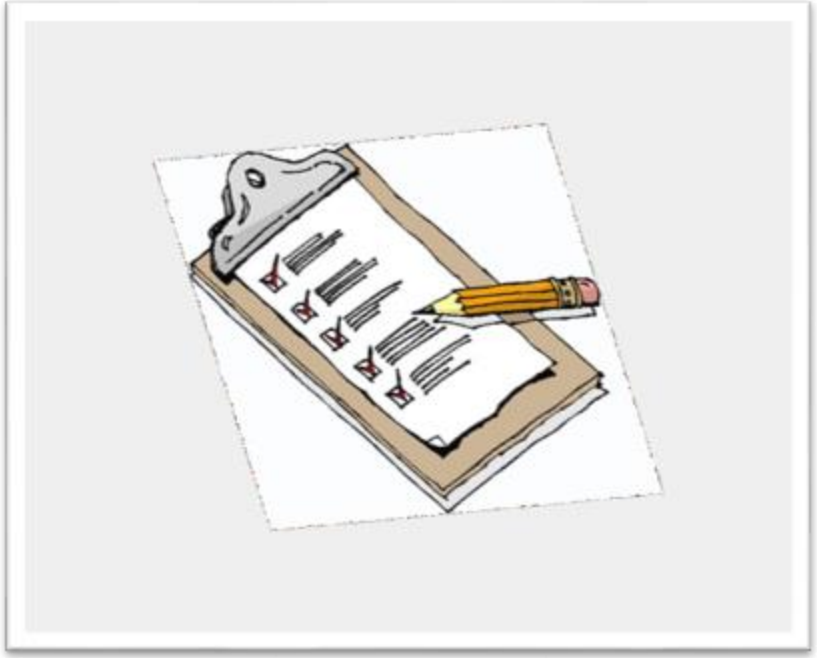
Slide 15

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?

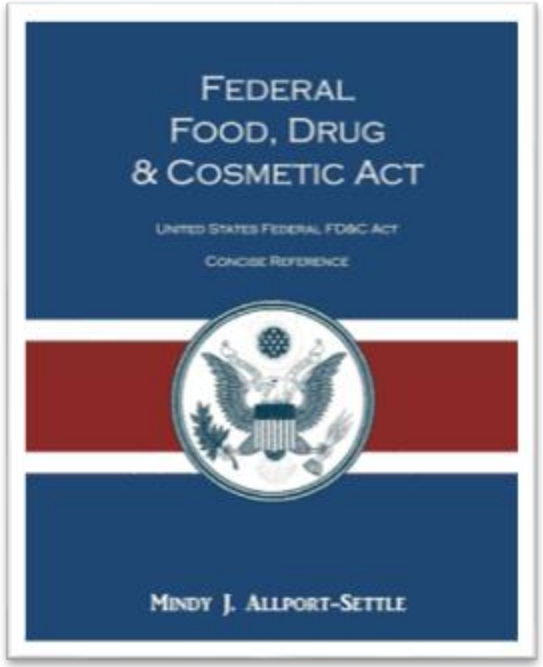
Slide 16

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

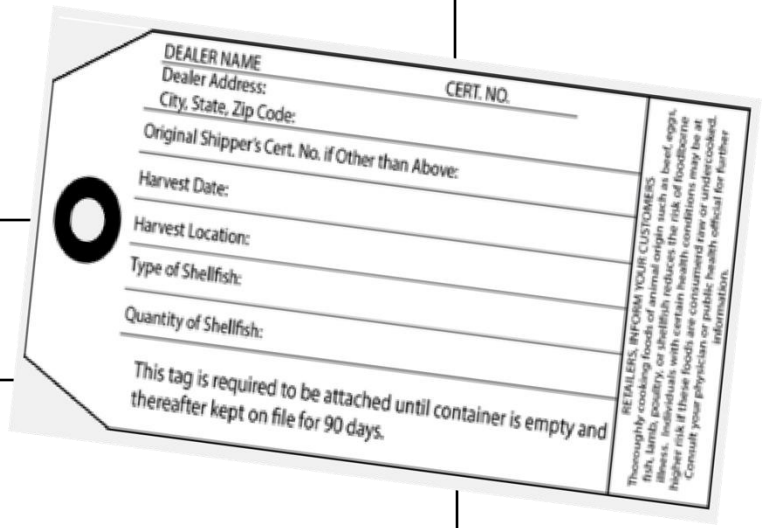
Raw Molluscan Shellfish 123.28
Shellstock Receiving:

- 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.

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

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