# Seafood HACCP Alliance Segment Two Course

Course Number:

Course Location:

Course Date:

AFDO Region:

Instructor:

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

# AGENDA (SHA Segment 2 Course)

PART 1: Lecture and Discussion

- FDA Seafood HACCP Regulation
- Using the Seafood Safety Hazards Guide
- Guidance for developing a HACCP Plans

PART 2: HACCP Group Exercise

- Practical group exercise to develop a model HACCP Plan
- Present HACCP Plan developed

# Purpose of this Training

Individuals who complete this course will meet the training requirement of the FDA Seafood HACCP regulation and can do the following:

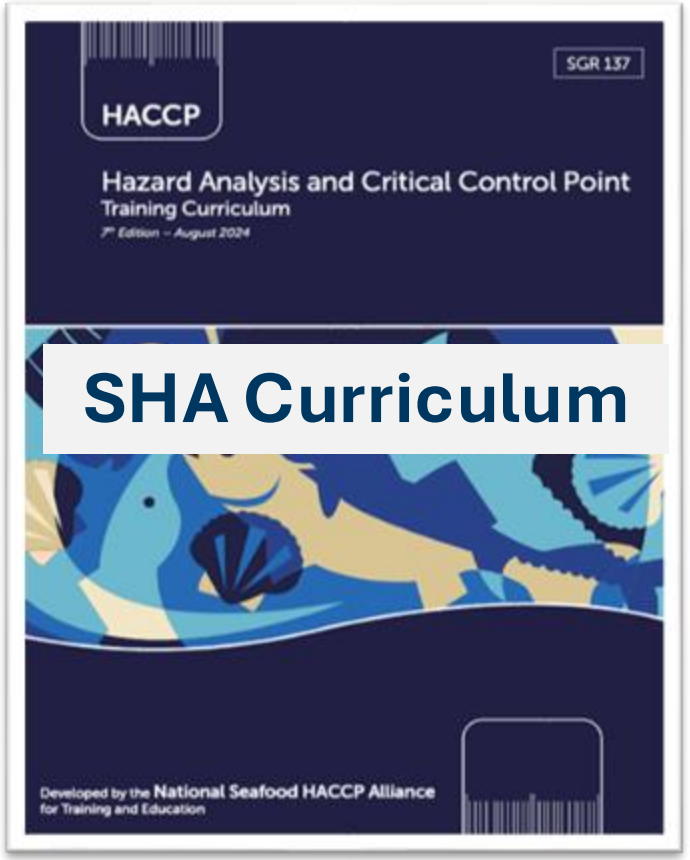
- Conduct a Hazard Analysis
- Develop a HACCP Plan for seafood products as required by the FDA regulation
- Reassess or modify a HACCP Plan as necessary and/or required by the FDA regulation
- Review HACCP Plan records as required by the FDA regulation

# Expectations for Training

Seafood HACCP Alliance courses provide:

- A basic introduction to the HACCP regulatory requirements for the processing of fish and fishery products.
- Instructions and exercises to help learn how to use the seafood HACCP Guidance manual (FDA Guide) to conduct a Hazard Analysis and develop a HACCP Plan.
- Receive explanations and examples for how to monitor the required Sanitation Control Procedures (SCP's).

# SHA Training Materials




**SHA Curriculum**

**BLUE BOOK**


**FDA GUIDE**

**GOLD BOOK**

# FDA Seafood HACCP Regulation

## 21 CFR Part 123
## Fish and Fishery Products

- Seafood HACCP
  - https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/seafood-haccp

- Fish and Fishery Products Hazards and Controls
  - https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls

# FDA Seafood HACCP Regulation
## 21 CFR Part 123

- Any fish or fishery products processed or imported in violation of this regulation can be considered adulterated and subject to regulatory action. CHP 12: 197
- A processor is any person engaged in commercial, custom or institutional processing of fish or fishery products either in the U.S. or in a foreign country. CHP 12: 192
- An importer is the U.S. owner/consignee or the U.S. agent/representative of the foreign owner/consignee at the time of the product entry into the United States. CHP 12: 191

AD1 - 1

# What Does Processing Include?

- Processing means:

  Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding fish or fishery products.

- The regulation does not apply to:
  - The harvest or transport of fish or fishery products
    - Including aquaculture farms unless processing
  - Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel
  - The operation of a retail establishment

AD1 - 2

CHP 12: 192

# What are fish or fishery products?

- **Fish** means freshwater or saltwater finfish, crustaceans, aquatic animal life (including alligators, frogs, aquatic turtles, jellyfish, sea cucumbers, sea urchins and roe) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.
  - Note: it is important to carefully read the definition of fish and note that mollusks (molluscan shellfish) are considered fish for purposes of this regulation.

- **Molluscan shellfish** means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

- **Fishery product** means any human food product where fish is a characterizing ingredient, such as clam chowder or fish sauce.

- **All products** intended for human consumption are covered.

AD1 - 2

CHP 12: 191

# What MUST all seafood processors do?

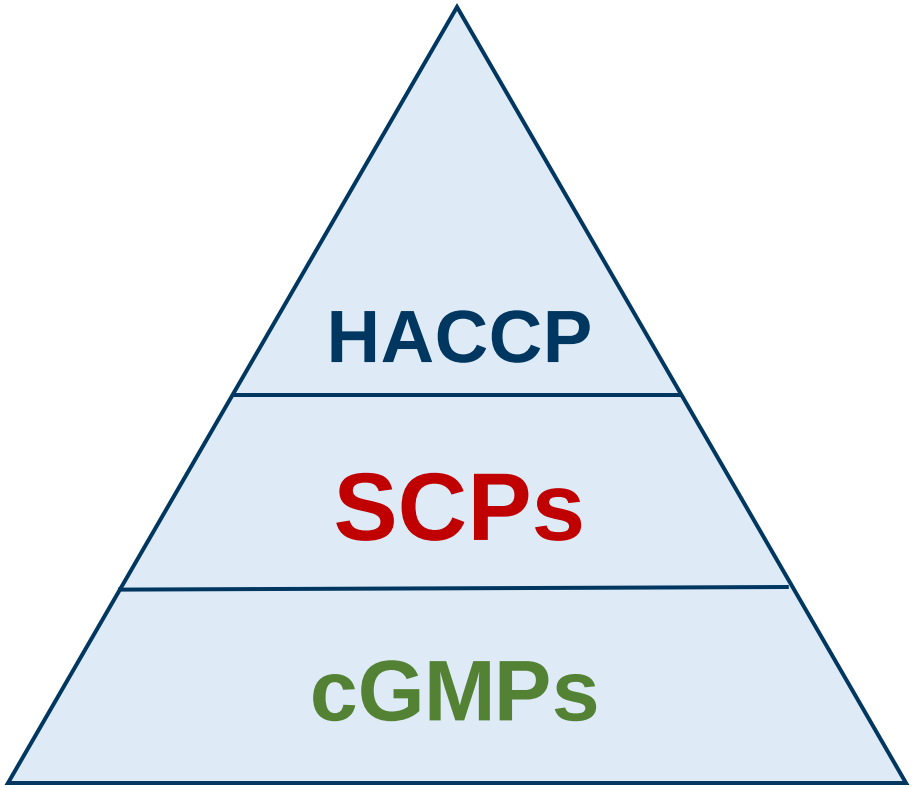
- Every processor **shall** conduct, or have conducted , a **Hazard Analysis**.
  - Complete a **Hazard Analysis** to determine if there are any significant hazards associated with your products(species) or process.
- Every processor **shall** have and implement a written **HACCP Plan** whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur. Monitor and keep records of monitoring results and corrections taken for 8 specified areas of **sanitation.**
- The HACCP plan shall be signed and dated:
  - By the most responsible individual at the processing facility or a higher level official.
    - Signed and dated:
      - Upon initial acceptance.
      - Upon any modification.*
      - At least annually.

      *This is a verification requirement.

CHP 12

# What MUST all seafood processors do?

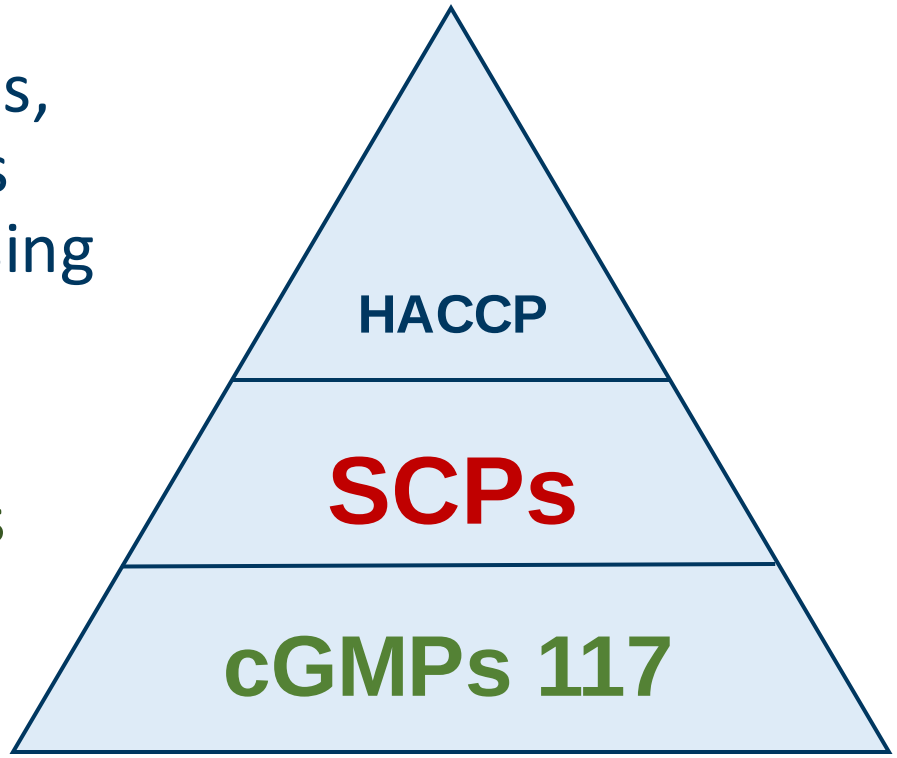
- Processors are **required** to develop and maintain a HACCP program, HACCP must be built upon current food safety programs such as:
- **Sanitation Control Procedures (SCPs—21 CFR 123.11)**
- **Current Good Manufacturing Practices (cGMPs—21 CFR 117)**
  - These programs are known as **"prerequisites"** that provide a foundation for the HACCP program




CHP 1: 7 | AD1 - 3 | AD1 - 7

# Sanitation Control Procedures (SCPs)

- Seafood processors are required to comply with cGMPs, monitor SCPs, correct problems, and keep records of their monitoring results and the corrections made during all processing operations
- As of 2016, the SCPs must be based on the most current Good Manufacturing Practices Part 117 that replaced GMPs Part 110




**SCPs are not featured in this Segment Two HACCP course, but they are the essential and required foundation for all HACCP Programs**

CHP 2: 15-21

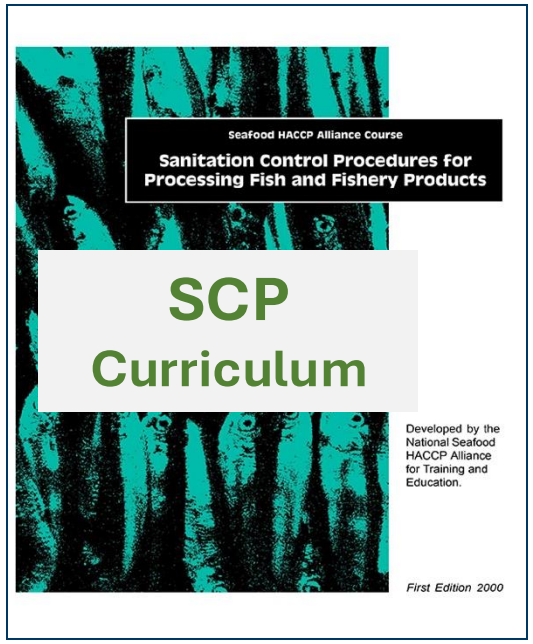
# Sanitation Control Procedures (SCPs)

Processors **must** monitor and keep records of monitoring results and corrections for **8 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

CHP 2: 17-21 | AD1 - 8

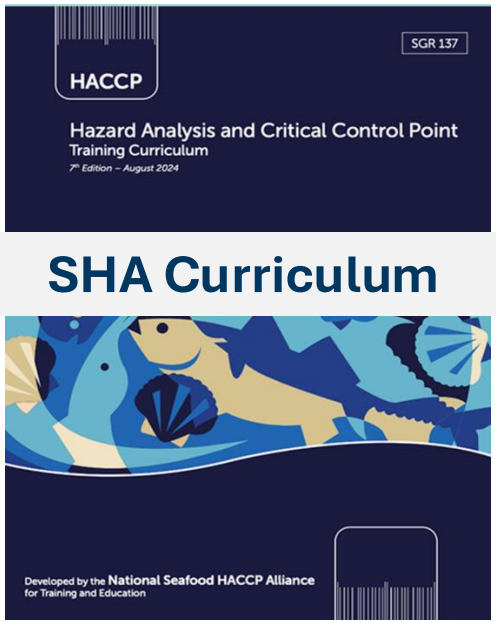
# Sanitation Control Procedures (SCPs)




**SCP Curriculum**

GREEN BOOK

SSOP-4 to SSOP-16




**SHA Curriculum**

BLUE BOOK

CHP 2: 29-39

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

Form 1

Daily Sanitation Control Record with all 8 Key Sanitation Areas

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

**Source: Florida Sea Grant** https://www.flseagrant.org/seafood/haccp/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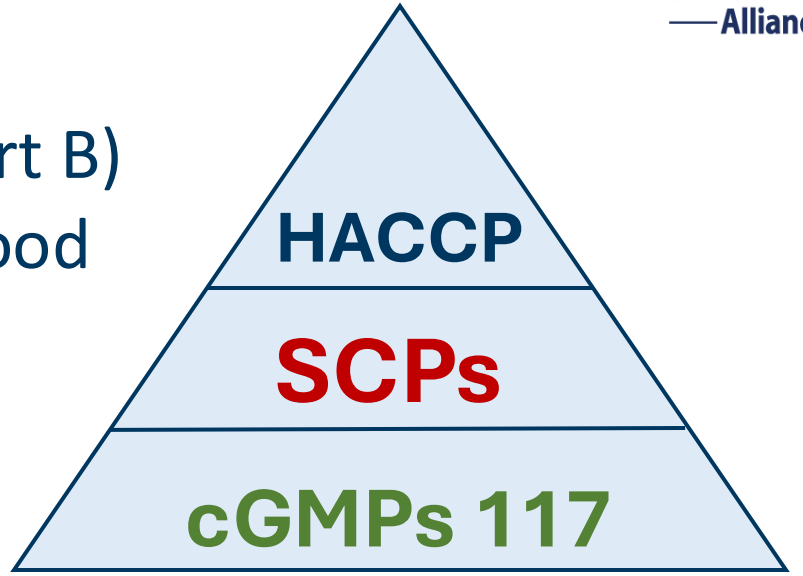
# Current Good Manufacturing Practices (cGMPs)

The new **current GMPs** (21 CFR Part 117 Subpart B) introduced additional requirements for all seafood processors:

Appendix 3: 233



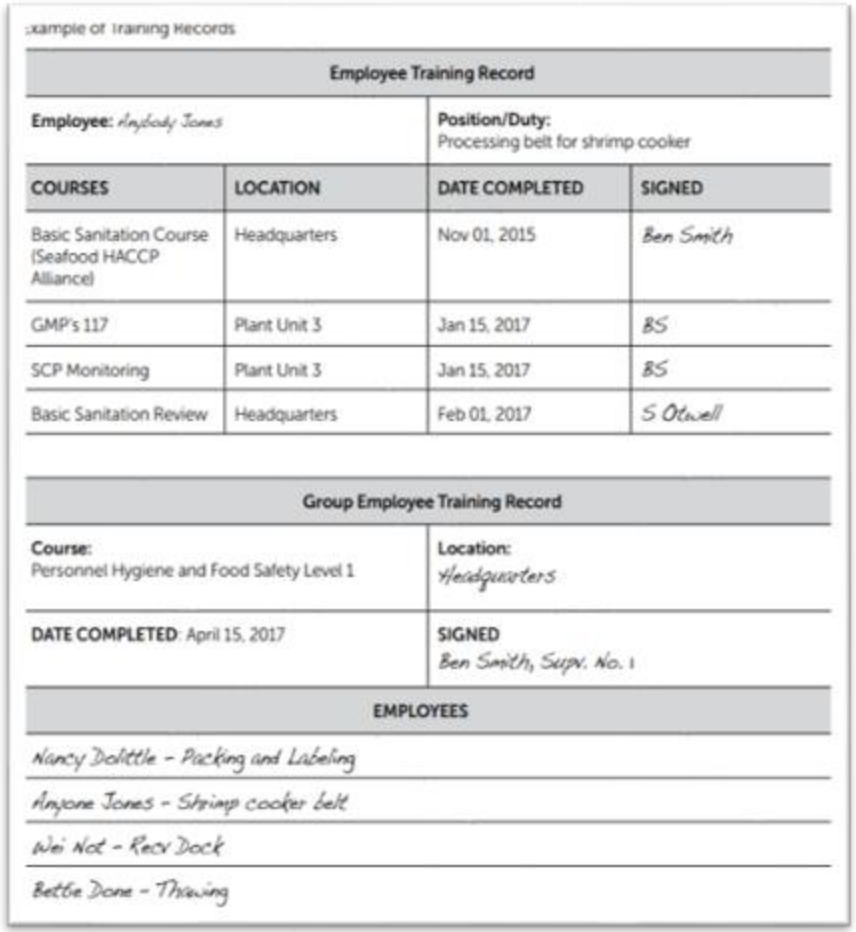

- Seafood processors are required to assess and record any necessary SCPs controls to prevent cross-contact resulting in *'unintended allergen presence'*

# 21 CFR Part 117 Subpart A: General Provisions

CHP 2: 13

## Employee Training Records

- Facilities are required to keep records that document the training on the principles of food hygiene and food safety for those who supervise or perform manufacturing, processing, packing, or holding activities for food.
- Processors must maintain records of this training for 2 years.
- There are no prescribed courses and performance remains the primary measure for effective training, but training records are mandatory



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 - Rear Dock | |
| Bettie Done - Thawing | |

# Required Parts of a HACCP Program

- Every processor **shall** conduct, or have conducted for it, a **hazard analysis** to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards.

- 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…

AD1 - 3

# HACCP Plan Requirements

- Each of the 7 Principles of HACCP has a section in the FDA regulation with specific requirements related to that principle.
- HACCP Plans must be specific for:
  - **Each** kind of **fishery product**
    - Products can be grouped if hazards, processing steps & controls are the same
  - **Each processing location**
- HACCP Plans must list **all** the required components for each identified food safety hazard (CCP, CL, monitoring, corrective actions, verification, recordkeeping).
- HACCP Plans must be **signed, dated** & **routinely implemented.**

AD1 - 4

# Review of 7 HACCP Principles

# Review of 7 HACCP Principles

Conduct a Hazard Analysis:

- Principle 1 – Conduct a Hazard Analysis (HA)
- Principle 2 – Identify Critical Control Points (CCPs)

Build a HACCP Plan

- Principle 3 – Establish Critical Limits (CL)
- Principle 4 – Establish CCP Monitoring Procedures
- Principle 5 – Establish Corrective Action Procedures (CA)
- Principle 6 – Establish Verification Procedures
- Principle 7 – Establish a Recordkeeping System

# Principle 1: Conduct a Hazard Analysis

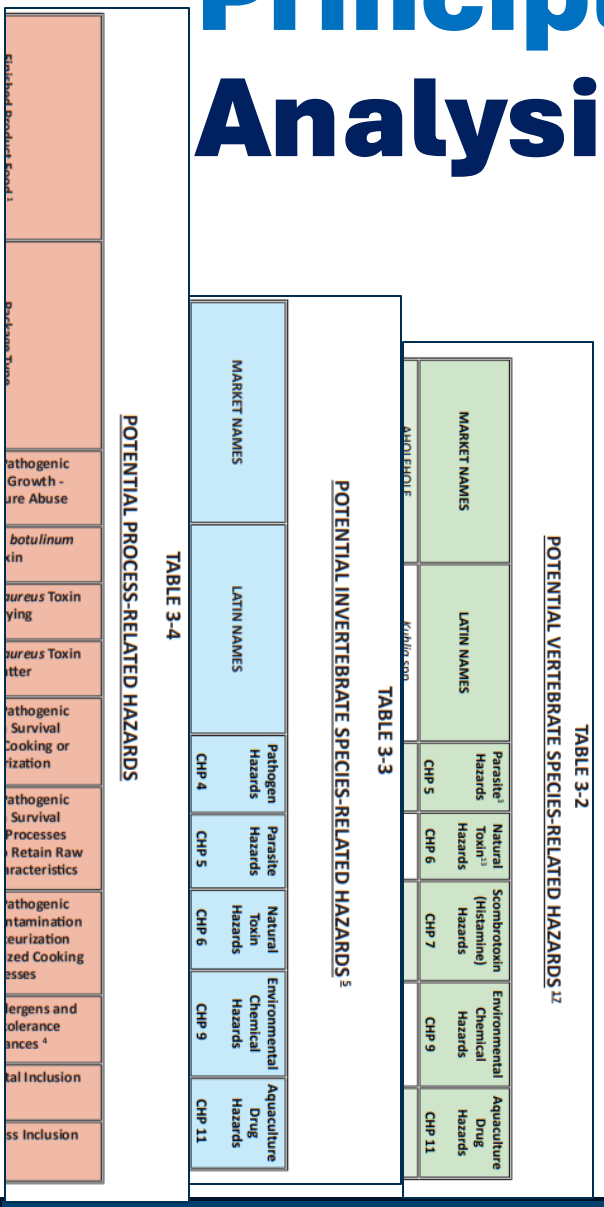


TABLE 3-4
POTENTIAL PROCESS-RELATED HAZARDS

| Finished Product Food[1] | Package Type | Pathogenic Growth - ure Abuse | botulinum xin | ureus Toxin ying | ureus Toxin tter | Pathogenic Survival Cooking or rization | Pathogenic Survival Processes Retain Raw aracteristics | Pathogenic ntamination eurization zed Cooking esses | lergens and olerance ances [4] | tal Inclusion | ss Inclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|


TABLE 3-3
POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS[5]

| MARKET NAMES | LATIN NAMES | Pathogen Hazards CHP 4 | Parasite Hazards CHP 5 | Natural Toxin Hazards CHP 6 | Environmental Chemical Hazards CHP 9 | Aquaculture Drug Hazards CHP 11 |
|---|---|---|---|---|---|---|


TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS[12]

| MARKET NAMES | LATIN NAMES | Parasite[3] Hazards CHP 5 | Natural Toxin[13] Hazards CHP 6 | Scombrotoxin (Histamine) Hazards CHP 7 | Environmental Chemical Hazards CHP 9 | Aquaculture Drug Hazards CHP 11 |
|---|---|---|---|---|---|---|
| AHOLEHOLE | Kuhlia spp. | | | | | |

Identify and list **ALL** potential food safety hazards associated with the product and process.

## Species Hazards

- CHP 5: 77
- CHP 3: 3-2
- CHP 3: 3-3

## Process Hazards

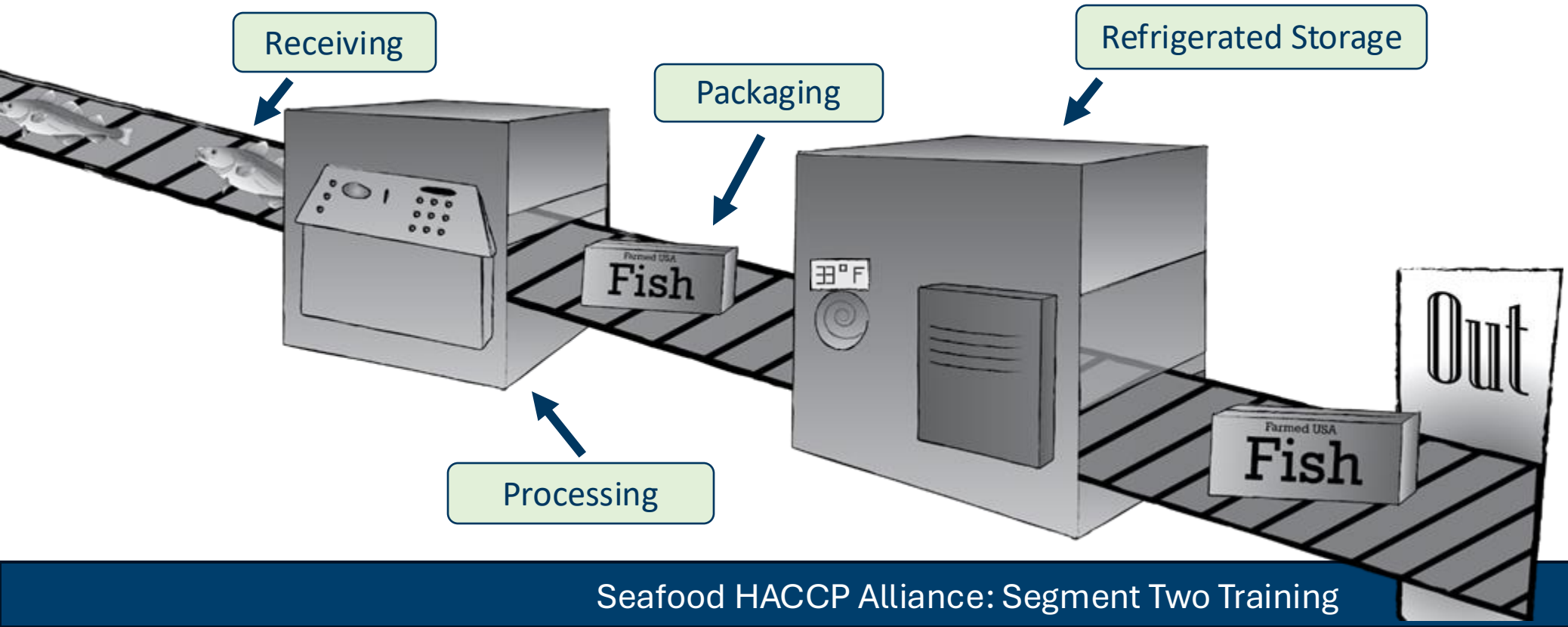
- CHP 5: 81
- CHP 3: 3-4

# Principle 2: Identify Critical Control Points (CCPs)

Identify what processing steps can be used to control the significant hazards.

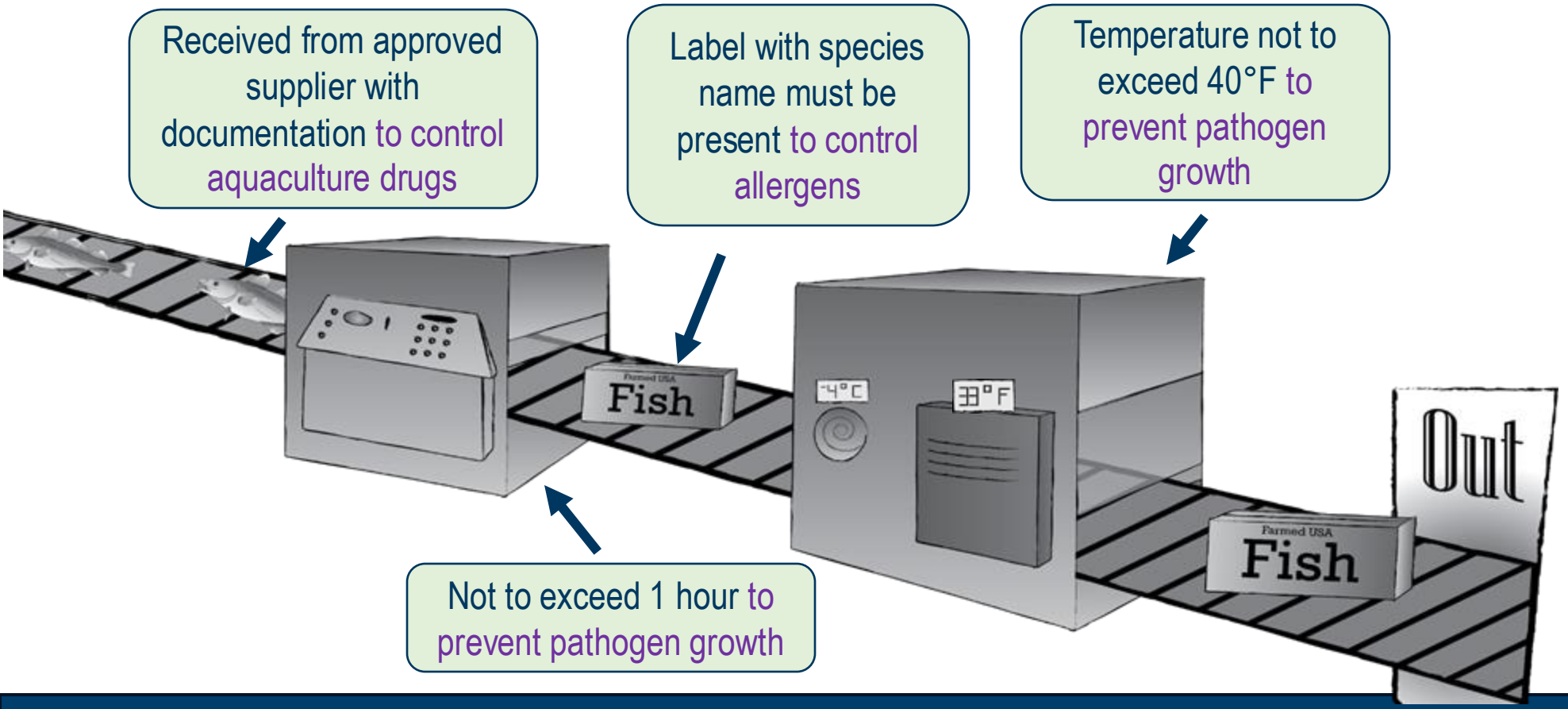
CHP 6: 99

CHP 2: 25



# Principle 3: Establish Critical Limits

Critical limits specify the maximum and/or minimum value to which a parameter (temperature, time) must be controlled at a CCP.



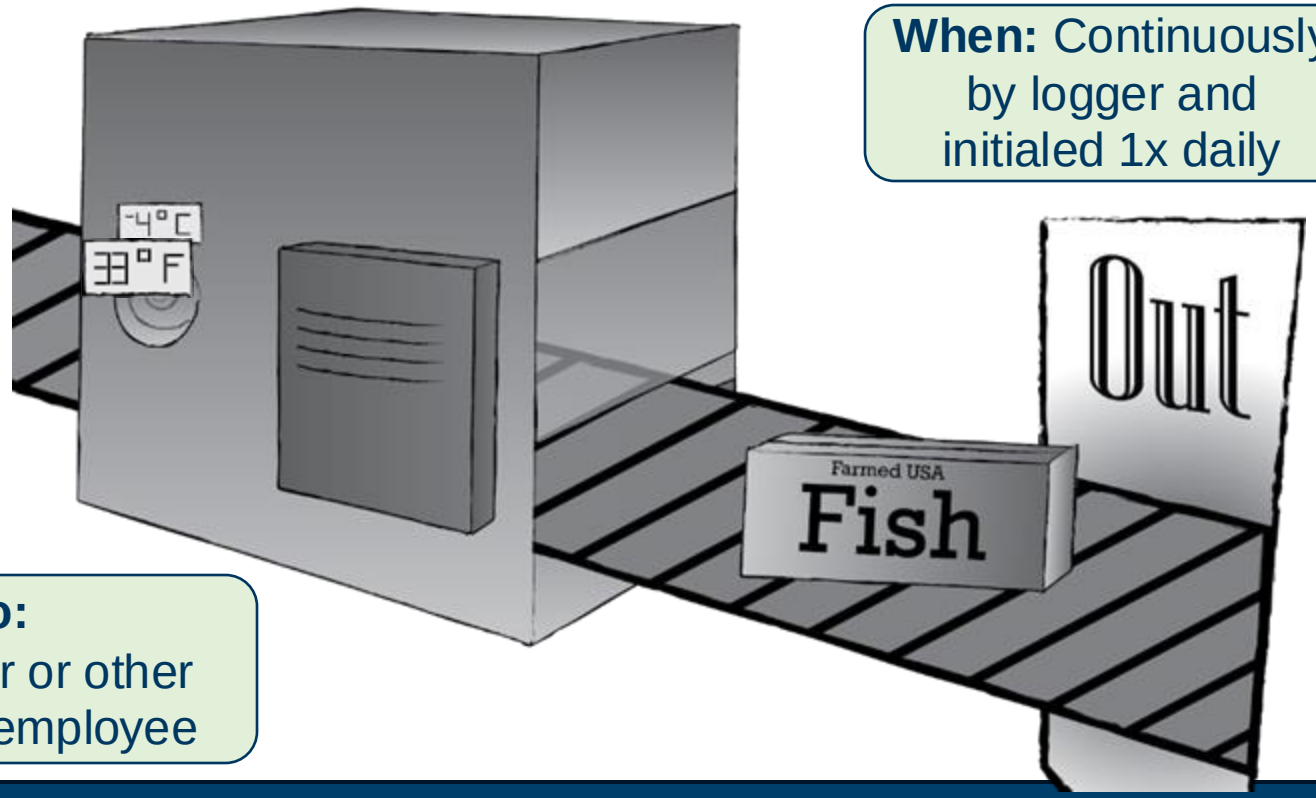

CHP 7: 109

CHP 2: 26

# Principle 4: Establish CCP Monitoring Procedures

Determine **what** will be monitored, **how** it will be monitored, **when** it will be monitored and by **who**.

**What:** Temperature




**When:** Continuously by logger and initialed 1x daily

CHP 8:119

CHP 2: 26

**How:** Temperature Logger

**Who:**
QA Manager or other designated employee

# Principle 5: Establish Corrective Actions

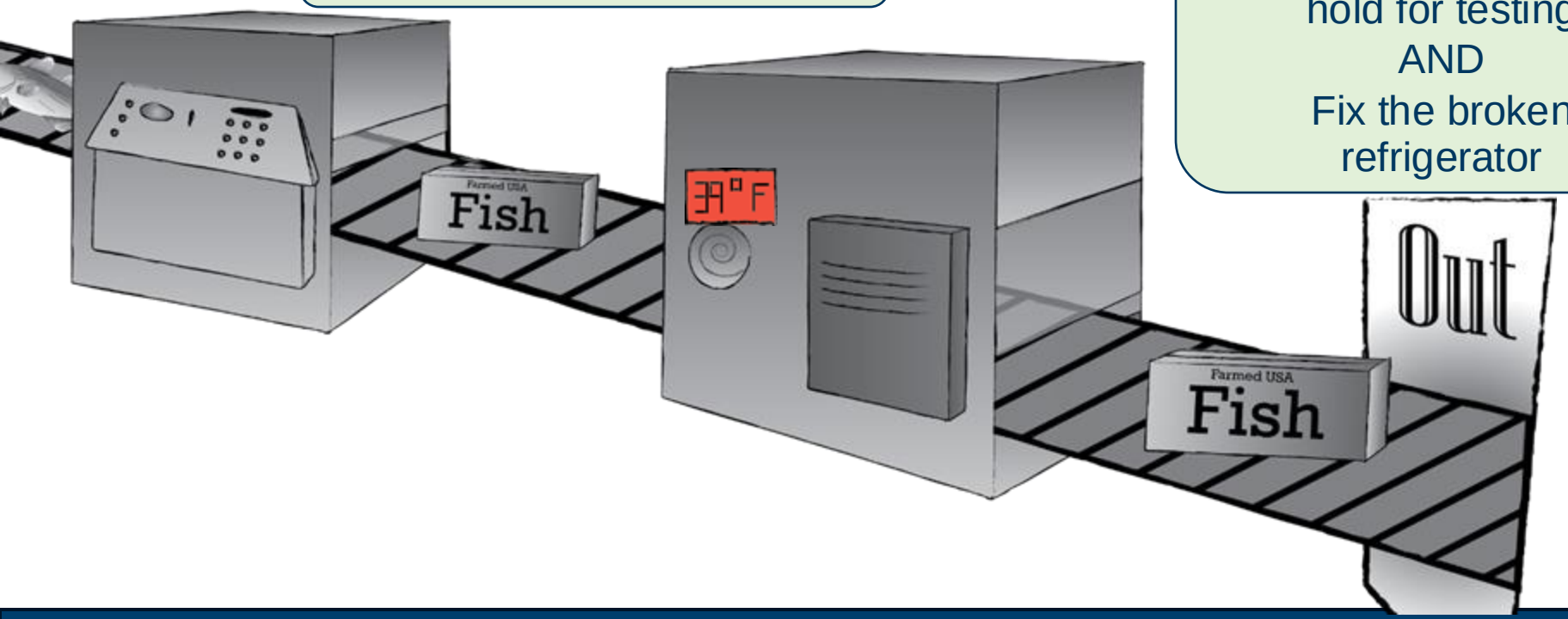
Determine what you will do if your critical limits are not met.

CHP 9: 129

CHP 2: 27

**If:** Temperature exceeds 40°F.

**Then:** Move product to a working refrigerator and hold for testing
AND
Fix the broken refrigerator




# Principle 6: Establish Verification Procedures

Implement procedures for validating that your HACCP plan is working properly.

CHP 10: 141

CHP 2: 28

- HACCP Plan Assessment
- Process Validation
- Equipment Calibration
- Equipment Accuracy Checks
- Targeted Sampling and Testing for Product Safety
- Review of Calibration, Monitoring, Corrective Actions Records

# Principle 7: Establish Recordkeeping Procedures

Tracks all monitoring procedures, corrective actions, and verifications of your system to ensure standards are met and facility is in compliance.

CHP 11: 159

CHP 2: 27

| **Form Title:** Refrigerator Temperature Log (Monitoring Record) | | | | | |
|---|---|---|---|---|---|
| **Firm Name:** | | | **Firm Location:** | | |
| **Production Identification:** | | | | | |
| **Critical Limits:** | | | **Monitoring Activities:** | | |
| Date | Time | Storage Unit # | Refrigerator Temperature | Critical Limit Met (Yes/No) | Line Operator (Initials) |
| | | | | | |
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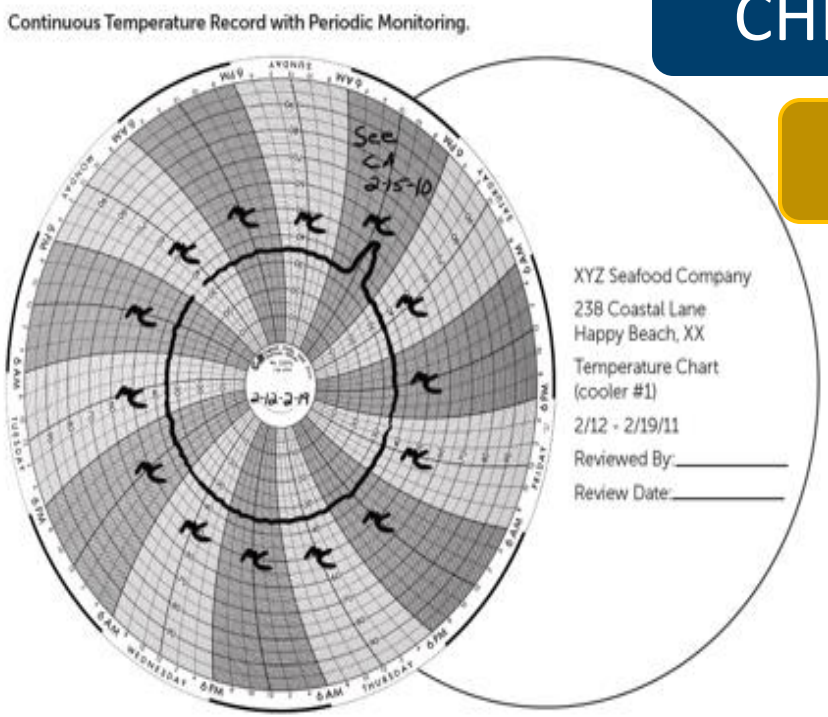
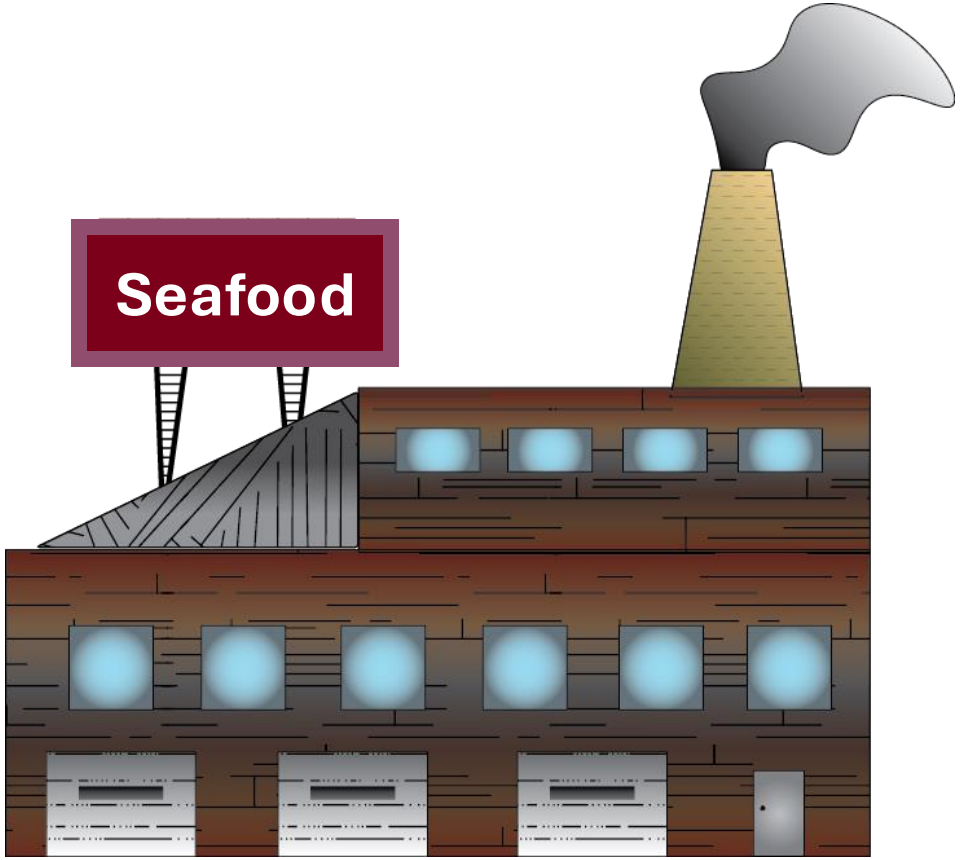
| | | | | | |
| **Reviewer Signature:** | | | | **Date of Review:** | |

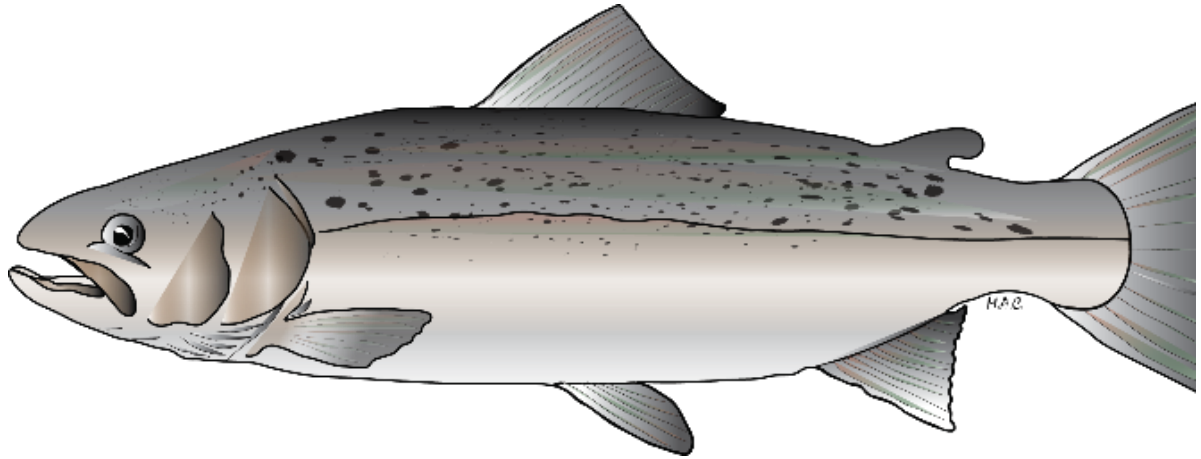


# Potential Seafood Safety Hazards

# Potential Seafood Safety Hazards




Process-Related Hazards



Species-Related Hazards

# Seafood Safety Hazards & Controls

Vertebrate Table 3-2
Invertebrates Table 3-3
Process Hazards Table 3-4

## Key Concepts:

**Species Hazards**

**Process Hazards**

P 41

**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[3,9] CHP 6 | Scombrotoxin (Histamine) CHP 7 | Environmental Chemicals CHP 9 | Aquaculture Drugs CHP 11 |
| AHOLEHOLE | *Kuhlia* spp. | | | | | |
| ALEWIFE or RIVER | *Alosa pseudoharengus* | | | ✓ | ✓ | |

**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* spp. | | | | ✓ | ✓ |

**TABLE 3-4**

**POTENTIAL PROCESS-RELATED HAZARDS**

| Finished Product Food [1] | 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 | |
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish | Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed) | | ✓ | | ✓ | | | | ✓ | ✓ | | ✓ |
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish | Other than reduced oxygen packaged | | | | ✓ | | | | ✓ | ✓ | | ✓ |
| Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and surimi-based analog products | Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil) | ✓ | ✓ | | | ✓ | | | ✓ | ✓ | | ✓ |
| Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, | Other than reduced oxygen packaged | ✓ | | | | ✓ | | | ✓ | ✓ | | ✓ |

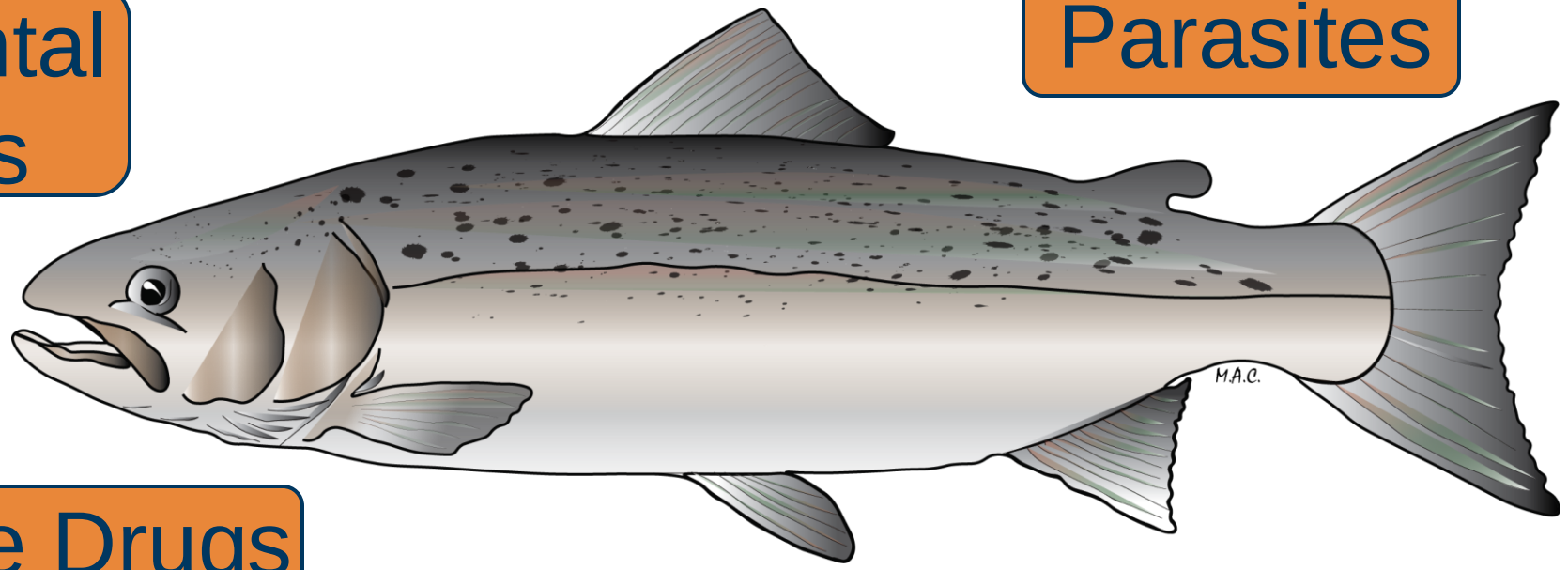
# Seafood Safety Hazards

**Species Hazards** – Hazards associated with specific types (species) of fish or shellfish and/or where they are harvested

CHP 3: 3-25

Environmental Chemicals

Parasites




Aquaculture Drugs

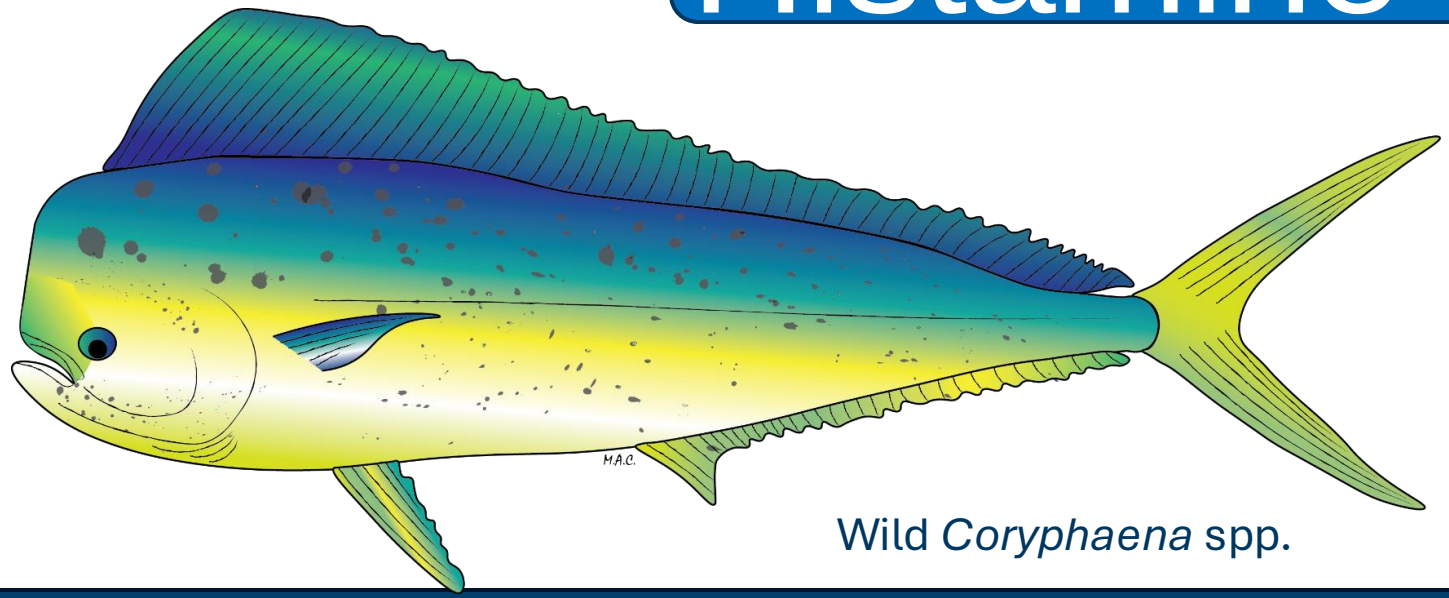
Salmon(Farmed *Salmo salar)*

# Seafood Safety Hazards

- **Species Hazards** – Hazards associated with specific types (species) of fish or shellfish and/or where they are harvested

CHP 3: 3-21

**Histamine**



Wild *Coryphaena* spp.

# Potential Seafood Hazards, SPECIES-Related Hazards

- Pathogens (harvest)
- Parasites
- Natural Toxins
- Histamine (elevated)
- Environmental Chemicals
- Aquaculture Drugs

Invertebrate Table 3-3
P 3-40

**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.* | ✓ | | ✓ | ✓ | |
| CLAM, HARD | *Arctica islandica* | ✓ | | ✓ | ✓ | |

Vertebrate Table 3-2 P 3-3

**TABLE 3-2**

**POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS**

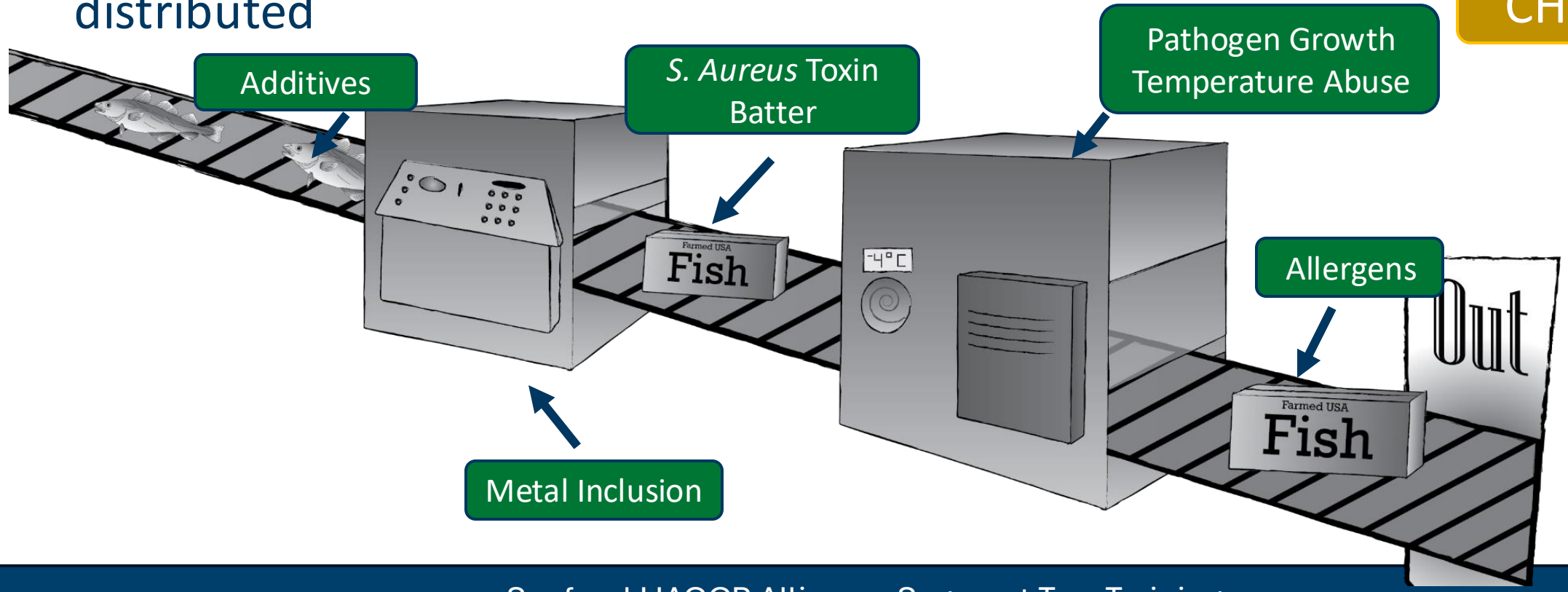
**Note:** You should identify pathogens from the harvest area as a potential species-related hazard if you know, or have reason to know, that the fish will be consumed without a process sufficient to kill pathogens or if you represent, label, or intend for the product to be so consumed. (See Chapter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

| MARKET NAMES | LATIN NAMES | HAZARDS | | | | |
|---|---|---|---|---|---|---|
| | | Parasites[9] CHP 5 | Natural Toxins[10] 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.* | | | | | |
| ATOR | *Alligator mississipiensis* | | | | ✓ | |
| | *Alligator sinensis* | | | | ✓ | |
| aquacultured | *Alligator mississipiensis* | | | | ✓ | ✓ |
| | *Alligator sinensis* | | | | ✓ | ✓ |
| RJACK | *Seriola dumerili* | | CFP | ✓ | | |
| | *S. rivoliana* | | CFP | ✓ | | |
| | *S. spp.* | | | ✓ | | |
| JACK or WTAIL | *Seriola lalandi* | | | ✓ | | |
| JACK or aquacultured | *Seriola lalandi* | ✓[4] | | ✓ | ✓ | ✓ |
| K or BURI, ultured | *Seriola quinqueradiata* | | | ✓ | ✓ | ✓ |
| OVY[12] | *Anchoa spp.* | ✓ | ASP[5] | ✓ | | |
| | *Anchoviella spp.* | ✓ | ASP[5] | ✓ | | |
| | *Cetengraulis mysticetus* | ✓ | ASP[5] | ✓ | | |
| | *Engraulis spp.* | ✓ | ASP[5] | ✓ | | |
| | *Stolephorus spp.* | ✓ | ASP[5] | ✓ | | |

# Seafood Safety Hazards

**Process Hazards** – Hazards associated with different products and product forms & how they are processed, packaged, stored or distributed

CHP3: 3-52



# Potential Seafood Hazards, Process-Related Hazards

- Pathogenic Bacteria Growth – Temperature Abuse
- *C. botulinum* toxin
- *S. aureus* Toxin – Drying
- *S. aureus* Toxin – Batter
- Pathogenic Bacteria Survival through Cooking and 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
- Metal Inclusion
- Glass Inclusion

Table 3-4
P 3-52

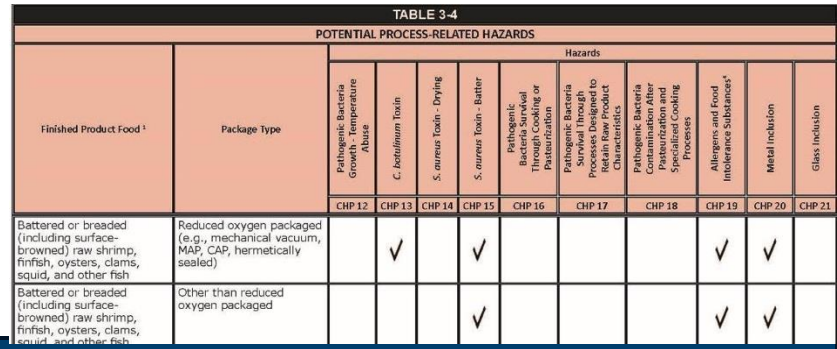


TABLE 3-4

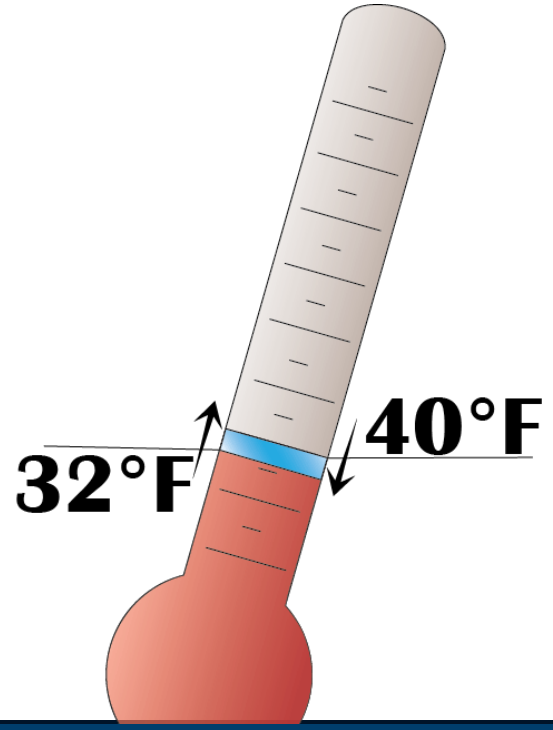
POTENTIAL PROCESS-RELATED HAZARDS

| 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 [2] | Metal Inclusion | Glass Inclusion |
| | | CHP 12 | CHP 13 | CHP 14 | CHP 15 | CHP 16 | CHP 17 | CHP 18 | CHP 19 | CHP 20 | CHP 21 |
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish | Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed) | | ✓ | | ✓ | | | | ✓ | ✓ | |
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish | Other than reduced oxygen packaged | | | | ✓ | | | | ✓ | ✓ | |

# Potential Seafood Safety Hazards and Their Controls

# Controls

Once a processor identifies a hazard – species or process-related, they must implement a **control strategy** to control the hazard

# Species-Related Food Safety Hazards

## Parasites:

CHP5:91

Hazard: Living parasites in certain fish or shellfish species that can infect humans.

Controls: Cooking or proper freezing.

HACCP Controls: A processor must properly freeze products that are likely to contain parasites if they will be consumed raw or partially cooked (e.g., sushi, sashimi, cold smoked, pickled, etc.).

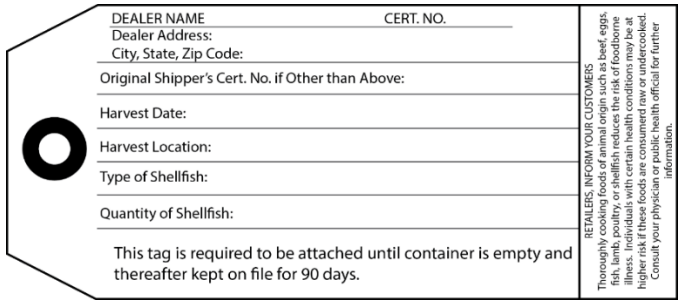
# Species-Related Food Safety Hazards

## Harvest Pathogens:

CHP4:75

Hazard: Harvest waters can have high pathogen levels that contaminate shellfish or some fish.

Controls: Cooking or restricting harvesting to approved waters with safe pathogen levels.




HACCP Controls: Bivalve molluscan shellfish are only harvested from approved waters and all processors ensure products are properly tagged or labeled to ensure traceability.

# Species-Related Food Safety Hazards

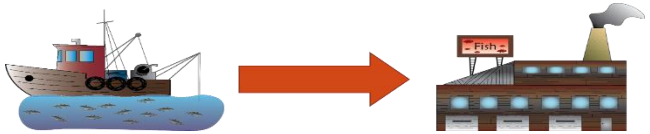
## Histamine or Scombrotoxin:

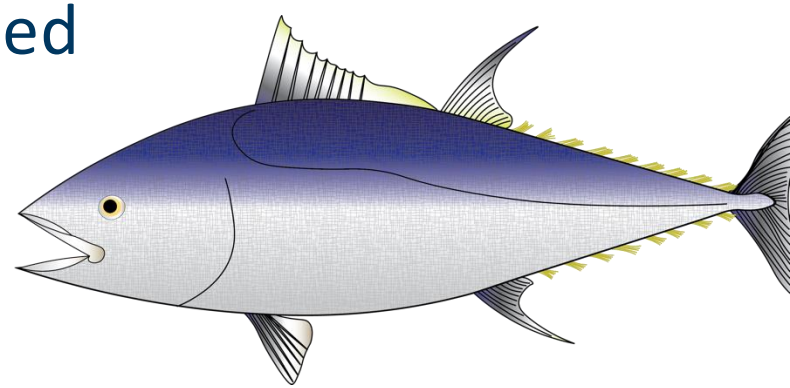
CHP4:113

Hazard: Elevated histamine levels can develop in certain fish species exposed to time and temperature abuse.

Controls: Prevent time and temperature abuse in fish species likely to develop scombrotoxin.

HACCP Controls: All processors must keep fish chilled and limit exposure times to unrefrigerated temperatures.



# Species-Related Food Safety Hazards

## Natural Toxins:

CHP6: 6-1

Hazard: Naturally occurring toxins can accumulate in shellfish and finfish harvested from contaminated waters.

Controls: Prohibit harvesting from contaminated waters.

HACCP Controls: Primary processors must confirm that the products they receive were not harvested from contaminated waters.

# Species-Related Food Safety Hazards

## Environmental Chemical Pollutants/Contaminants:

CHP9: 9-1

Hazard: Environmental or industrial chemicals can accumulate in finfish or shellfish harvested from polluted waters.

Controls: Prohibit harvesting from contaminated waters.

HACCP Controls: Primary processors must confirm that the products they receive were not harvested from waters that have a health advisory because of pollution.

# Species-Related Food Safety Hazards

## Aquaculture Drugs:

CHP11: 11 - 1

Hazard: Drugs used in aquaculture facilities must be approved by FDA and properly used.

Controls: Prohibit use of unapproved drugs and follow expert advice on proper use of approved drugs.

HACCP Controls: Primary processors must confirm that the products they receive from aquaculture suppliers are following Good Aquaculture Practices, including following the drug usage instructions and FDA requirements.

# Process-Related Food Safety Hazards

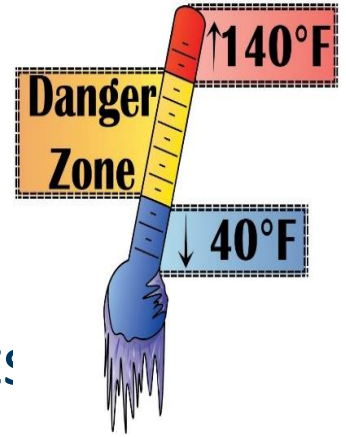
Pathogen Growth caused by time/temperature abuse:

CHP12: 209

Hazard: Pathogen growth in products that will not be cooked before they are consumed could cause consumer illness.

Controls: Prevent time and temperature abuse of ready-to-eat products (e.g., smoked products, cooked or pasteurized products, salads, sushi).

HACCP Controls: All processors must keep ready-to-eat products adequately chilled and strictly limit exposure times to unrefrigerated conditions.



# Process-Related Food Safety Hazards

*Clostridium botulinum* toxin production:

CHP13: 245

Hazard: *C. bot* can grow in smoked, salted, & pickled products and products packed in reduced oxygen packages (ROP) that are subjected to time and temperature abuse.

Controls: Ensure that adequate secondary barriers (e.g., pH, water activity) are in place and prevent exposures to unsafe times and temperatures.

HACCP Controls: All processors must use validated smoking, drying, salting, pasteurization and pickling procedures that are supported by scientific studies and that are adequately implemented; prevent time and temperature abuse; and use Time Temperature Indicators(TTI) when adequate secondary barriers are not in place or when products require more stringent storage controls.

# Process-Related Food Safety Hazards

CHP15: 309

*Staph. aureus* toxin production:

Hazard: *S. aureus* can grow in products where competing bacteria have been reduced or eliminated, such as cooked, battered, and salted products that are subjected to time and temperature abuse.

Controls: Prevent time and temperature abuse.

HACCP Controls: Processors must keep batters refrigerated and products chilled during and after processing steps where competing bacteria have been eliminated, strictly limiting exposure times to unsafe temperatures.

# Process-Related Food Safety Hazards

## Cooking, Pasteurization and Non-thermal Processes:

CHP16: 315
CHP 17: 331
CHP 18: 345

Hazard: Improperly cooked, pasteurized, or non-thermally processed foods can contain pathogens and cause consumer illness.

Controls: Scientifically validated cooking, pasteurization, or non-thermal processes must be used to kill all pathogens.

HACCP Controls: Processors must continuously monitor their cooking, pasteurization, or non-thermal processes to ensure that pre-determined validated limits have been met.

# Process-Related Food Safety Hazards

CHP 19: 19 -1

## Undeclared Food Allergens:

Hazard: All finfish and crustaceans are considered a major food allergen. Additional ingredients can introduce allergens.

Controls: Finfish and crustacean products and seafood products that contain allergens must be labeled with their correct market name for the species in addition to any other allergenic ingredients in accordance with FALCPA requirements.

HACCP Controls: Processors must ensure that all containers or packages that contain fish, crustaceans, or other allergenic ingredients declare the presence of all allergens.

# Process-Related Food Safety Hazards

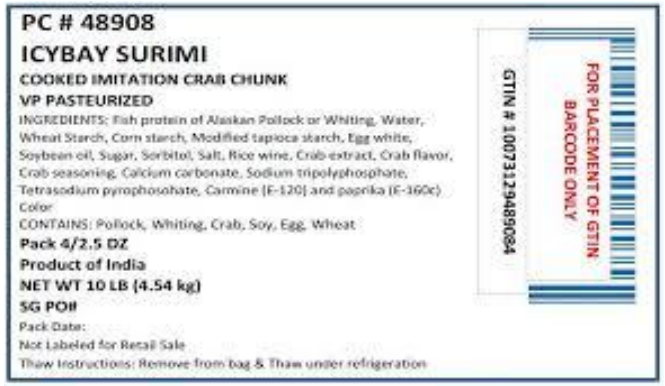
## Food Intolerance Substances:

CHP 19: 19 -3

Hazard: Sulfites and some coloring agents can cause a food intolerance reaction in sensitive consumers.

Controls: Products that contain food intolerance substances must be properly labeled to alert consumers.

HACCP Controls: Processors must ensure that products that contain food intolerance substances are properly labeled.



# Process-Related Food Safety Hazards

## Metal inclusion in finished products:

CHP 20: 385

Hazard: Undetected metal fragments in food can cause injury to consumers.

Controls: Metal detection when it is likely that manufacturing could introduce metal fragments into the food or equipment checks to identify when metal fragments may have been introduced.

HACCP Controls: Processors either implement controls to detect metal fragments or identify when breakage of equipment may have introduced metal fragments into the food.

# Process-Related Food Safety Hazards

Glass inclusion in finished products:

CHP 21: 395

Hazard: Undetected glass fragments in food can cause physical injury to consumers.

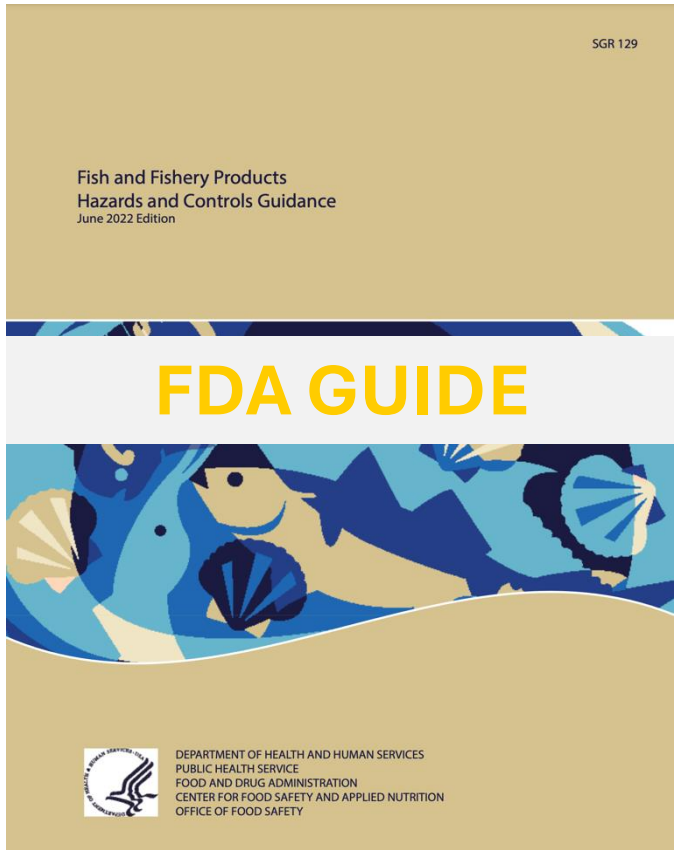
Controls: Glass containers are inspected and cleaned to prevent glass contaminating the food. Or work areas are inspected to identify when glass breakage has occurred.

HACCP Controls: Processors must inspect glass containers to detect breaking, cracking or other types of glass contamination to ensure that contaminated products are not sold. Or inspect the processing area around lines for broken glass to identify when contamination may have occurred.

# Seafood Hazards & Controls

Each ‘potential’ seafood safety hazard and recommendations for respective control options are briefly explained in the FDA Guide:

- How processors can determine which ‘potential’ hazards should be considered for their species and products.
- How the hazards and controls can vary for primary and secondary processors

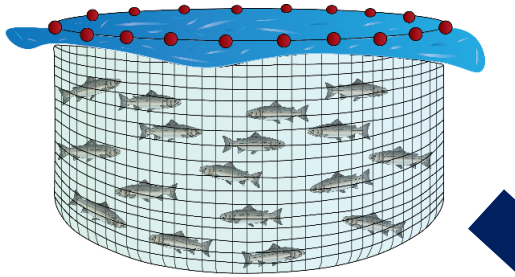



GOLD BOOK

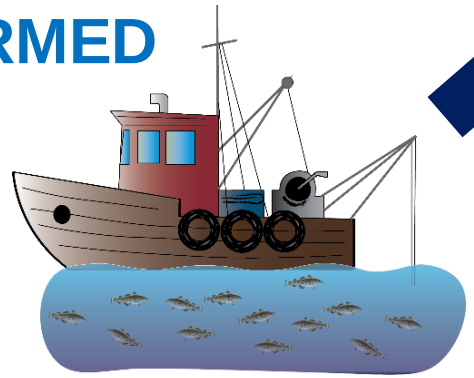
NOTE

**In HACCP regulations processors are responsible for Hazard Controls, so it is important to understand the difference between primary and secondary processing**

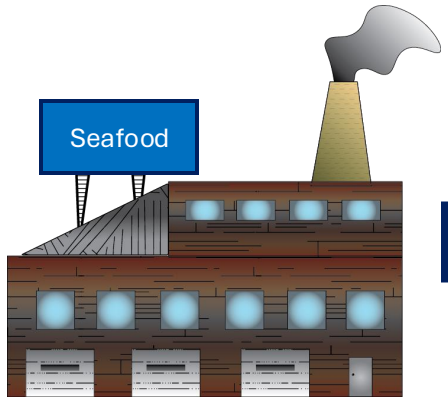
CHP 7: 125

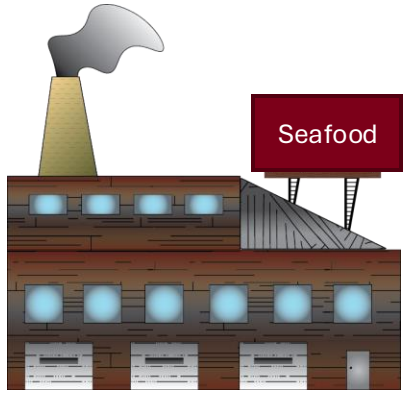


FARMED



WILD




**Primary Processor:**
first receiver from the fisherman or fish farm

**Secondary Processor:**
receives products from other processors

# Controlling Hazards

Once a processor identifies a hazard – species or process-related, they must implement a control strategy to control the hazard

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

CHP 7: 125

TABLE OF CONTENTS: **FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE** - JUNE 2022 EDITION






# Chapter Structure and Content

- Understand the Potential Hazard
- Determine whether the hazard is significant
- Identifying CCPs
- Develop a Control Strategy
  - Set Critical Limits
  - Establish Monitoring Procedures
  - Corrective Actions
  - Establish a Recordkeeping System
  - Establish Verification Procedures
- Example HACCP Plan(s)
- Bibliography

# Format of Chapters

1. General Background P 315

**Hazard Analysis**

2. Determine if Hazard is Significant P 320
3. Identify Critical Control Points P 320

**HACCP Plan**

4. Develop Control Strategies
   a. Set Critical Limits P 321
   b. Establish Monitoring Procedures P 321
   c. Establish Corrective Actions P 323
   d. Establish a Recordkeeping System P 323
   e. Establish Verification Procedures P 324

**Example Plan**

## CHAPTER DISSECTION

Gold Book

Example

Chapter 16 Pathogenic bacteria survival through cooking or pasteurization

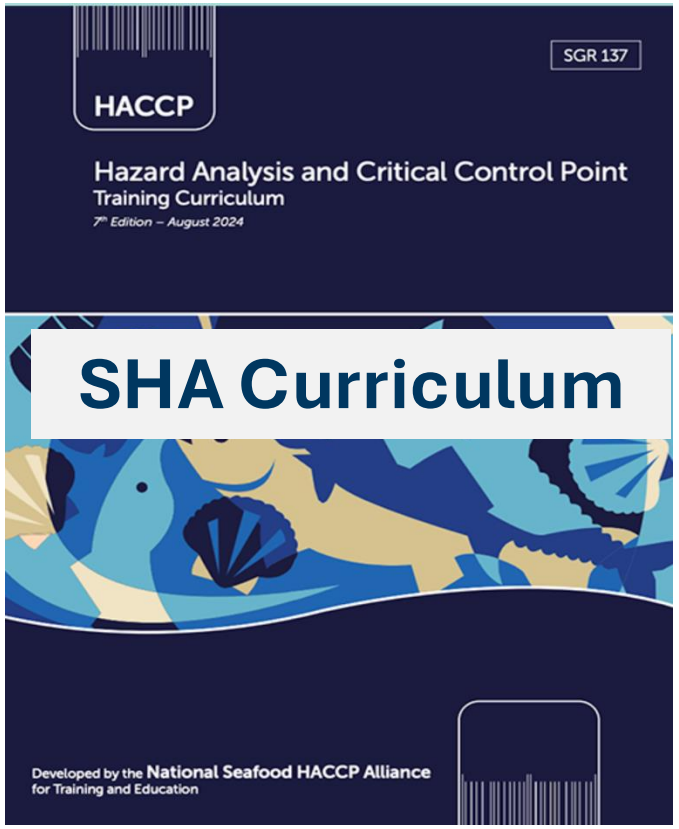
P 315

Hazard Analysis = CCPs

HACCP Plan = 

# Developing A HACCP Program

# Building the HACCP Plan




BLUE BOOK

The Blue Book provides an example for how to develop a HACCP Plan and its preliminary steps

Slide 2 **CHP4:69 Mahi-mahi Fillets**

Preliminary steps:

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

# Building the HACCP Plan


GOLD BOOK

The Segment 2 course will explain how the HACCP plan was developed using the recommendations in the

**FDA Guide**

# Preliminary Steps

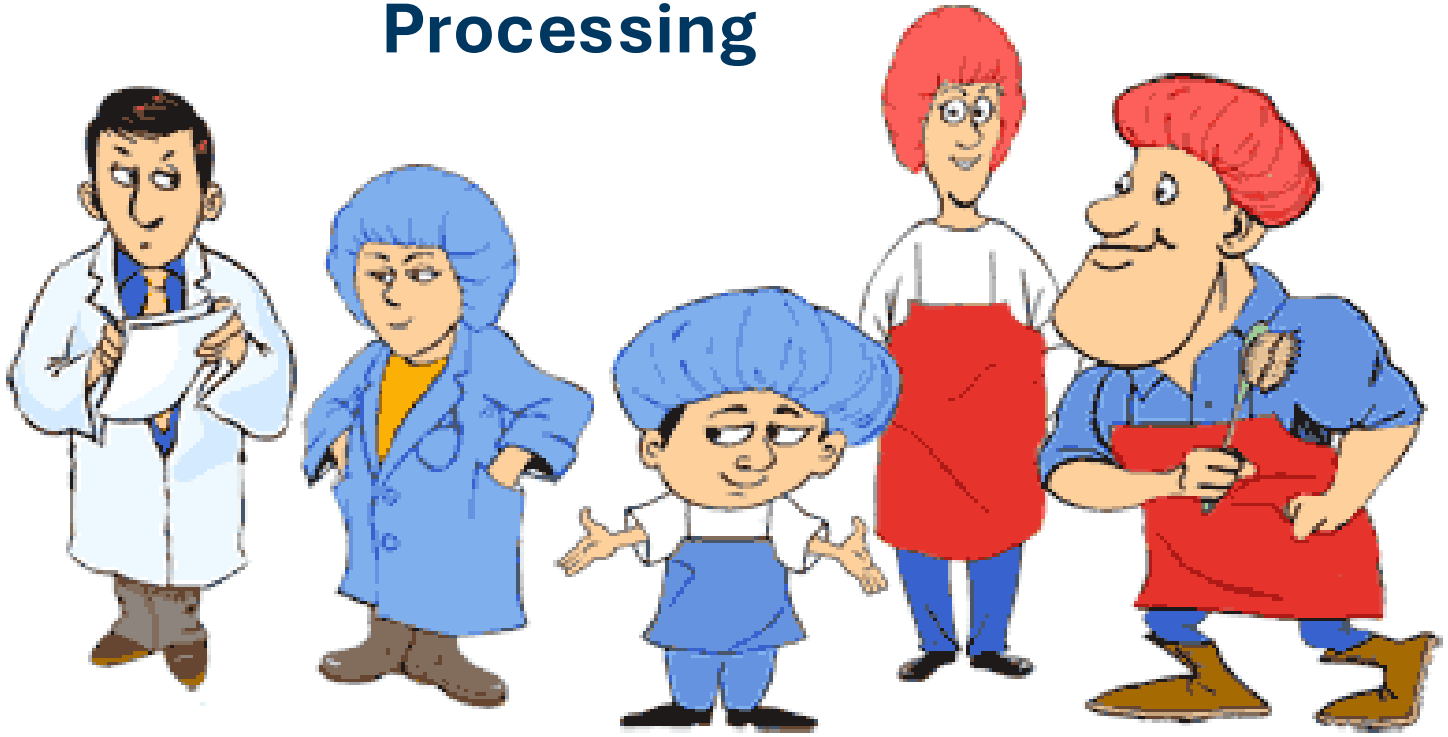
# Preliminary Step 1. Assemble the HACCP Team

Managers

Sanitation

Processing

CHP4: 74

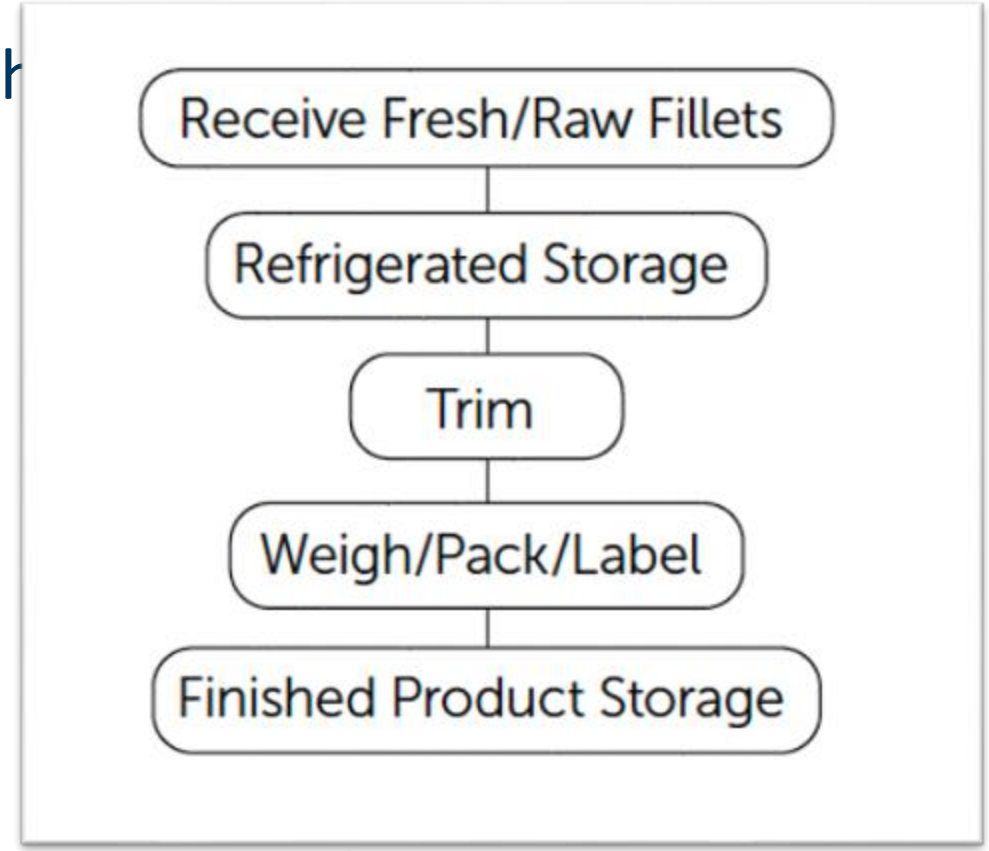


# Preliminary Step 2. Process Flow Chart

Develop a Process Flow Diagram and understand or describe what happens at each step (Process Narrative)

Example: Fresh Mahi-mahi fillets

CHP4: 75



# A brief processing narrative can be used to help explain the Processing Flow Chart (1 of 2)

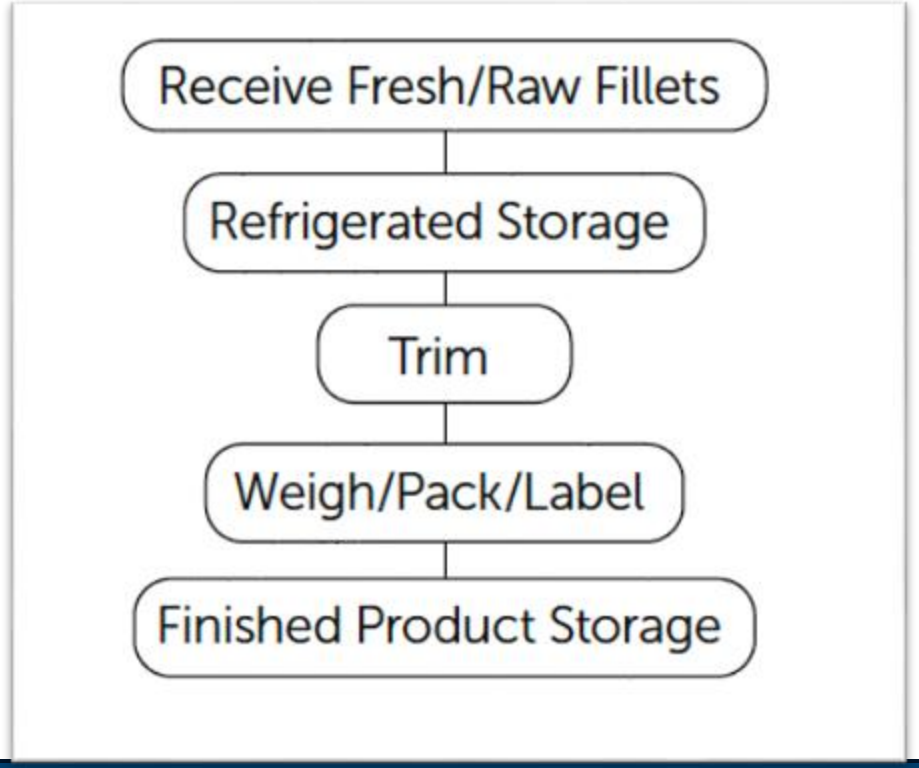
CHP4: 75-76

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

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

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

**Fresh/Raw mahi-mahi fillets process flow chart**



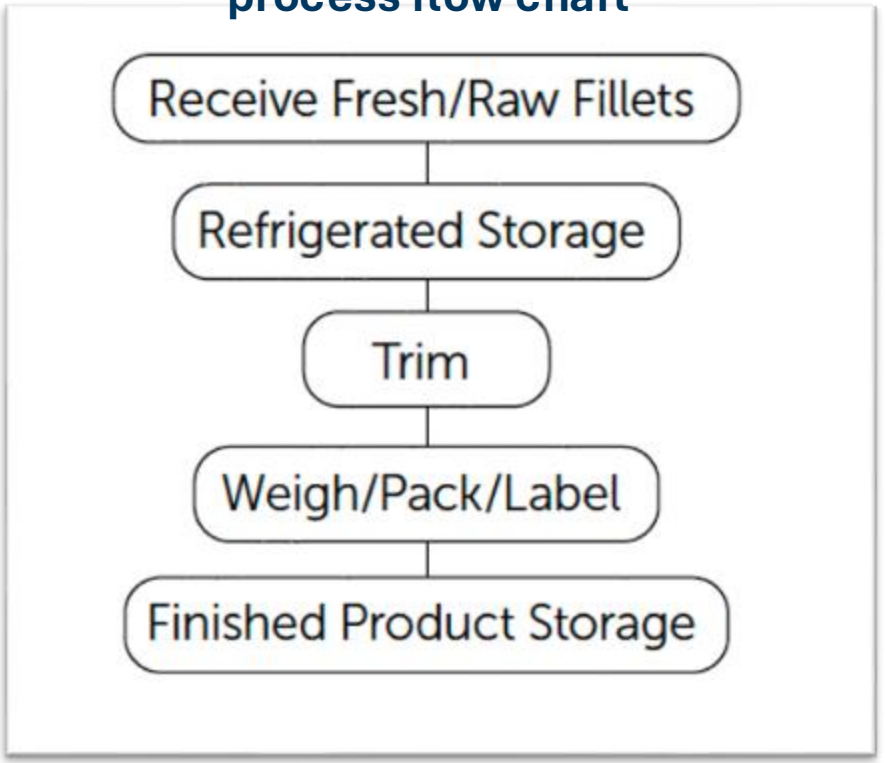
# A brief processing narrative can be used to help explain the Processing Flow Chart (2 of 2)

Weigh/Pack/Label – Per customer order, mahi-mahi fillets are weighed, packed into containers, and each container is labeled with a handwritten or printed label that contains the market name of the species of fish that it contains. Individual containers are completely surrounded by ice and assembled into master cartons for each customer order. The weigh/pack/label steps are completed in 30 minutes or less.

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

CHP4: 75-76

**Fresh/Raw mahi-mahi fillets process flow chart**



# Preliminary Step 3. Describe Product

CHP4: 74

XYZ Seafood Company Product Description Form for Fish and Shellfish Species

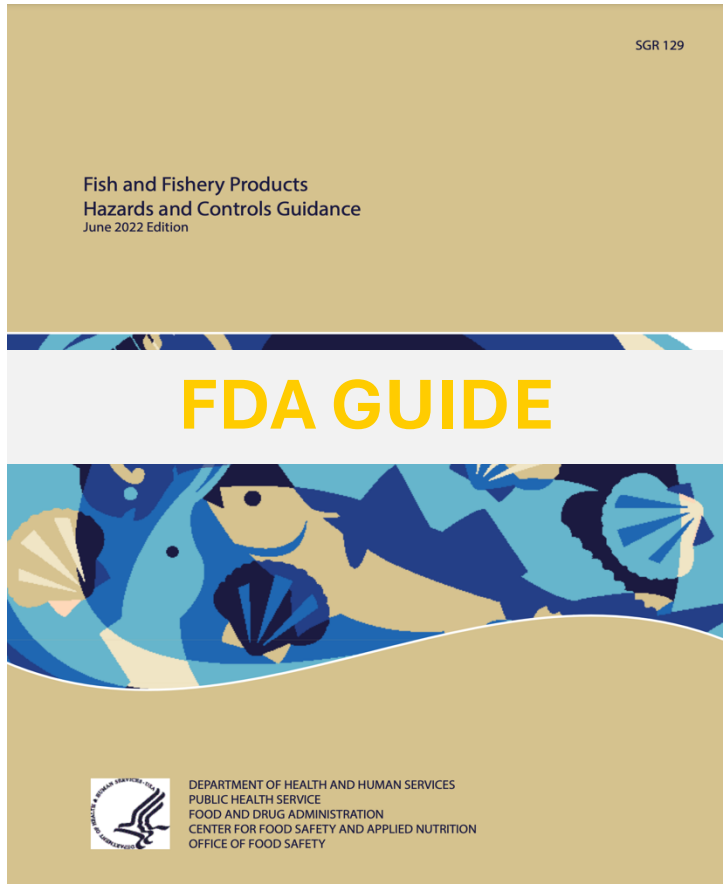
| Acceptable Market Name & Species | Where Product Is Purchased (Source) | | | How Product Is Received | | | | How Product Is Stored | | | | How Product Is Shipped | | | | How Product is Packaged | | Intended Use | | | Intended Consumer | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 | |
| | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |

Blue Book provides a useful form for preliminary information

Appendix 2: 226

# Hazard Analysis

# Required Hazard Analysis




**GOLD BOOK**

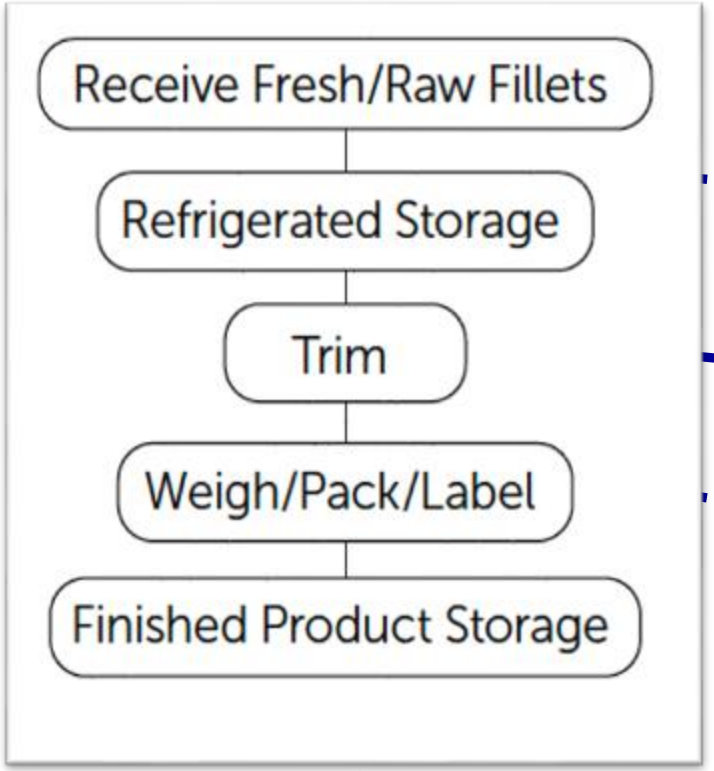
- Use the preliminary information
  - Process Description
  - Processing Flow Chart
  - Accompanying process narrative

with recommendations from the **FDA Guide** beginning with a Hazard Analysis Worksheet

Appendix 2: 227-228

# Hazard Analysis Worksheet

## Fresh/Raw mahi-mahi fillets process flow chart




### Hazard Analysis Worksheet

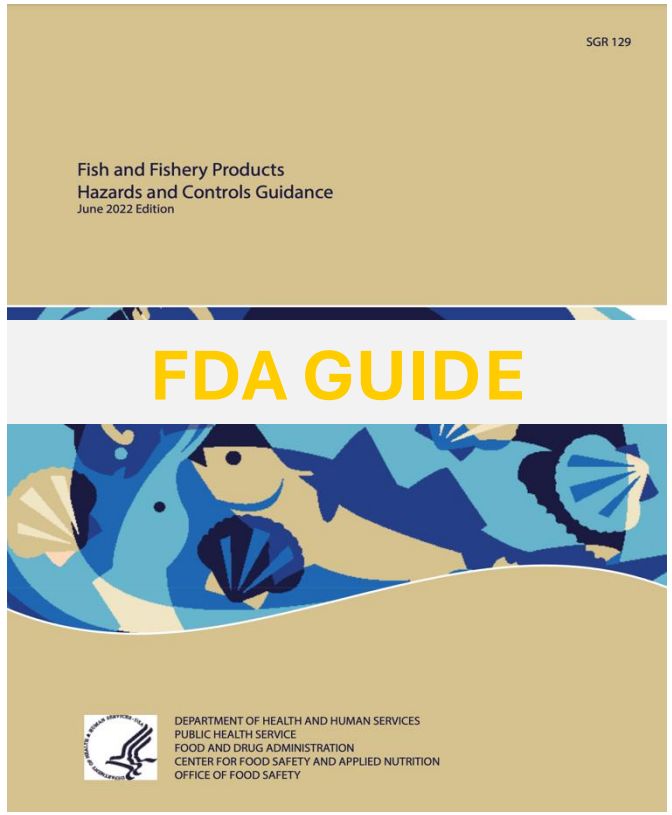
| | |
|---|---|
| **Firm Name: XYZ** Seafood Company | **Product Description:** Fresh/Raw mahi-mahi fillets |
| **Firm Location:** 238 Coastal Lane, Happy Beach, XX | **Method of Storage & Distribution:** Stored and distributed on ice |
| | **Intended Use & Consumer:** To be cooked and consumed by the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

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

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

Seafood HACCP Alliance

# Use the FDA Hazard Guide to help identify the potential hazards for analysis




**GOLD BOOK**

**AD1-3**

"… guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations …"

Recommendations lead to successful compliance

# Search for the potential hazards for the Fresh/Raw 'Wild' Mahi-mahi Fillets (XYZ Seafood Company)

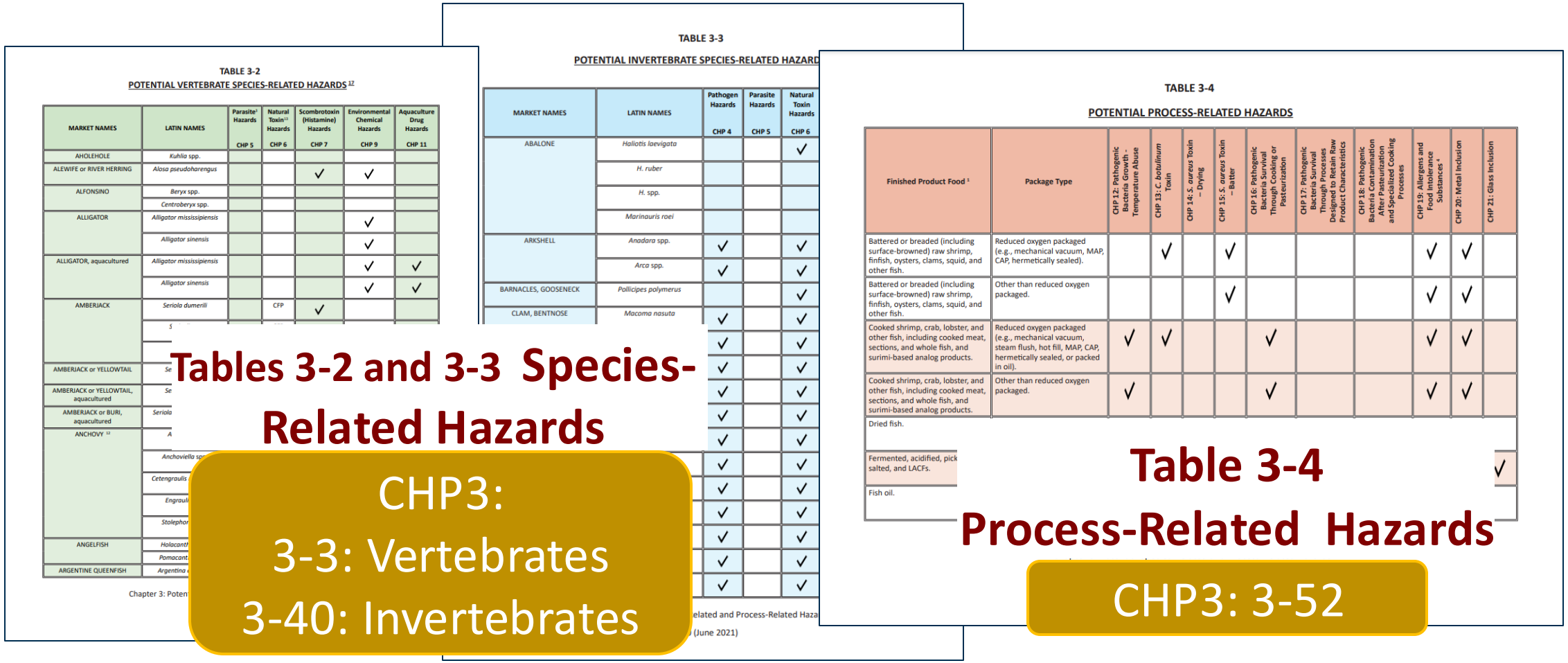


TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

| MARKET NAMES | LATIN NAMES | Parasite[1] Hazards CHP 5 | Natural Toxin[11] Hazards CHP 6 | Scombrotoxin (Histamine) Hazards CHP 7 | Environmental Chemical Hazards CHP 9 | Aquaculture Drug Hazards 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* | | | | | |
| AMBERJACK or YELLOWTAIL | *Se* | | | | | |
| AMBERJACK or YELLOWTAIL, aquacultured | *Se* | | | | | |
| AMBERJACK or BURI, aquacultured | *Seriola* | | | | | |
| ANCHOVY [12] | *A* | | | | | |
| | *Anchoviella sp* | | | | | |
| | *Cetengraulis* | | | | | |
| | *Engraul* | | | | | |
| | *Stolephor* | | | | | |
| ANGELFISH | *Holacanth* | | | | | |
| | *Pomacant* | | | | | |
| ARGENTINE QUEENFISH | *Argentina* | | | | | |

Chapter 3: Poten

TABLE 3-3
POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARD

| MARKET NAMES | LATIN NAMES | Pathogen Hazards CHP 4 | Parasite Hazards CHP 5 | Natural Toxin Hazards CHP 6 |
|---|---|---|---|---|
| ABALONE | *Haliotis laevigata* | | | ✓ |
| | *H. ruber* | | | |
| | *H. spp.* | | | |
| | *Marinauris roei* | | | |
| ARKSHELL | *Anadara spp.* | ✓ | | ✓ |
| | *Arca spp.* | ✓ | | ✓ |
| BARNACLES, GOOSENECK | *Pollicipes polymerus* | | | ✓ |
| CLAM, BENTNOSE | *Macoma nasuta* | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |
| | | ✓ | | ✓ |

elated and Process-Related Haza
(June 2021)

TABLE 3-4
POTENTIAL PROCESS-RELATED HAZARDS

| Finished Product Food [1] | Package Type | CHP 12: Pathogenic Bacteria Growth - Temperature Abuse | CHP 13: *C. botulinum* Toxin | CHP 14: *S. aureus* Toxin – Drying | CHP 15: *S. aureus* Toxin – Batter | CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization | CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics | CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes | CHP 19: Allergens and Food Intolerance Substances [4] | CHP 20: Metal Inclusion | CHP 21: Glass Inclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish. | Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed). | | ✓ | | ✓ | | | | ✓ | ✓ | |
| Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish. | Other than reduced oxygen packaged. | | | | ✓ | | | | ✓ | ✓ | |
| Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and surimi-based analog products. | Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil). | ✓ | ✓ | | | ✓ | | | ✓ | ✓ | |
| Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and surimi-based analog products. | Other than reduced oxygen packaged. | ✓ | | | | ✓ | | | ✓ | ✓ | |
| Dried fish. | | | | | | | | | | | |
| Fermented, acidified, pick salted, and LACFs. | | | | | | | | | | | ✓ |
| Fish oil. | | | | | | | | | | | |

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

CHP3:
3-3: Vertebrates
3-40: Invertebrates

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

CHP3: 3-52

# One Species-related hazard

Table 3-2
Page 3-21

**TABLE 3-2**

**POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS** [17]

| MARKET NAMES | LATIN NAMES | Parasite[3] Hazards CHP 5 | Natural Toxin[13] Hazard CHP 6 | Scombrotoxin (Histamine) Hazards CHP 7 | Environmental Chemical Hazards CHP 9 | Aquaculture Drug Hazards CHP 11 |
|---|---|---|---|---|---|---|
| MACKEREL, SPANISH | *Scomberomorus* spp. | ✓ | | ✓ | | |
| MACKEREL, SPANISH or CERO | *Scomberomorus regalis* | ✓ | CFP | ✓ | | |
| MACKEREL, SPANISH or KING | *Scomberomorus cavalla* | ✓ | CFP | ✓ | | |
| MACKEREL, SPANISH or NARROW-BARRED | *Scomberomorus commerson* | | CFP | ✓ | | |
| MAHI-MAHI | *Coryphaena* spp. | | | ✓ | | |
| MAHI-MAHI, aquacultured | *Coryphaena* spp. | | | ✓ | ✓ | ✓ |

# Four Process-related Hazards

Notice two hazards in Chapter 19

Table 3-4

| Finished Product Food [1] | Package Type | CHP 12: Pathogenic Bacteria Growth - Temperature Abuse | CHP 13: *C. botulinum* Toxin | CHP 14: *S. aureus* Toxin – Drying | CHP 15: *S. aureus* Toxin – Batter | CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization | CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics | CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes | CHP 19: Allergens and Food Intolerance Substances [4] | CHP 20: Metal Inclusion | CHP 21: Glass Inclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fully cooked prepared foods. | Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil). | ✓ | ✓ | | | ✓ | | | ✓ | ✓ | ✓ |
| Fully cooked prepared foods. | Other than reduced oxygen packaged. | ✓ | | | | ✓ | | | ✓ | ✓ | ✓ |
| Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products. | Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP hermetically sealed, or packed in oil). | ✓ | ✓ | | | ✓ | | ✓ | ✓ | ✓ | |
| Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products. | Other than reduced oxygen packaged. | ✓ | | | | ✓ | | ✓ | ✓ | ✓ | |
| 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. | ✓ | | | | | | | ✓ | ✓ | |

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

- Species-related Hazards (Table 3-2)

1. Histamine formation CHP 7

- Process-related Hazards (Table 3-4)

2. Pathogenic bacterial growth-temperature abuse CHP 12
3. Allergens CHP 19
3. Food Intolerance Substances CHP 19
4. Metal inclusion CHP 20

# Inclusive Method

**List <u>every</u> potential hazard at <u>each</u> processing step**

**Hazard Analysis Worksheet**

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

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

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

# 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 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 | | | | |

**Answer the questions, in order, for each listed potential hazard at each processing step using the appropriate chapter of the FDA Guide.**

**The FDA Guide provides information in the respective hazard chapters to help determine if the hazard is reasonably likely to occur and recommendations for control strategies.**

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

| Hazard Analysis Worksheet | | | | |
|---|---|---|---|---|
| (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 this significant hazard? |
| Receive Fresh/Raw Fillets | Histamine | Yes CHP7: 121 | If the product does not remain sufficiently chilled, histamine could form | Mahi-mahi fillets are shipped in tubs or containers completely surrounded by ice (Proper Icing) CHP7: 123 |
| | Pathogen Growth due to Temperature Abuse | No CHP12: 214 | Product will be cooked prior to consumption | N/A CHP 12 |
| | Allergens | Yes CHP19: 19-6 | Fish is one of the top 8 food allergens | Will be controlled at labeling (Proper Labeling) CHP19: 19-7 |
| | Food Intolerance Substances | No CHP19: 19-6 | No FIS used or added in this processing operation | N/A CHP 19 |
| | Metal Inclusion | No CHP20: 386 | Not likely to occur at this step | N/A CHP 20 |

# Completed Hazard Analysis Worksheet

## Page 1

Completed Hazard Analysis 105-107

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

**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 | |
| | 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 | | YES |
| | 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 |
| | 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 Worksheet

## Page 2

Completed Hazard Analysis 105-107

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

| | | | | | |
|---|---|---|---|---|---|
| Trim | Histamine | NO | Not likely to occur, time at this step is 30 min or less | | |
| | Pathogen Growth-Temp. Abuse | NO | Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption | | |
| | Undeclared Food Allergens | YES | Mahi is a food allergen | Containers of fillets will be labeled with market name at labeling step | NO |
| | Food Intolerance Substances | NO | No FIS used or added to the fresh fish | | |
| | Metal Inclusion | NO | Fillet knifes are not likely to chip and contaminate product with metal | | |
| Weigh/Pack/ Label | Histamine | NO | Not likely to occur, time at this step is 30 min or less | | |
| | Pathogen Growth-Temp. Abuse | NO | Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption | | |
| | Undeclared Food Allergens | YES | Mahi is a food allergen | Fillets are labeled with market name at this step (proper labeling) | YES |
| | Food Intolerance Substances | NO | No FIS used or added to the fresh fish | | |
| | Metal Inclusion | NO | Not likely to occur at this step | | |
| Finished Product Refrigerated Storage | Histamine | YES | Time/temp. abuse could occur during storage | Mahi fillets are buried in ice & stored in a refrigerated cooler (proper icing) | YES |
| | Pathogen Growth-Temp. Abuse | NO | Not likely to cause illness as the intended use of the product is to be cooked by or for the consumer prior to consumption | | |
| | Undeclared Food Allergens | NO | Fillets are labeled with market name at weigh/pack/label step | | |
| | Food Intolerance Substances | NO | No FIS used or added to the fresh fish | | |
| | Metal Inclusion | NO | Not likely to occur at this step | | |

CCP

CCP

# Conclusions from the Hazard Analysis

- Histamine is a significant food safety hazard and there are three CCPs for this hazard:

  CCP 1. Receive fresh fish

  CCP 2. Refrigerated storage, and

  CCP 3. Finished product refrigerated storage

- Food allergens is a significant food safety hazard and there is one CCP for this hazard:

  CCP 4. Weigh/Pack/Label

# Building HACCP Plan


# Building the HACCP Plan

Seafood HACCP Alliance

## 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: |
|---|---|

Appendix 2

# Optional HACCP Plan Forms
## (both must contain same information)

Appendix 2:
101 and 102

Seafood HACCP Alliance

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

Landscape

| Firm Name: XYZ Seafood Company | Product: Fresh Mahi-Mahi Fillets |
|---|---|
| Address: 238 Coastal Lane, Happy Beach, XX | Method Storage & Distribution: Stored and distributed on ice |
| Signature: Xxxxxxxxxxxx<br>Printed: Xxxxxxxxxx | Intended Use: To be cooked and consumed by the general public<br>Date: (-*signed date*-) |

| | CCP number 1 |
|---|---|
| Critical Control Point (CCP) | RECEIVING |
| Significant Hazard | Histamine |
| Critical Limits | |
| Monitoring — When | |
| Monitoring — Who | |
| Corrective Action | |
| Verifications | |
| Records | |

Portrait

# Set up 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 |
| | Food Intolerance Substances | No | No FIS are used on fresh fillets | | |
| | Metal Inclusion | No | Not likely to occur at this step | | |

*XYZ Seafood Company* — **HACCP Plan Form** — *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**

# Principle 3: Set Critical Limits using the FDA Hazards Guide

CHP 7: 125

**CONTROL STRATEGY** selected from the FDA Guide

CCP – Receiving
Hazard - Histamine

Example 3
CHP 7: 137

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

# Principle 3: Set Critical Limits using the FDA Hazards Guide

- **TRANSIT CONTROL OPTIONS (Example 3)**
  Critical limits will depend on how product is received.

1. Fish delivered refrigerated (not frozen), **or**
2. Fish delivered under ice, **or**
3. Fish delivered under ice on an open-bed truck, **or**
4. Fish delivered under chemical cooling media, **or**
5. Fish delivered refrigerated (not frozen) with transit time of 4 hours or less

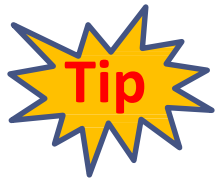
CHP 7: 137

# Principle 3: Set Critical Limits using the FDA Hazards Guide

- **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

CHP 7: 137




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

# Principle 3: Establish CRITICAL LIMITS

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Records |
|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | Who | | |
| Receiving | Histamine | Tubs 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 | | | | | | |
| Finished Product Refrigerated Storage | Histamine | Containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | | | | | | |

CHP7: 109

Receiving - Transit Control
Example 3 - CHP 7: 137

**Based on recommendations in the FDA Guide**

# Principle 4: Establish Monitoring Procedures

Follow the same option selected for Critical Limits

**Example:** Control Strategy = Transit control

**Critical Limit Option:** Surrounded by ice

CHP 7: 137-139

- **What** will be monitored?
- **How** will monitoring be done?
- **How often** will monitoring be done (frequency)?
- **Who** will do the monitoring?

# Principle 4: Establish CCP MONITORING

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | 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 comparision of the label again 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 | | | |

CHP8: 119

Example 3
CHP 7: 137-139

**Based on FDA Guide**

# Principle 5: Establish Corrective Actions

Follow the same option selected for Critical Limits

Example: Control Strategy = Transit control

Critical Limit Option:  Surrounded by ice

CHP 7: 139

Corrective Actions must cover two parts that include actions to assure safe products and to fix the problem before further processing

# Principle 5: CORRECTIVE ACTIONS (Page 1 of 2)

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | 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<br>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;<br>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. | | |

CHP 9: 129

Example 3
CHP 7: 139

# Principle 5: CORRECTIVE ACTIONS (Page 2 of 2)

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | Who | | | |
| Weight/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. | Packaging 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. | | |
| Finished Product Refrigerated Storage | Histamine | 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 workday | 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 | | |

# Principle 6: Establish Verifications

Select the Verification options that apply to the critical limit chosen:

- Weekly record review applies to all options
- Periodic check of internal temperature of fish to ensure ice keeps below 40° F
- Thermometers must be checked for accuracy and periodically calibrated
- Annual Review of HACCP Plan

CHP 7: 139 - 140

# Principle 6: VERIFICATIONS (Page 1 of 2)

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | 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<br>**Then:** reject product, and ca 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.<br>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.<br>Annual calibration of thermometer used to check internal temp. | |
| 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;<br>**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.<br>Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use.<br>Annual calibration of thermometer used to check internal temp. | |

CHP10: 141

Example 3 CHP 7: 139 -140

# Principle 6: VERIFICATIONS (Page 2 of 2)

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | Who | | | |
| Weight/Pack/ Label | Food Allergens | All finished product containers will be labelled with the correct market name of the fish. | The marketname 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. | Packaging manager | **If:** a container is improperly labelled. **Then**: Hold and isolate labelled products since the last acceptable inspection of labels; inspect 100% of affected products and relabeled mislabeled products; inspect remaining labels staged for use; and remove inaccurate labels from the 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. | |
| Finished Product Refrigerated Storage | Histamine | 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 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 temperature. | |

# Principle 7: Establish Record Keeping Procedures

Enter the name of the records that will be kept for that CCP on the HACCP Plan Form

Your Records must be designed to meet the requirements of 21 CFR Part 123.9 to document the results of the Monitoring, Corrective Action, and Verification components of the HACCP Plan

CHP 7: 139

# Principle 7: RECORDS (Page 1 of 2)

CHP11:159

Example 3
CHP 7: 139

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | 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<br>**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.<br>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.<br>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.<br>Corrective Action records<br>Verification Record<br>• Accuracy Check Log<br>• Calibration Log |
| Refrigerated Storage | Histamine | Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time. | Adequacy of ice surrounding tubs or containers of mahi-mahi fillets | Visual check of adequacy of ice in a representative number of containers in cooler storage | At the beginning and end of the workday | Cooler Manager | **If:** the amount of ice is not adequate;<br>**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.<br>Check internal temperature of fish quarterly to ensure that ice maintains product temperature<br>Check the accuracy of the thermometer before each use.<br>Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice.<br>Corrective Action records<br>Verification Records<br>• Accuracy Check Record<br>• Annual Calibration Log |

# Principle 7: RECORDS (Page 2 of 2)

CHP11:159

| CCP | Hazard | Critical Limits for each Control Measure | Monitoring | | | | Corrective Action | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | When | 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. | Packaging 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. | Packing Room Log that documents: the number of containers checked, the number of containers in the order, and the results of the label check. Corrective Action records Verification Records |
| 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:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it. | Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice. Corrective Action records Verification Records<br>• Accuracy Check Record<br>• Annual Calibration Log |

# Complete HACCP

CHP11: 181-187

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 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. | 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 record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage, and the results of checks for adequacy of ice. Corrective Action records Verification Records • Accuracy Check Record • Annual Calibration Log |

| | Corrective Action | Verification | Records |
|---|---|---|---|
| ho | | | |
| er | **If:** finished product containers do not have adequate ice; **Then:** chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations, and determine if there is a problem with the cooler and fix it. | Weekly review of Cooler Ice Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish quarterly to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp. | Cooler Ice Log that documents: the number of containers examined, the approximate number of containers in storage and the ~~results of checks for~~ adequacy of ice. ~~Corrective Action records~~ ~~Verification Records~~ • Accuracy Check Record • Annual Calibration Log |

/Raw Mahi-Mahi Fillets

**rage and Distribution:** Stored and distributed buried in ice

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

# HACCP Plans can be built for any Hazard in the same way using the appropriate chapter in the FDA Hazards Guide

- ✓ Select the Control Strategy that applies to your situation & CCP
- ✓ Select one or more Critical Limit options for your situation
- ✓ Follow the same option(s) to determine Monitoring, Corrective Action, Verification and Record keeping procedures

# Other Resources in the FDA Hazards Guide

- Appendices 1-3 (A1-1, A2-1, & A3-1) Blank Forms, flow diagram, and CCP decision tree.
- Appendix 4 (417) Bacterial Pathogen Growth and Inactivation Tables A-1 to A-4.
- Appendix 5 (A5-1) FDA & EPA Safety Levels in Regulations and Guidance.
- Appendix 9 & 10 (A9-1 & A10-1) Allergen cleaning, sanitation and cross-contact prevention.
- Appendix 11 & 12 (A11-1 & A12-1) Approved and unapproved aquaculture drugs.
- Addendums 1 & 2 (AD1-1 & AD2-1) Fish and Fishery Products (21 CFR 123) and Control of Communicable Diseases (21 CFR 1240.60) [Formerly Appendix 8] and cGMP Regulation.

# WORK SESSIONS

- Each group will:
- Get organized: choose a leader, scribe & presenter
- Read and review the Preliminary Steps Handout (product description, process narrative, & process flow chart for the model)
- Conduct Your Hazard Analysis:
  - Set up a Hazard Analysis Worksheet (fill in heading & Column 1 – enter all process steps from Process Flow Diagram)
  - Look up all potential Species & Process Hazards in **Tables 3-2, 3-3 & 3-4 in the FDA Hazards Guide** and enter results in Column 2
  - Determine which potential hazards are significant using **Chapters 4-21 of the FDA Hazards Guide** and enter results in Columns 3 and 4
  - For all significant hazards (YES in column 3) identify control measures in Column 5
  - Determine if each step is a CCP for the significant hazards that you have identified using **Chapters 4-21 of FDA Hazards Guide**
  - Every 'Yes' in Column 3 requires responses in Column 4,5, and 6 (Identified CCPs).

# WORK SESSIONS -continued

Each group will:

Develop a HACCP Plan for each significant hazard at each CCP identified in the Hazard Analysis by completing the following:

- Set up a HACCP Plan Form by filling in company & product information and columns 1 and 2 (CCP and Hazard)
- Identify a Control Strategy and the corresponding Critical Limit using **Chapters 4-21 in FDA Hazards Guide** and enter result in Column 3
- Complete the HACCP Plan Form by identifying the appropriate monitoring, corrective action, verification and records associated with the Control Strategy that was selected from **Chapters 4-21**. Enter the results in Columns 4-10 of the HACCP Plan Form

Finalize your group's results for presentation to the rest of the class and determine who from your group will do the presentation.

# WORK SESSIONS -continued

Finally, to complete the learning process,

Each group will present results for their Hazard Analysis and HACCP plan for open discussion

# 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.

# QUESTIONS

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

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