

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:

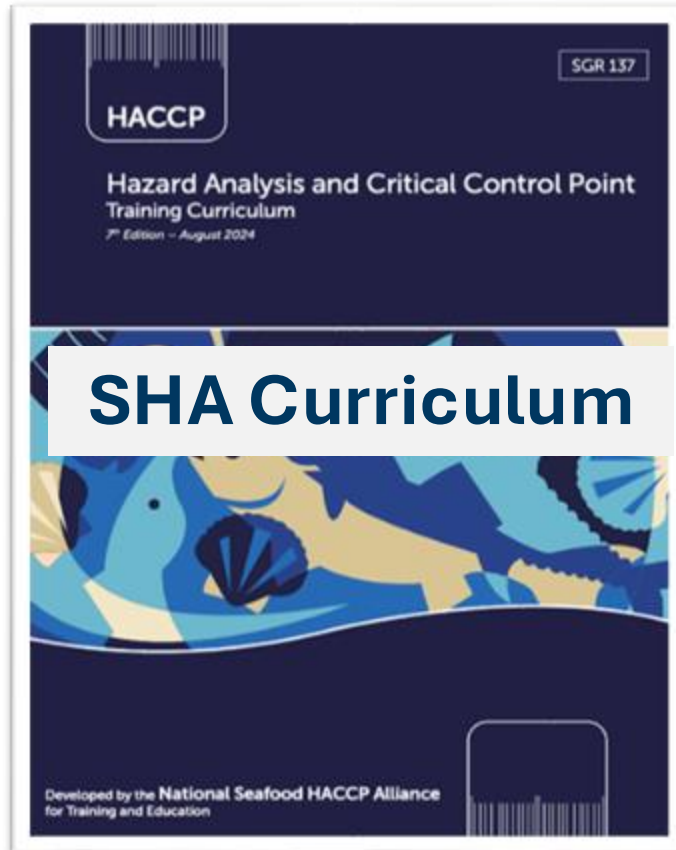
- Conduct a Hazard Analysis
- Develop a HACCP Plan for seafood products as required by the FDA regulation
- Reassess or modify a HACCP Plan as necessary and/or required by the FDA regulation
- Review HACCP Plan records as required by the FDA regulation

Expectations for Training

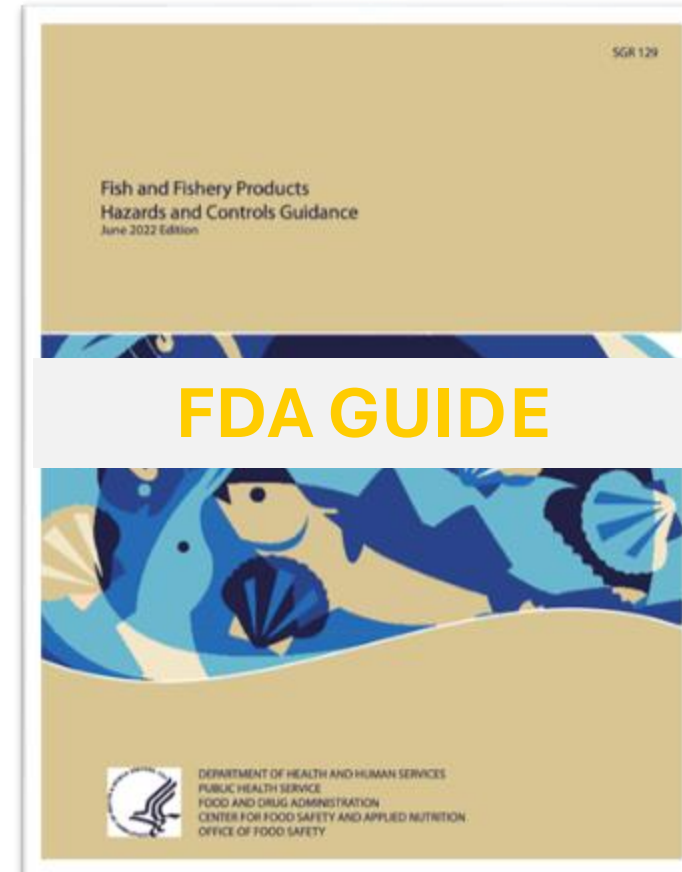
Seafood HACCP Alliance courses provide:

- 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



BLUE BOOK



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

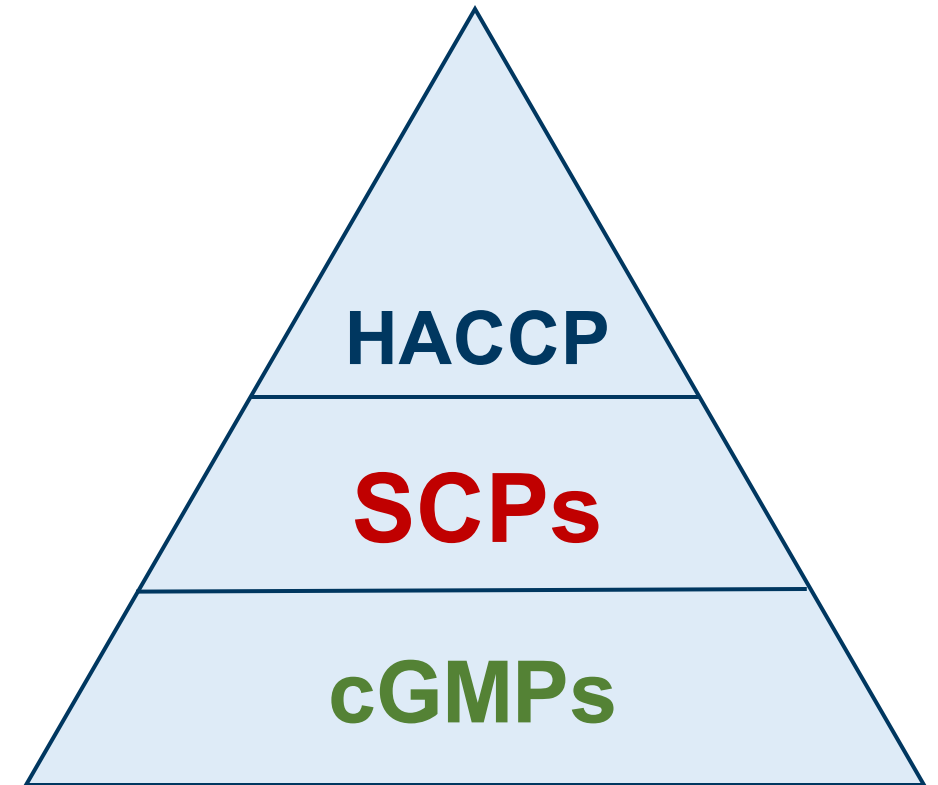
CHP 12: 191

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.

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



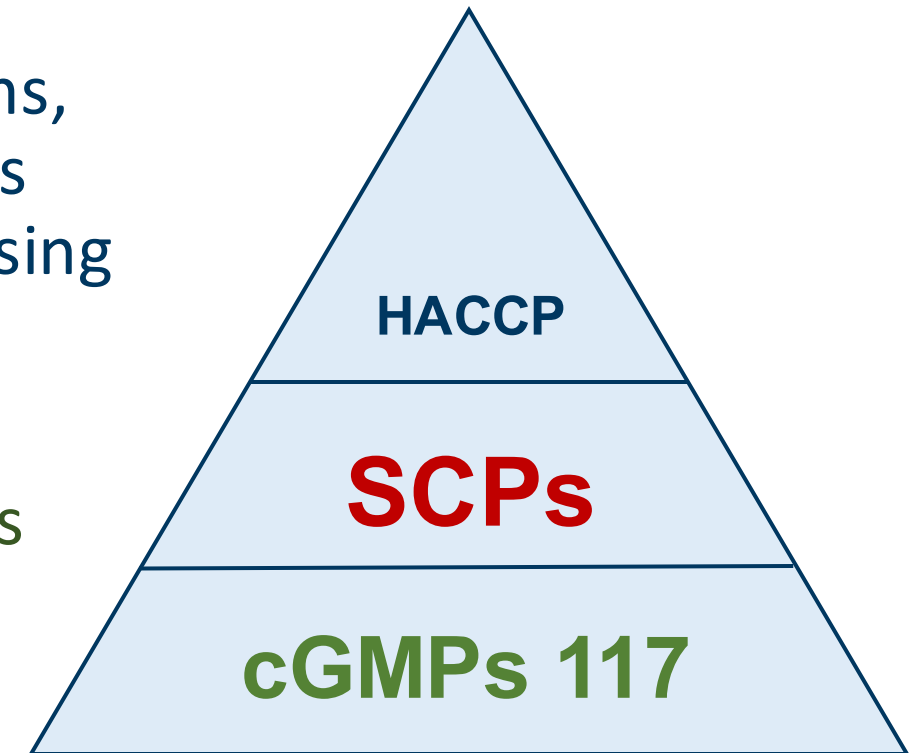
CHP 1: 7

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)

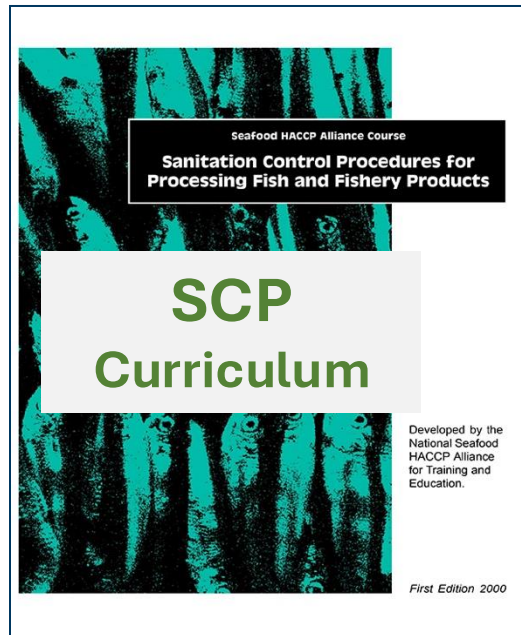
Processors **must** monitor and keep records of monitoring results and corrections for **8 key areas of sanitation**:

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

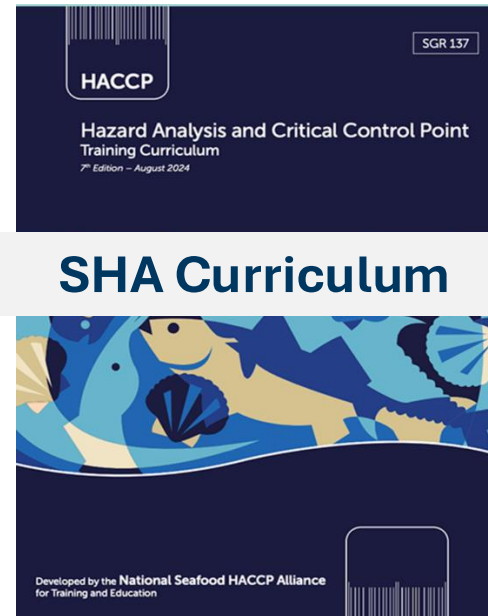
AD1 - 8

Sanitation Control Procedures (SCPs)



GREEN BOOK

SSOP-4 to SSOP-16



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

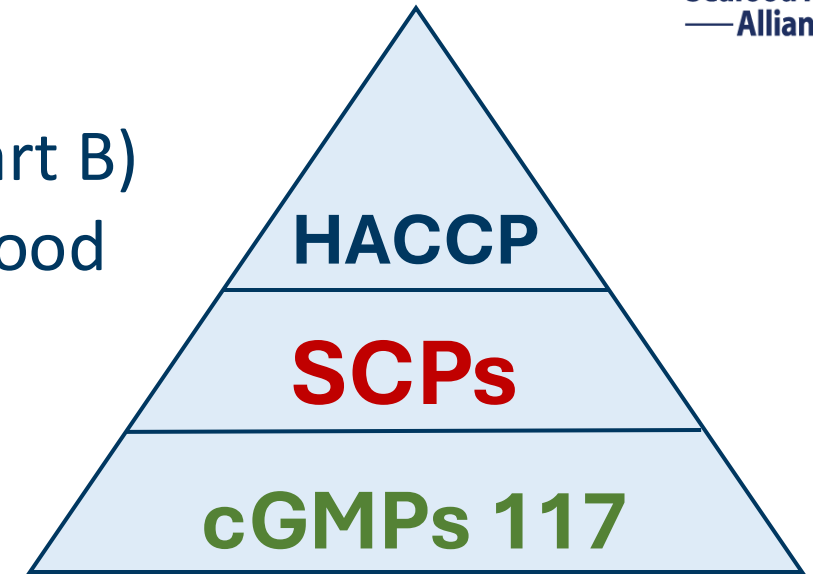
*S = Satisfactory / U = Unsatisfactory

Source: Florida Sea Grant <https://www.flseagrant.org/seafood/haccp/>

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

Group Employee Training Record	
Course: <i>Personnel Hygiene and Food Safety Level 1</i>	Location: <i>Headquarters</i>
DATE COMPLETED: <i>April 15, 2017</i>	SIGNED <i>Ben Smith, Supv. No. 1</i>

EMPLOYEES
<i>Nancy Doherty - Packing and Labeling</i>
<i>Anybody Jones - Shrimp cooker belt</i>
<i>Wei Not - Recv Dock</i>
<i>Bettie Done - Throwing</i>

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...

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

Species Hazards

Process Hazards

CHP 3: 3-2

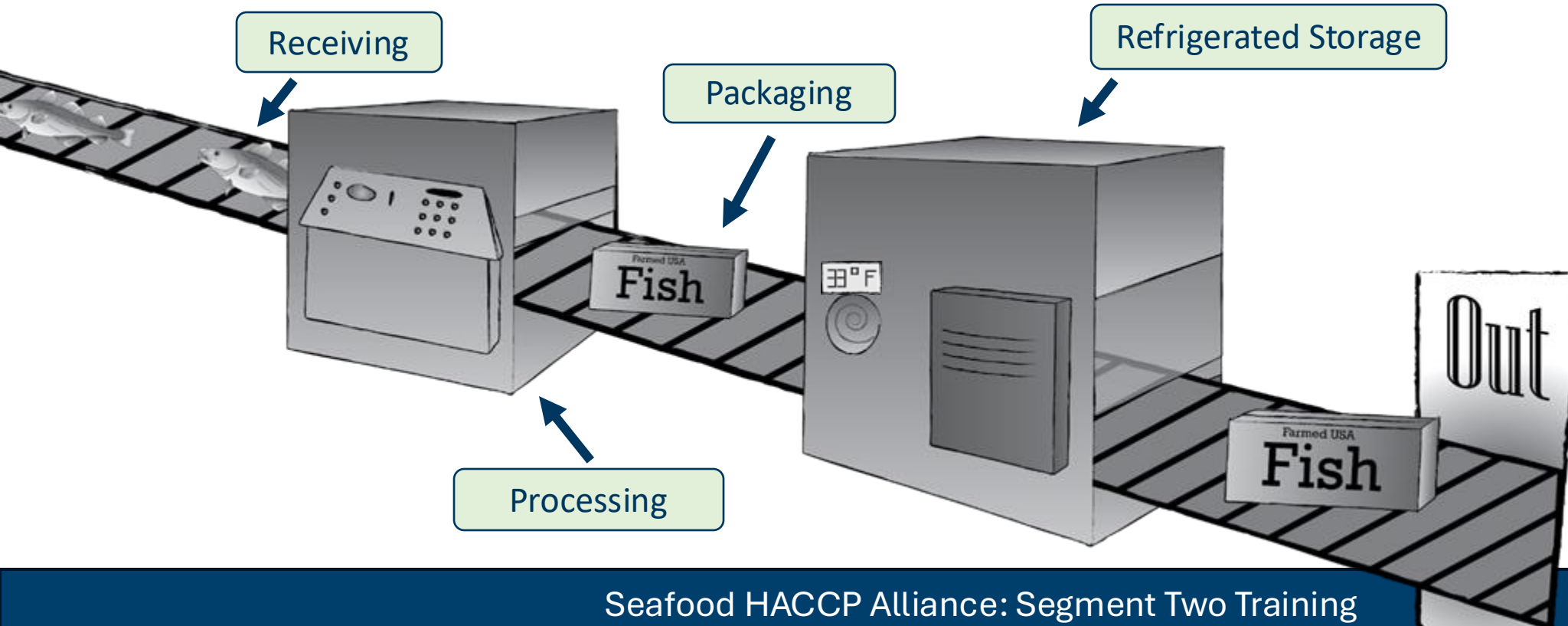
CHP 3: 3-4

CHP 3: 3-3

Seafood HACCP Alliance: Segment Two Training

Principle 2: Identify Critical Control Points (CCPs)

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

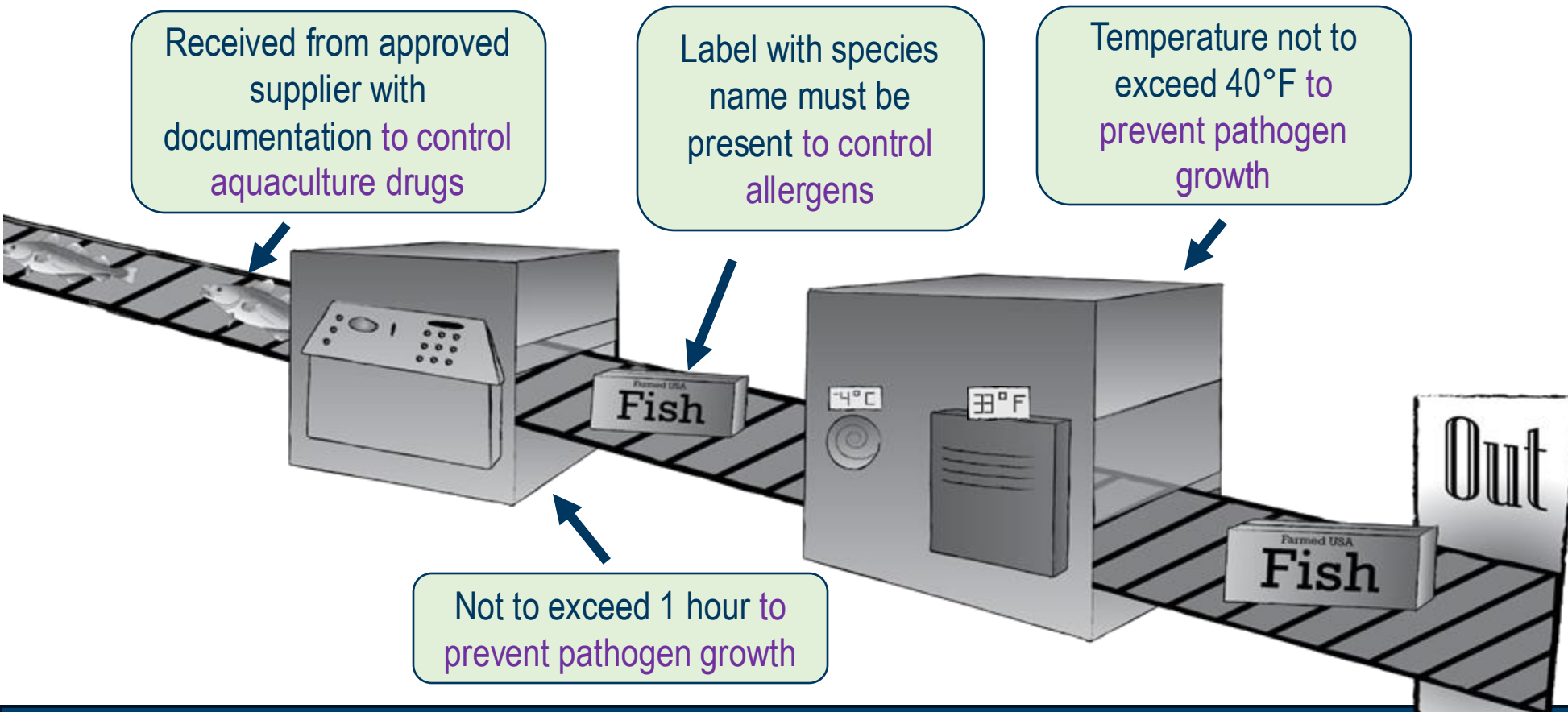


CHP 6: 99

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

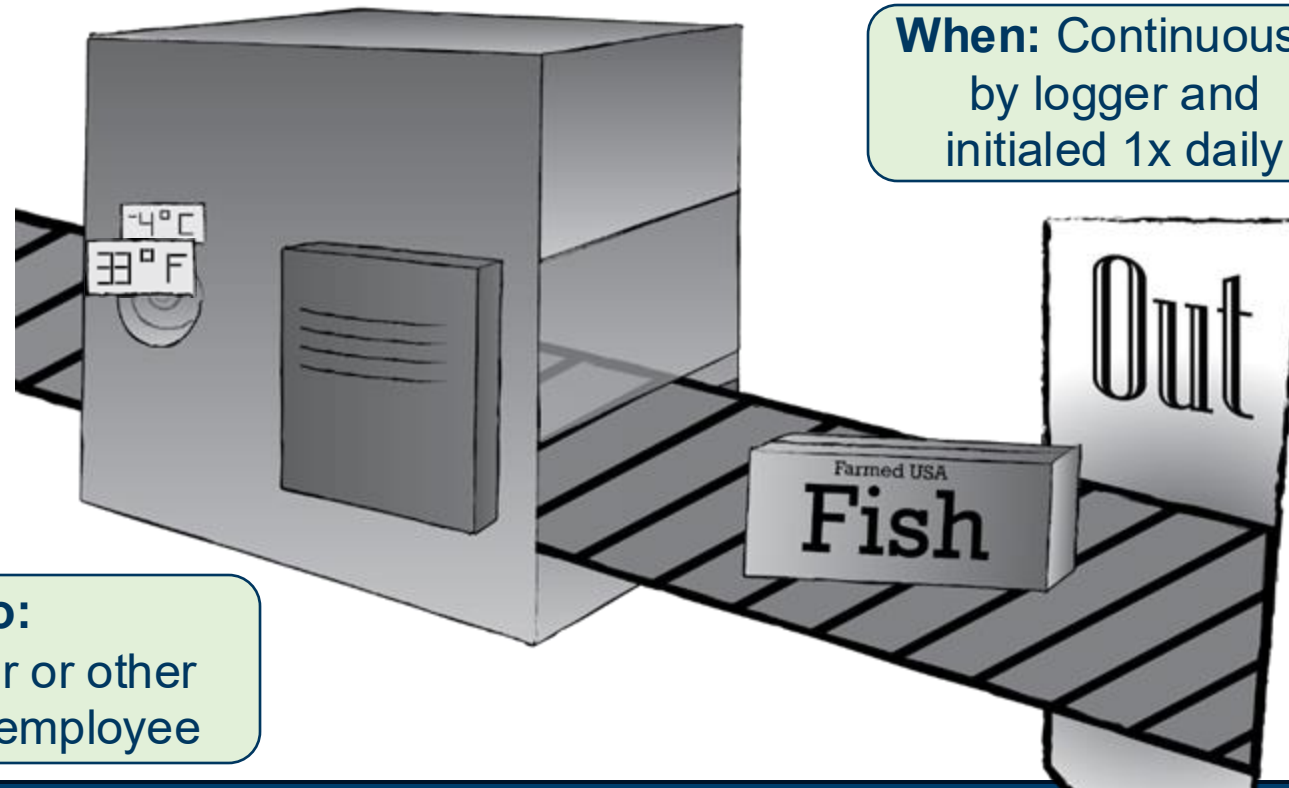


Determine **what** will be monitored, **how** it will be monitored, **when** it will be monitored and by **who**.

What: Temperature



Who:
QA Manager or other
designated employee



When: Continuously
by logger and
initialed 1x daily

CHP 8:119

CHP 2: 26

How: Temperature
Logger

Principle 5: Establish Corrective Actions

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

If: Temperature exceeds
40°F.

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

CHP 9: 129

CHP 2: 27



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



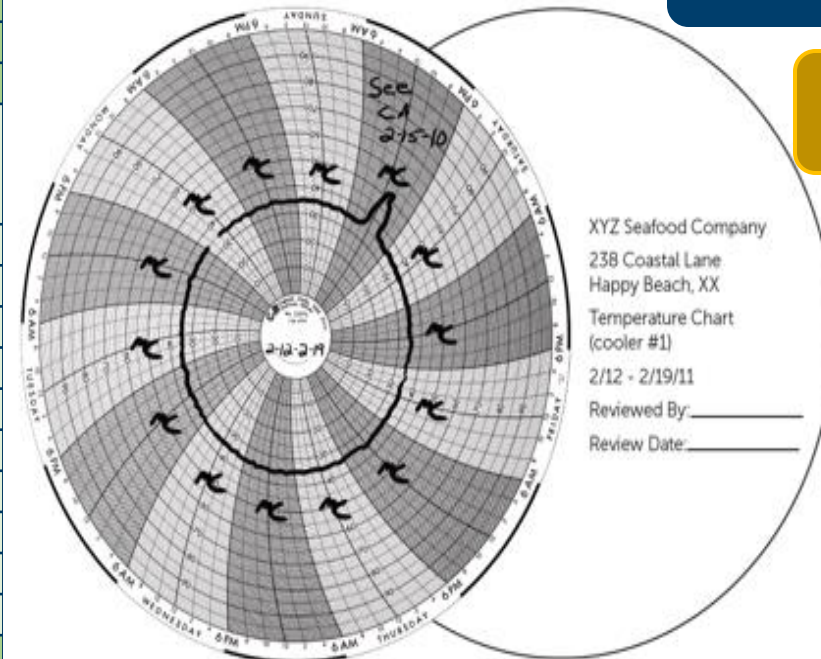
Principle 7: Establish Recordkeeping Procedures

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



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)
Reviewer Signature:			Date of Review:		

Continuous Temperature Record with Periodic Monitoring.

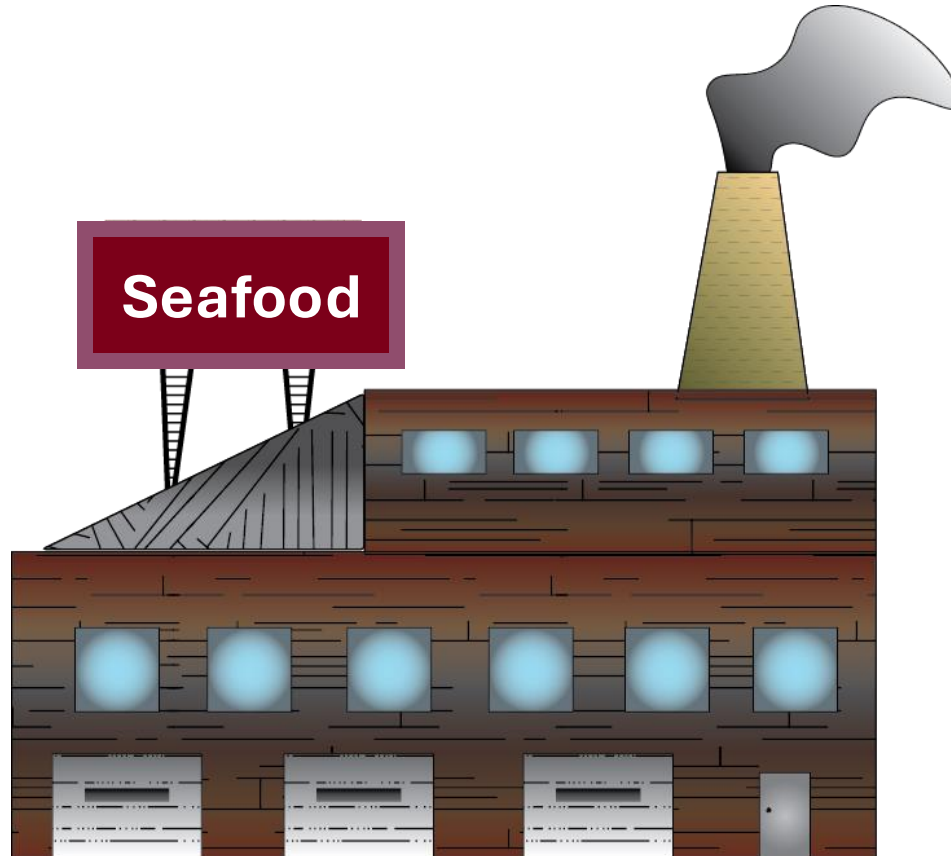


CHP 11: 159

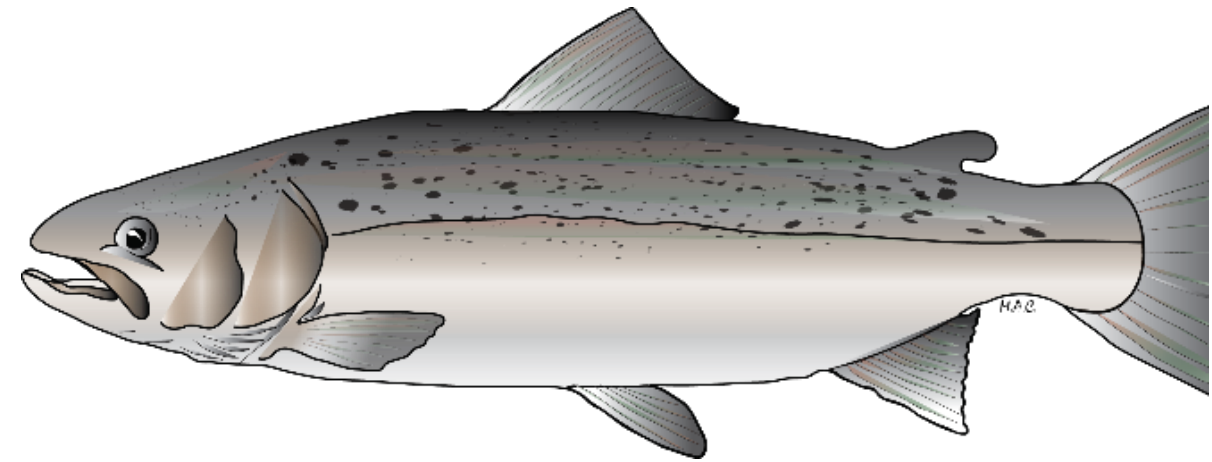
CHP 2: 27

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	Natural Toxins ¹¹	Scombrototoxin (Histamine)	Environmental Chemicals	Aquaculture Drugs
		CHP 5	CHP 6	CHP 7	CHP 9	CHP 11
AHOLEHOLE	<i>Kuhlia</i> spp.					
ALEWIFE or RIVER	<i>Alosa pseudoharengus</i>			✓	✓	

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	Parasites	Natural Toxins	Environmental Chemicals	Aquaculture Drugs
		CHP 4	CHP 5	CHP 6	CHP 9	CHP 11
						✓

TABLE 3-4 POTENTIAL PROCESS-RELATED HAZARDS											
Finished Product Food ¹	Package Type	Hazards									
		Pathogenic Bacteria Growth - Temperature Abuse	<i>C. botulinum</i> Toxin	<i>S. aureus</i> Toxin - Drying	<i>S. aureus</i> Toxin - Batter	Pathogenic Bacteria Survival Through Cooking or Pasteurization	Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	Pathogenic Bacteria Contamination After Processing and Specified Cooking Processes	Allergens and Food Intolerance Substances ⁴	Metal Inclusion	Glass Inclusion
		CHP 12	CHP 13	CHP 14	CHP 15	CHP 16	CHP 17	CHP 18	CHP 19	CHP 20	CHP 21
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

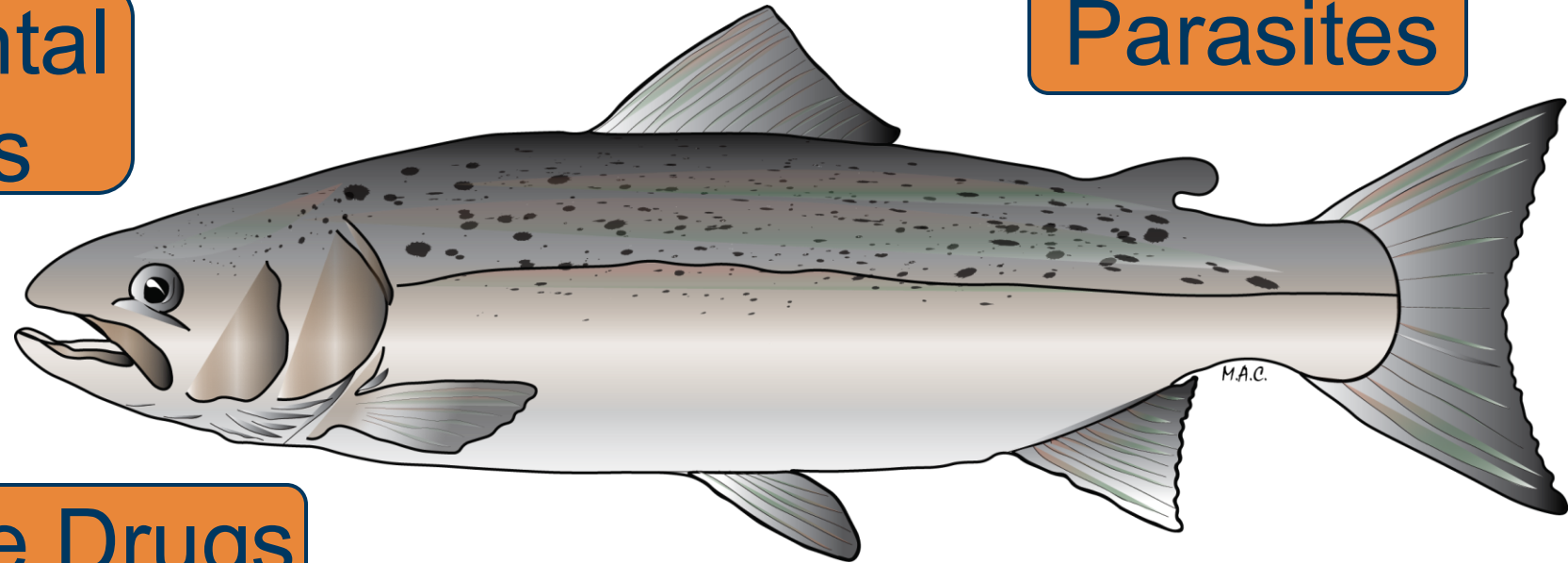
Species Hazards – Hazards associated with specific types (species) of fish or shellfish and/or where they are harvested

CHP 3: 3-25

Environmental
Chemicals

Parasites

Aquaculture Drugs



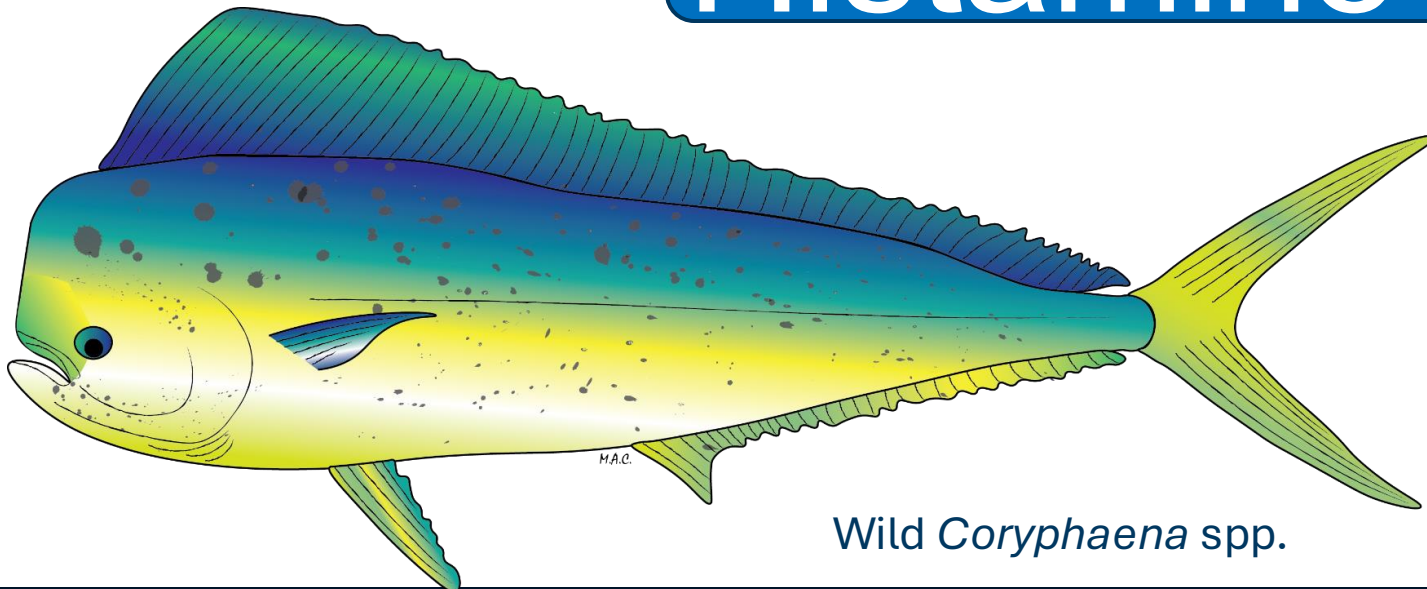
Salmon(Farmed *Salmo salar*)

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

Vertebrate Table 3-2 P 3-3

Invertebrate Table 3-3 P 3-40

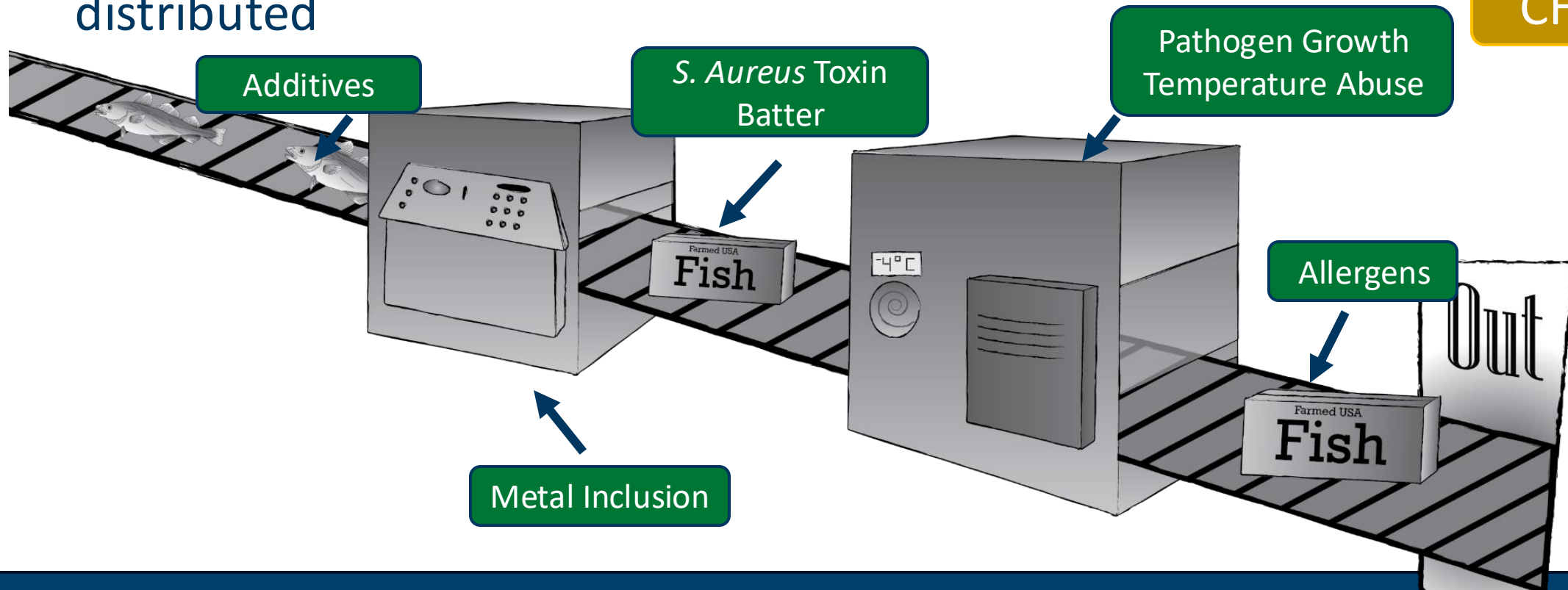
MARKET NAMES	LATIN NAMES	HAZARDS				
		Parasites ¹ CHP 5	Natural Toxins ¹² CHP 6	Scombrototoxin (Histamine) CHP 7	Environmental Chemicals CHP 9	Aquaculture Drugs CHP 11
AHOLEHOLE	<i>Kuhlia</i> spp.					
ALEWIFE or RIVER HERRING	<i>Alosa pseudoharengus</i>			✓	✓	
ALFONSINO	<i>Beryx</i> spp. <i>Centroberyx</i> spp.					
ALLIGATOR	<i>Alligator mississippiensis</i>				✓	
	<i>Alligator sinensis</i>				✓	
AQUACULTURED	<i>Alligator mississippiensis</i>				✓	✓
	<i>Alligator sinensis</i>				✓	✓
BASS or JACK	<i>Seriola dumerili</i>		CFP	✓		
	<i>S. rivoliana</i>		CFP	✓		
	<i>S. spp.</i>			✓		
BASS or JACK or WTAIL	<i>Seriola lalandi</i>			✓		
	<i>Seriola lalandi</i>	✓ ¹		✓	✓	✓
BASS or JACK or BURI, cultured	<i>Seriola quinqueradiata</i>			✓	✓	✓
BASS or JACK or BURI, cultured	<i>Anchoa</i> spp.	✓	ASP ⁵	✓		
	<i>Anchoviella</i> spp.	✓	ASP ⁵	✓		
	<i>Cetengraulis mysticetus</i>	✓	ASP ⁵	✓		
	<i>Engraulis</i> spp.	✓	ASP ⁵	✓		
	<i>Stenophis</i> spp.	✓	ASP ⁵	✓		

MARKET NAMES	LATIN NAMES	HAZARDS				
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Environmental Chemicals CHP 9	Aquaculture Drugs CHP 11
ABALONE	<i>Haliotis laevis</i>			✓	✓	
	<i>H. ruber</i>				✓	
	<i>H. spp.</i>				✓	
	<i>Marinauris roei</i>				✓	
ARKSHELL	<i>Anadara</i> spp.	✓		✓	✓	
	<i>Arca</i> spp.	✓		✓	✓	
CLAM, BENTNOSE	<i>Macoma nasuta</i>	✓		✓	✓	
CLAM BUTTER	<i>Saxidomus</i> spp.	✓		✓	✓	
CLAM, CALICO	<i>Macrocallista maculata</i>	✓		✓	✓	
CLAM, GEODUCK	<i>Panopea bitruncata</i>	✓		✓	✓	
	<i>P. spp.</i>	✓		✓	✓	
CLAM, HARD	<i>Arctica islandica</i>	✓		✓	✓	

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 Contamination After Pasteurization and Specialized Cooking Processes
- Allergens and Food Intolerance Substances
- Metal Inclusion
- Glass Inclusion
- Pathogenic Bacteria Survival through Processes Designed to Retain Raw Product Characteristics

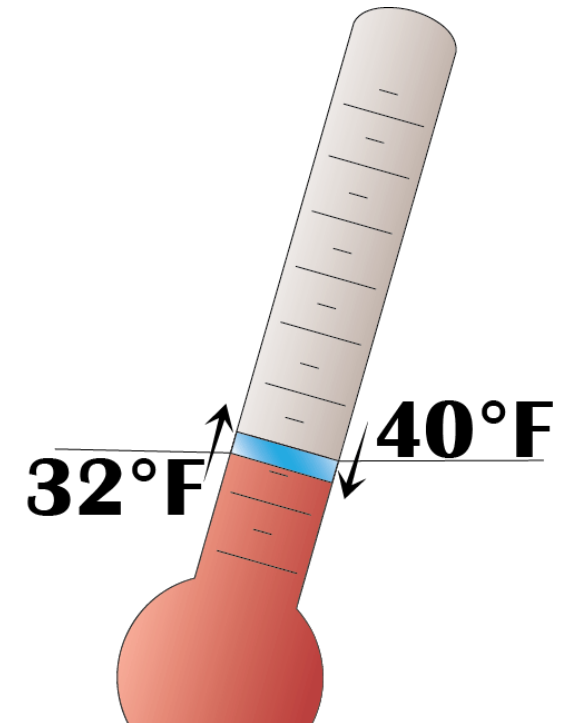
Table 3-4
P 3-52

TABLE 3-4 POTENTIAL PROCESS-RELATED HAZARDS										
Finished Product Food ¹	Package Type	Hazards								
		Pathogenic Bacteria Growth - Temperature Abuse	<i>C. botulinum</i> Toxin	<i>S. aureus</i> Toxin - Drying	<i>S. aureus</i> Toxin - Batter	Pathogenic Bacteria Survival through Cooking or Pasteurization	Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	Allergens and Food Intolerance Substances ²	Metal Inclusion
		CHP 12	CHP 13	CHP 14	CHP 15	CHP 16	CHP 17	CHP 18	CHP 19	CHP 20
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:

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

CHP4:75

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.

DEALER NAME	CERT. NO.
Dealer Address:	
City, State, Zip Code:	
Original Shipper's Cert. No. if Other than Above:	
Harvest Date:	
Harvest Location:	
Type of Shellfish:	
Quantity of Shellfish:	
This tag is required to be attached until container is empty and thereafter kept on file for 90 days.	

RETAILERS, INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at increased risk of foodborne illness. For more information, consult your physician or public health official for further information.

Species-Related Food Safety Hazards



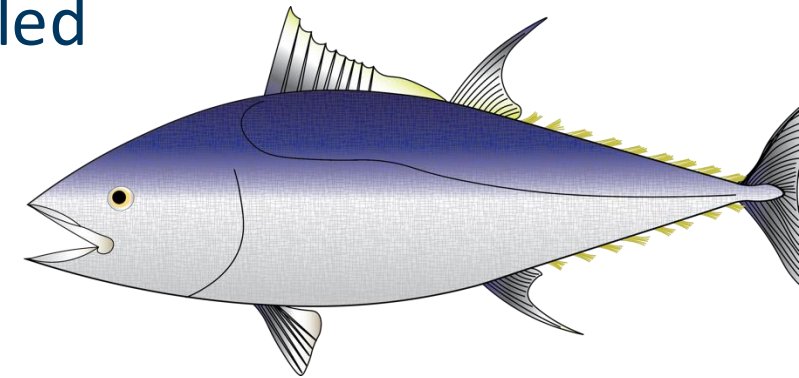
Histamine or Scombrototoxin:

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 scombrototoxin.

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:

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

CHP11: 11 - 1

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



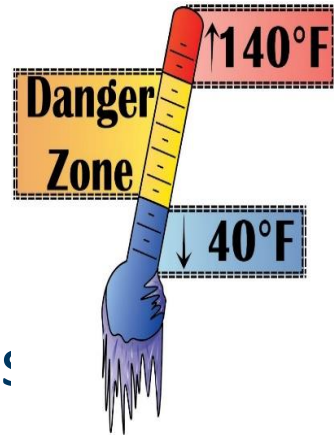
Pathogen Growth caused by time/temperature abuse:

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:

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

CHP16: 315

CHP 17: 331

CHP 18: 345

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



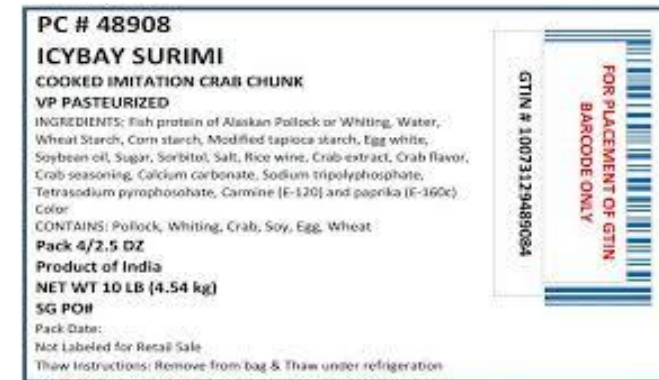
Food Intolerance Substances:

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.

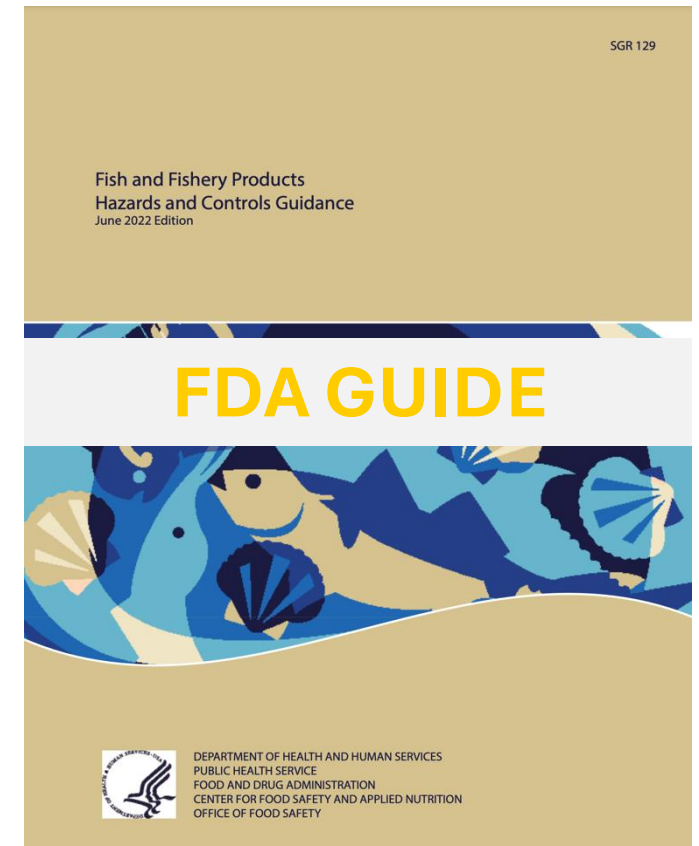
HACCP Controls: Processors must inspect glass containers to detect breaking, cracking or other types of glass contamination to ensure that contaminated products are not sold. Or inspect the processing area around lines for broken glass to identify when contamination may have occurred.



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

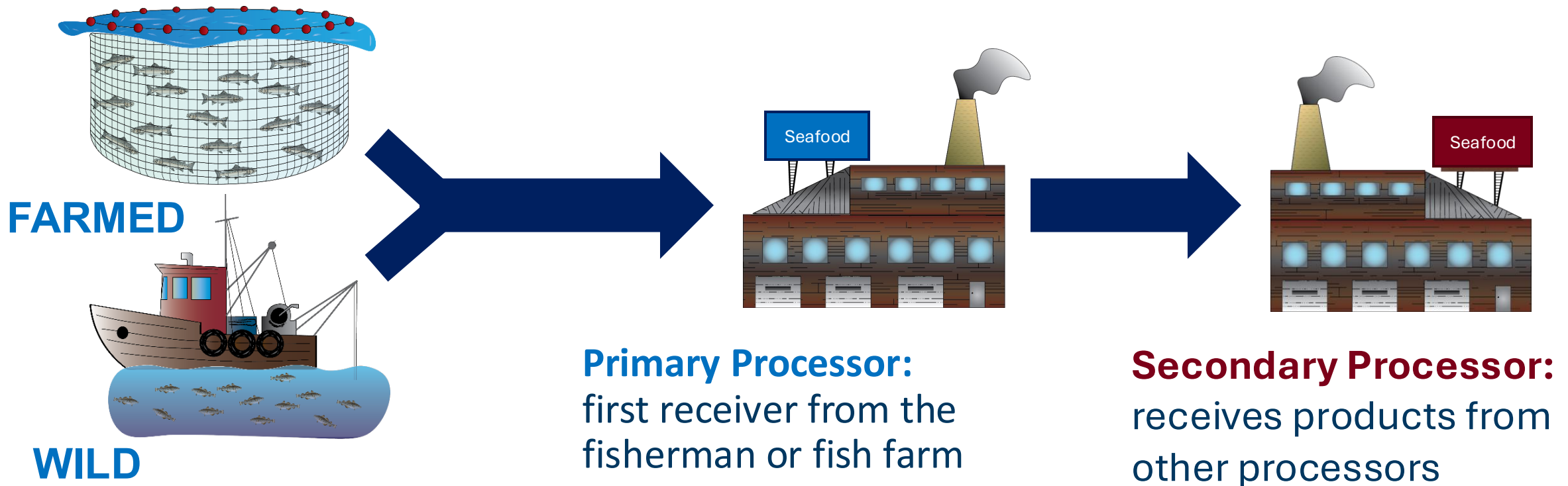


GOLD BOOK

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



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

Chapter Structure and Content



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- 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

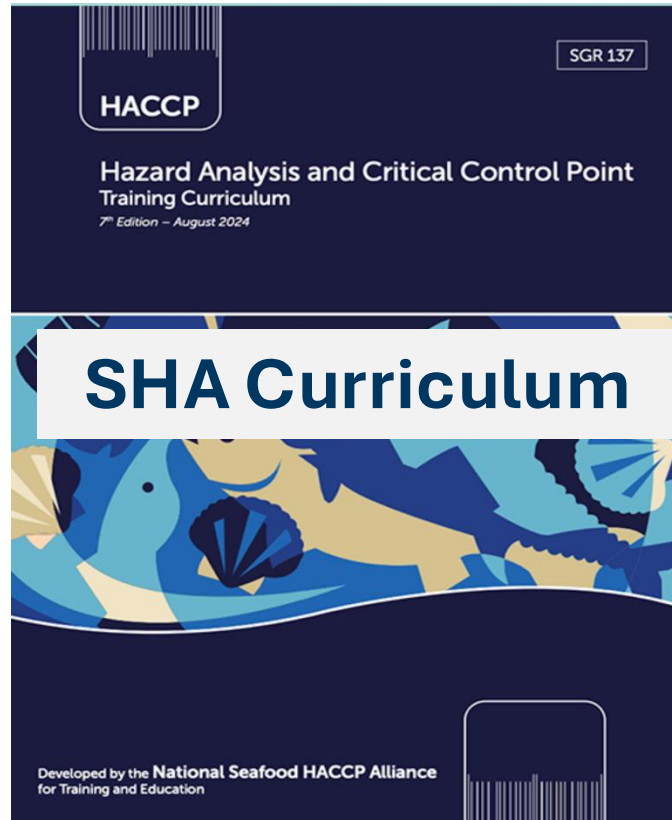
P 315

Hazard Analysis = 

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

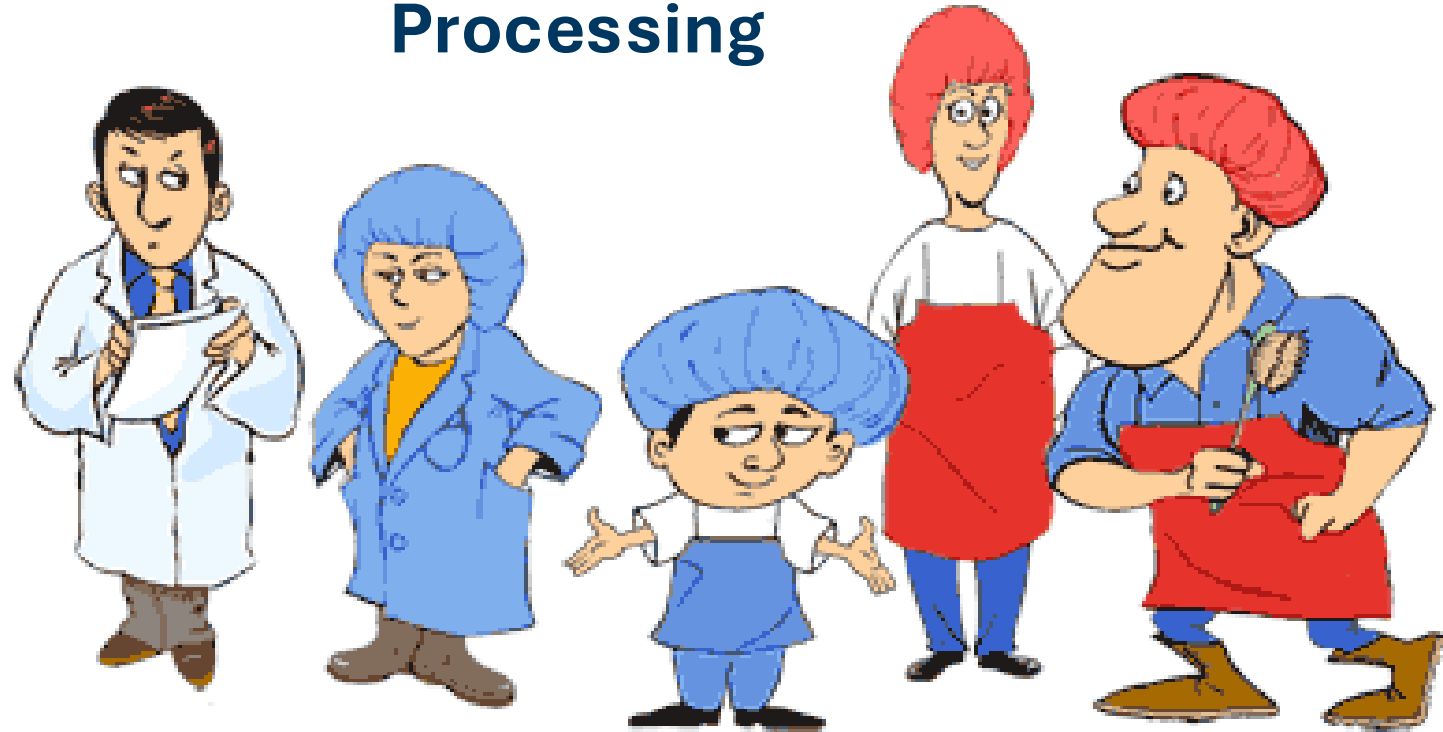
Preliminary Step 1. Assemble the HACCP Team

Managers

Sanitation

Processing

CHP4: 74

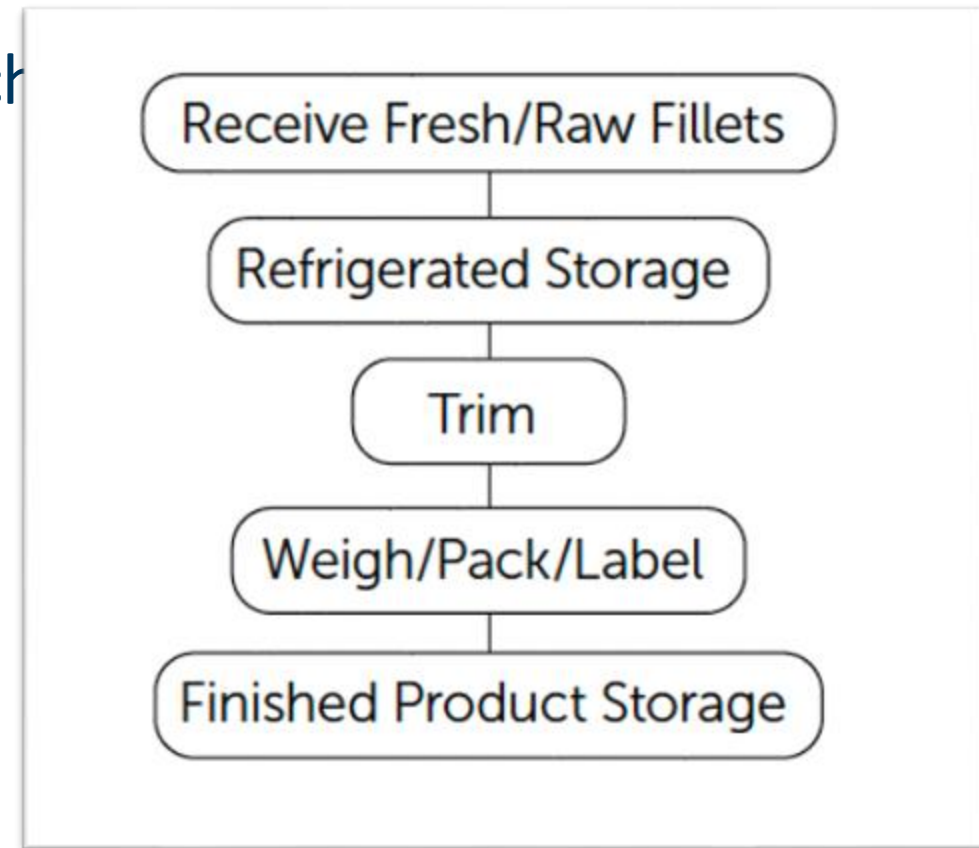


Preliminary Step 2. Process Flow Chart

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)



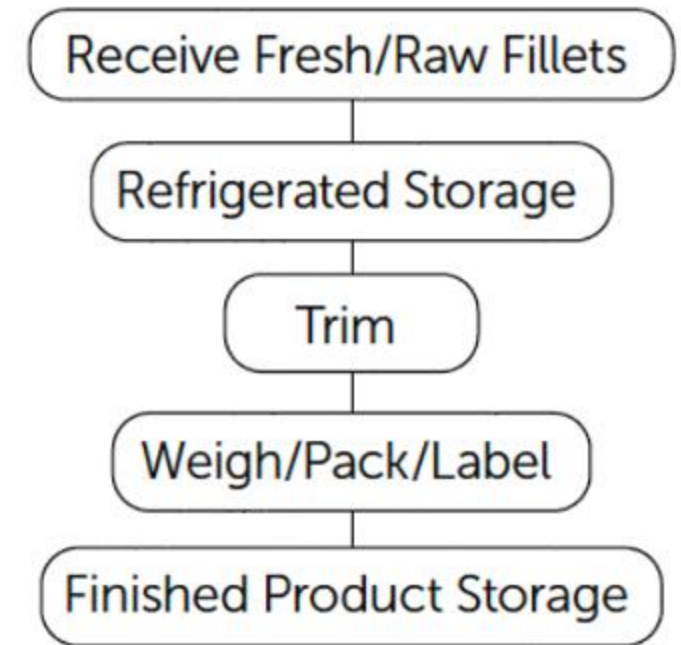
Receive Fresh/Raw Fish – Fresh/Raw wild-caught mahi-mahi (*Coryphaena* species, not aquacultured) fillets are received from several domestic suppliers (processors). Delivery truck transit times range from 2 to 8 hours. Tubs or other containers of mahi-mahi fillets are received along with other fresh 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.

CHP4: 75-76

Fresh/Raw mahi-mahi fillets process flow chart



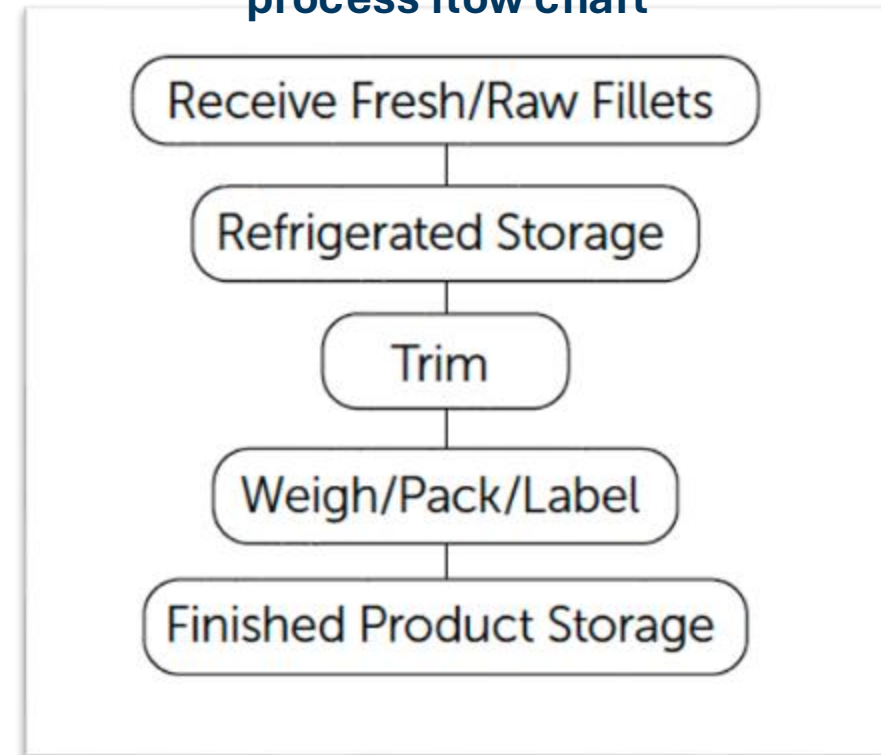
A brief processing narrative can be used to help explain the Processing Flow Chart (2 of 2)

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

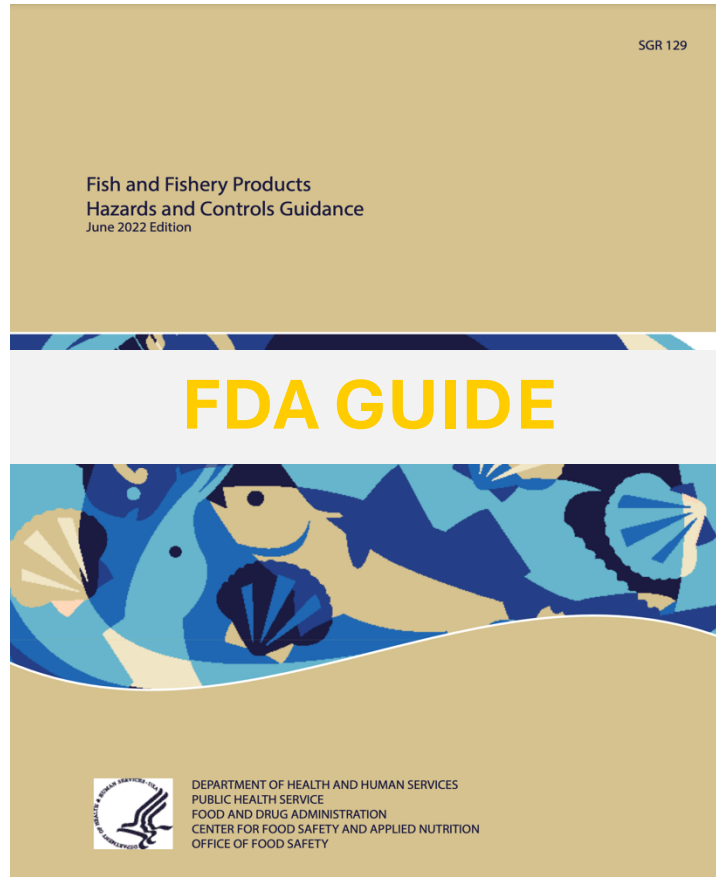
Acceptable Market Name & Species	Where Product Is Purchased (Source)			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use			Intended Consumer	
	Fisherman	Fish Farm	Processor/ Dealer	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced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

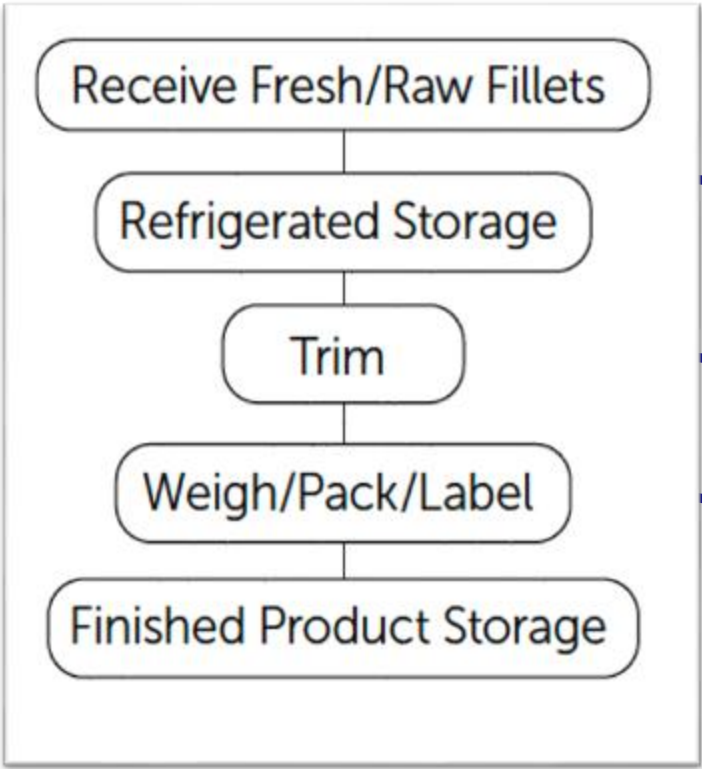
with recommendations from the **FDA Guide** beginning with a Hazard Analysis Worksheet

Appendix 2: 227-228

Hazard Analysis Worksheet



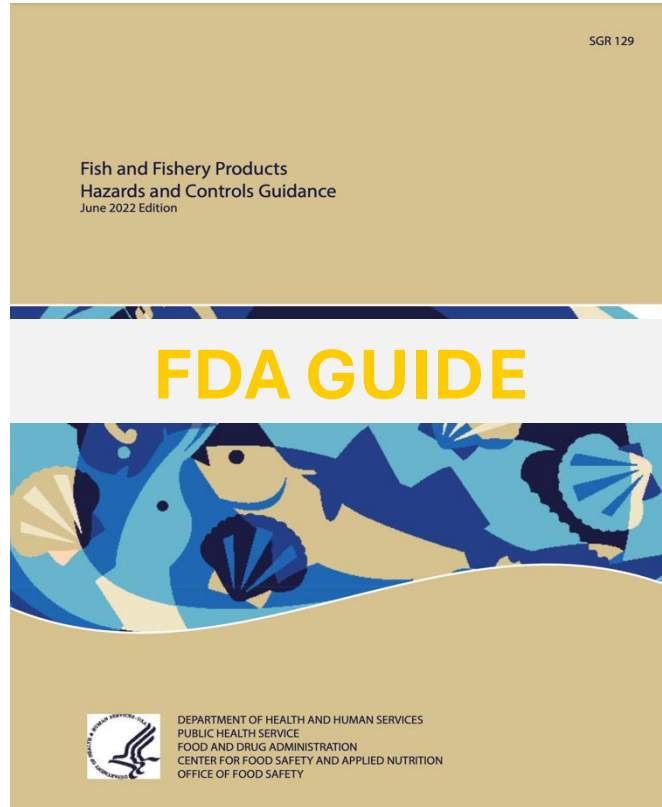
Fresh/Raw mahi-mahi
fillets process flow chart



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

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 ¹²

MARKET NAMES	LATIN NAMES	Parasite 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	<i>Kuhlia</i> spp.					
ALEWIFE or RIVER HERRING	<i>Alosa pseudoharengus</i>			✓	✓	
ALFONSINO	<i>Beryx</i> spp. <i>Centroberyx</i> spp.					
ALLIGATOR	<i>Alligator mississippiensis</i>				✓	
ALLIGATOR, aquacultured	<i>Alligator sinensis</i>				✓	
ALLIGATOR, aquacultured	<i>Alligator mississippiensis</i>				✓	✓
ALLIGATOR, aquacultured	<i>Alligator sinensis</i>				✓	✓
AMBERJACK	<i>Seriola dumeril</i>		CFP	✓		
AMBERJACK or YELLOWTAIL	<i>S.</i>					
AMBERJACK or YELLOWTAIL, aquacultured	<i>Se</i>					
AMBERJACK or BURU, aquacultured	<i>Seriola</i>					
ANCHOVY ¹⁴	<i>A.</i>					
	<i>Anchoviella</i> spp.					
	<i>Cetengraulis</i>					
	<i>Engraulis</i>					
	<i>Stolephorus</i>					
ANGELFISH	<i>Holocentrus</i>					
ARGENTINE QUEENFISH	<i>Pomacanthus</i>					
	<i>Argentina</i>					

Chapter 3: Pot

TABLE 3-3
POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6
ABALONE	<i>Haliotis laevis</i>			✓
	<i>H. ruber</i>			
	<i>H. spp.</i>			
	<i>Marinusauris raei</i>			
ARKSHELL	<i>Anadara</i> spp.	✓		✓
	<i>Arca</i> spp.	✓		✓
BARNACLES, GOOSENECK	<i>Pollicipes polymerus</i>			✓
CLAM, BENTNOSE	<i>Macoma nasuta</i>	✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓

related and Process-Related Hazards
(June 2021)

TABLE 3-4
POTENTIAL PROCESS-RELATED HAZARDS

Finished Product Food ¹	Package Type	CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: <i>C. botulinum</i> Toxin	CHP 14: <i>S. aureus</i> Toxin - Drying	CHP 15: <i>S. aureus</i> Toxin - Bacter	CHP 16: Pathogenic Bacteria Survival Through Cooling 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, pickled, salted, and LACFs.											✓
Fish oil.											

Table 3-4
Process-Related Hazards

CHP3: 3-52

Tables 3-2 and 3-3 Species-Related Hazards
CHP3:
3-3: Vertebrates
3-40: Invertebrates

One Species-related hazard

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS ¹⁷

Table 3-2
Page 3-21

MARKET NAMES	LATIN NAMES	Parasite ³ Hazards CHP 5	Natural Toxin ¹³ Hazard CHP 6	Scombrototoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
MACKEREL, SPANISH	<i>Scomberomorus</i> spp.	✓		✓		
MACKEREL, SPANISH or CERO	<i>Scomberomorus regalis</i>	✓	CFP	✓		
MACKEREL, SPANISH or KING	<i>Scomberomorus cavalla</i>	✓	CFP	✓		
MACKEREL, SPANISH or NARROW-BARRED	<i>Scomberomorus commerson</i>		CFP	✓		
MAHI-MAHI	<i>Coryphaena</i> spp.			✓		
MAHI-MAHI, aquacultured	<i>Coryphaena</i> 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: <i>C. botulinum</i> Toxin	CHP 14: <i>S. aureus</i> Toxin - Drying	CHP 15: <i>S. aureus</i> 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-finish).	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-finish).	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 every
potential hazard
at each
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		
			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		Column 2: List <u>every</u> hazard that is reasonably likely to occur at <u>each</u> processing step		
	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				

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) <u>at this step?</u> (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	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



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 knives 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		

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



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)	(5)	(6)	(7)			
			What	How	Frequency	Who			
Signature:							Date:		

Appendix 2

Optional HACCP Plan Forms

(both must contain same information)

Appendix 2: 101 and 102



Firm Name: Address:			Product Description:						
Signature: (printed name)			Method of Distribution & Storage:						
Date:			Intended Use & Consumers:						
(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4) (5) (6) (7) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
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: <u>XXXXXXXXXX</u>		Intended Use: To be cooked and consumed by the general public	
Printed: <u>XXXXXXXXXXXX</u>		Date: (-signed date-)	
CCP number 1			
Critical Control Point (CCP)	RECEIVING		
Significant Hazard	Histamine		
Critical Limits			
Monitoring	Portrait		
Who			
Corrective Action			
Verifications			
Records			

Set up a HACCP Plan Form for each CCP



Seafood HACCP
Alliance

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) (5) (6) (7) Monitoring				(8) Corrective Action(s)
			What	How	Frequency	Who	
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



HACCP
e—

CCP	Hazard	Critical Limits for each Control Measure	Monitoring				Corrective Action	CHP7: 109	Records
			What	How	When	Who			
Receiving	Histamine	Tubs or containers of Mahi-mahi fillets are completely surrounded with ice at receipt.	Based on recommendations in the FDA Guide	Receiving - Transit Control Example 3 - CHP 7: 137					
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.							

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	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	<div>CHP8: 119</div> <div>Based on FDA Guide</div> <div>Example 3 CHP 7: 137-139</div>	
Refrigerated Storage	Histamine	Tubs or containers of Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding tubs or containers of mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of the work day	Cooler Manager		
Weigh/Pack/Label	Food Allergens	All finished product containers will be labeled with the correct market name	The market name on each container of finished product	Visual comparison of the label 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		

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	<p>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.</p>	<div>CHP 9: 129</div> <div>Example 3 CHP 7: 139</div>	
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	<p>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.</p>		

Principle 5: CORRECTIVE ACTIONS (Page 2 of 2)



CP

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 Then: reject product, and call supplier to let them know CL was not met and provide product delivery specifications, and discontinue use of supplier until their transport procedures are corrected.	Weekly review of Receiving Log (Monitoring record) and Corrective Action. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	
Refrigerated Storage	Histamine	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.	

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	<p>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.</p>	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.	<p>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.</p> <p>Corrective Action records</p> <p>Verification Record</p> <ul style="list-style-type: none"> 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 workday	Cooler Manager	<p>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.</p>	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.	<p>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.</p> <p>Corrective Action records</p> <p>Verification Records</p> <ul style="list-style-type: none"> Accuracy Check Record Annual Calibration Log

Principle 7: RECORDS (Page 2 of 2)

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 a 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 <ul style="list-style-type: none">• Accuracy Check Record• 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. <u>Corrective Action records</u> • 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. <u>Corrective Action records</u> • Accuracy Check Record • Annual Calibration Log

	Corrective Action	Verification	Records
ho	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. <u>Corrective Action records</u> • Accuracy Check Record • Annual Calibration Log

/Raw Mahi-Mahi Fillets

Storage and Distribution: Stored and distributed buried in ice

End 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.



Training Evaluation

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

bit.ly/SHAEvaluation



QUESTIONS

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

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