Seafood HACCP Alliance Segment Two Course

Course Number:

Course Location:

Course Date:

AFDO Region:

Instructor:

AGENDA (SHA Segment 2 Course)

PART 1: Lecture and Discussion

- FDA Seafood HACCP Regulation
- Seafood Safety Hazards & Controls
- Developing a HACCP Program

PART 2: Course Work Assignment

- Team Work Groups & Presentations

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:

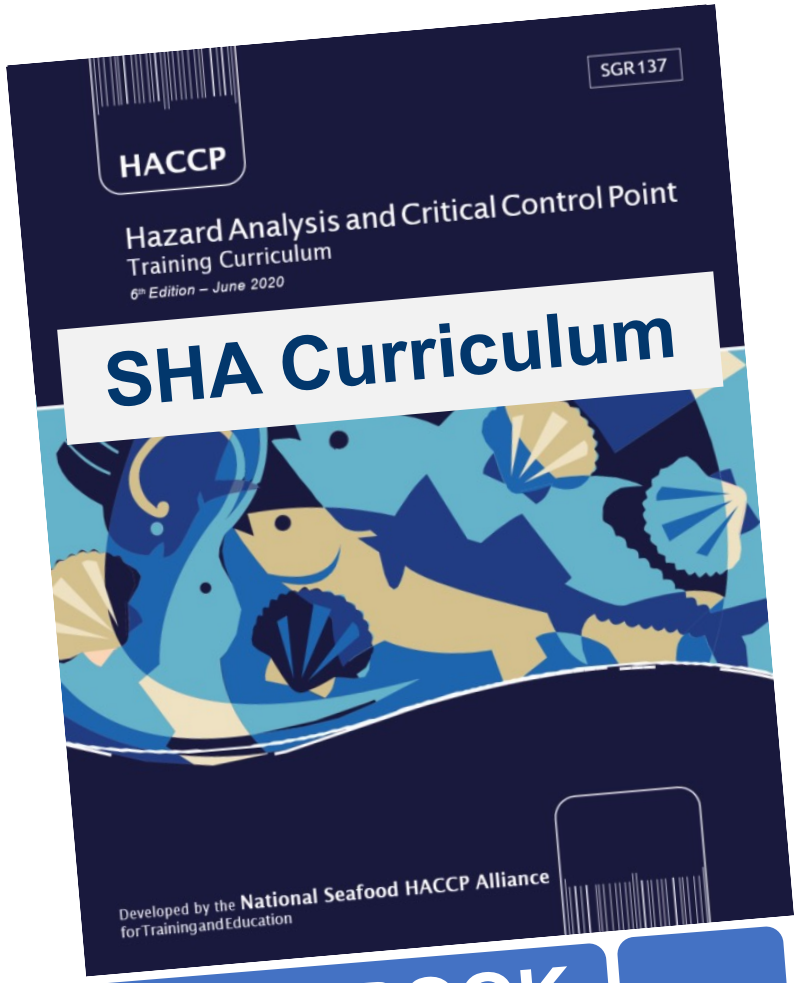
- Conduct a Hazard Analysis
- Develop a HACCP Plan for seafood products as required by the FDA regulation
- Reassess or modify a HACCP Plan as necessary and/or required by the FDA regulation
- Review HACCP Plan records as required by the FDA regulation

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.

SHA Training Materials



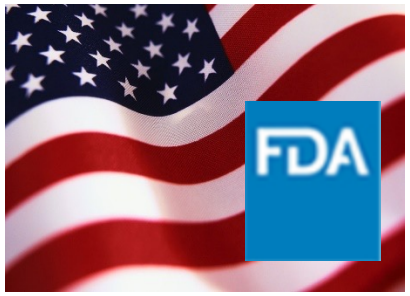
BLUE BOOK

GOLD BOOK

FDA Seafood HACCP Regulation

21 CFR Part 123

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



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
- 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
- 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.

AD1 - 1 CHP12:185

What Does Processing Include?

- Processing means:

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

- The regulation does not apply to:
  - Harvesting,
    - Including aquaculture farms unless processing
  - Transporting,
  - Heading, eviscerating or freezing on a harvest vessel intended solely to hold the fish,
  - Retail operations.

AD1 - 2

CHP12:188

What are fish or fishery products?

- Fish means: fresh or saltwater finfish, crustaceans, mollusks, other forms of aquatic animal life (e.g., alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, roe), other than birds or mammals.

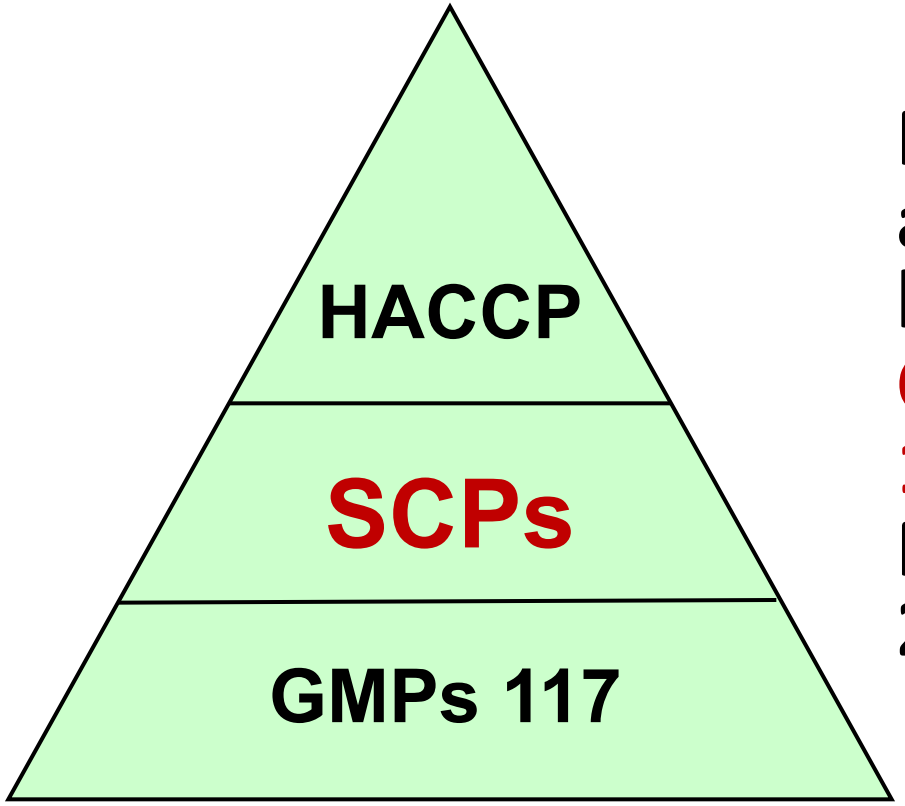
- Fishery product means: any food product where fish is a characterizing ingredient.

- All products intended for human consumption are covered.

What MUST all seafood processors do?

- Complete a **Hazard Analysis** to determine if there are any significant hazards associated with your products or process
- Develop and implement a **HACCP Plan** to control any significant food safety hazards that are identified
- Monitor and keep records of monitoring results and corrections taken for 8 specified areas of **sanitation**
- HACCP Plans must be signed, dated and reassessed yearly by a trained individual

What MUST all seafood processors do?



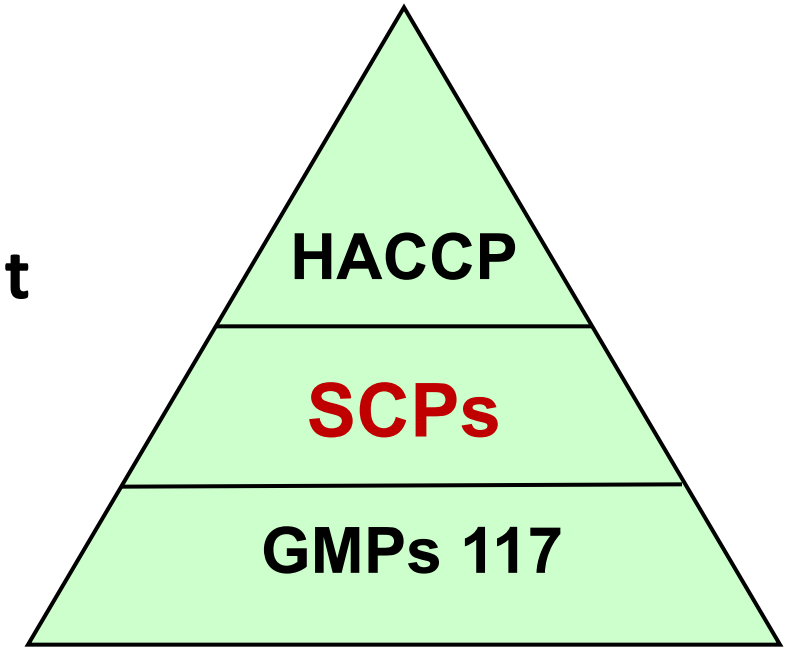
Processors are required to develop and maintain a HACCP program based on a foundation of Sanitation Control Procedures (SCPs—21 CFR 123.11) and the current Good Manufacturing Practices (GMPs—21 CFR 117)

CHP1:7 AD1-3

CHP 2: 15-16

Sanitation Control Procedures (SCPs)

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



- Seafood processors are required to comply with GMPs, 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 110

CHP 2: 17

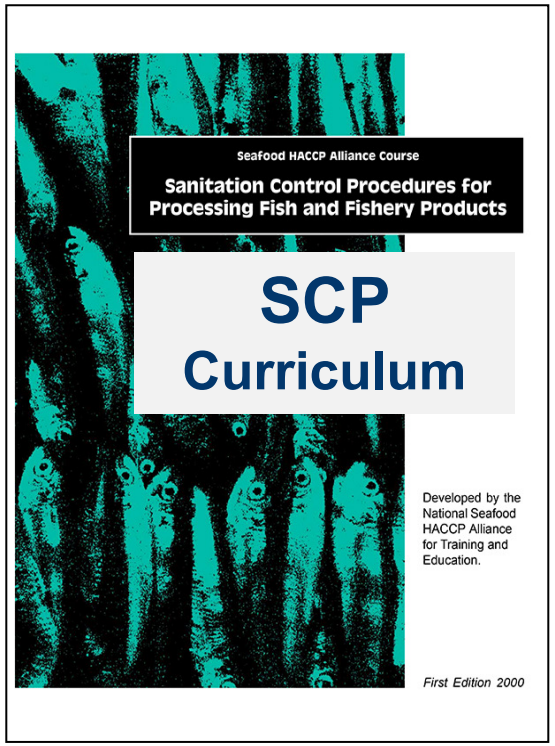
Sanitation Control Procedures (SCPs)

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

1. Safety of water;
2. Condition & cleanliness of food contact surfaces;
3. Prevention of cross contamination;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of food, food packaging material, and food contact surfaces from adulteration;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions; and
8. Exclusion of pests from the food plant.

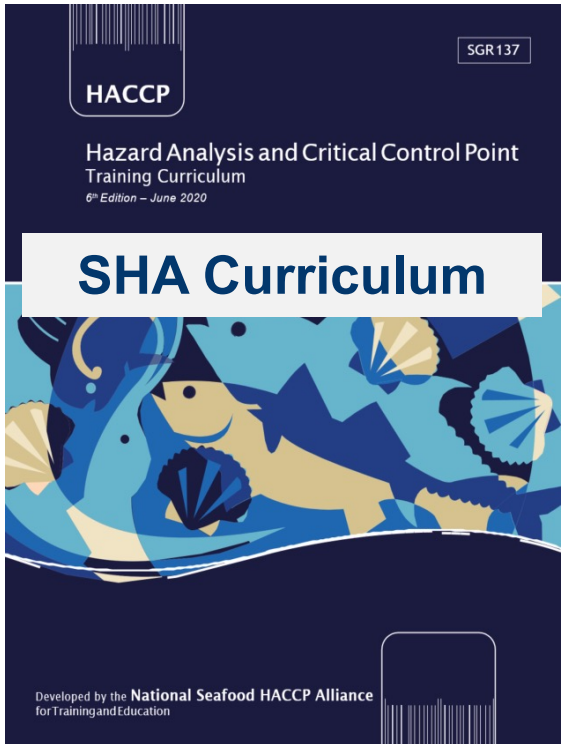
AD1-8

Sanitation Control Procedures (SCPs)



GREEN BOOK

SSOP-4 to SSOP-16



BLUE BOOK

CHP 2: 30-40

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

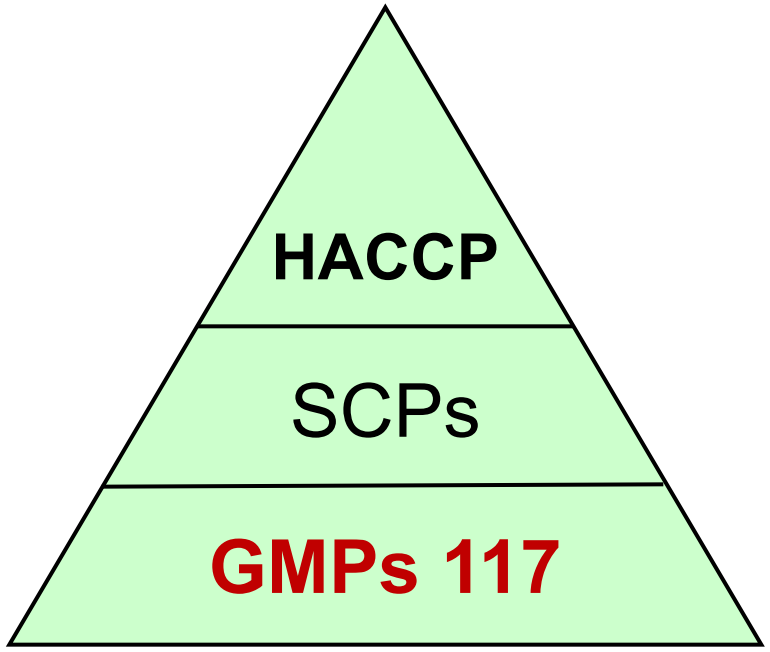
Form 1

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

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

Good Manufacturing Practices (GMPs)



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

Appendix 3

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

21 CFR Part 117 Subpart A: General Provisions

CHP 2: 13

Example of Training Records

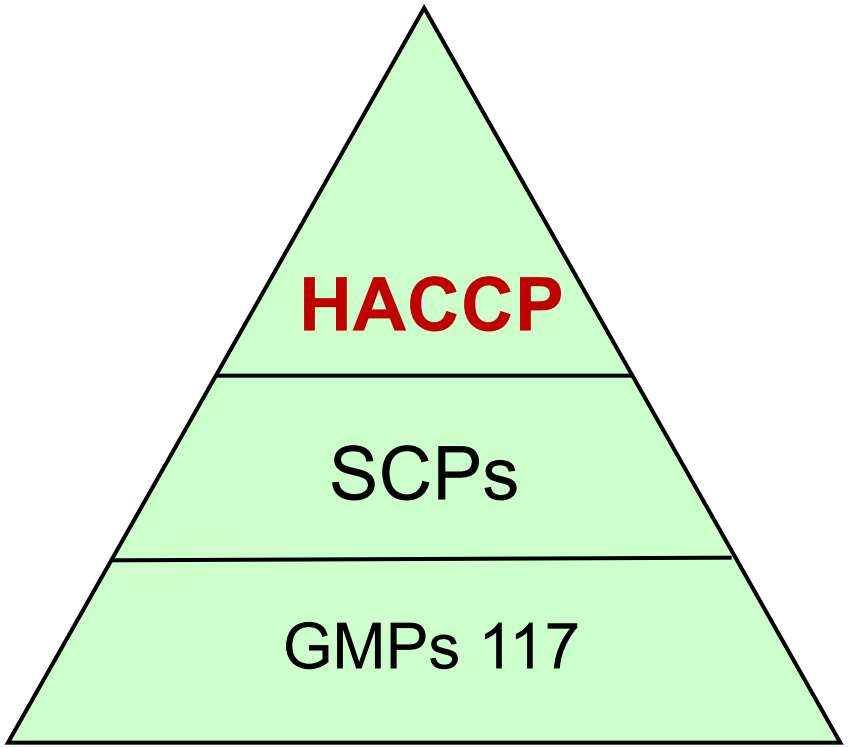
Employee Training Record			
Employee: *Anybody Jones*		**Position/Duty:** Processing belt for shrimp cooker	
COURSES	**LOCATION**	**DATE COMPLETED**	**SIGNED**
Basic Sanitation Course (Seafood HACCP Alliance)	Headquarters	Nov 01, 2015	*Ben Smith*
GMP's 117	Plant Unit 3	Jan 15, 2017	*BS*
SCP Monitoring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

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

EMPLOYEE TRAINING RECORDS

- Records for additional training are required for all workers in the processing operations
- There are no prescribed courses and performance remains the primary measure for effective training, but training records are mandatory

Required parts of a HACCP Program



- Shall conduct a **Hazard Analysis** to determine if there are any significant hazards associated with your products or process.
- Develop and implement a **HACCP Plan** to control any significant food safety hazards that are identified.

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 (CCP, significant hazard, CL, monitoring, corrective actions, record-keeping, verification).

- HACCP Plans must be **signed**, **dated** & **routinely implemented**.

AD1-4

Review of 7 HACCP Principles

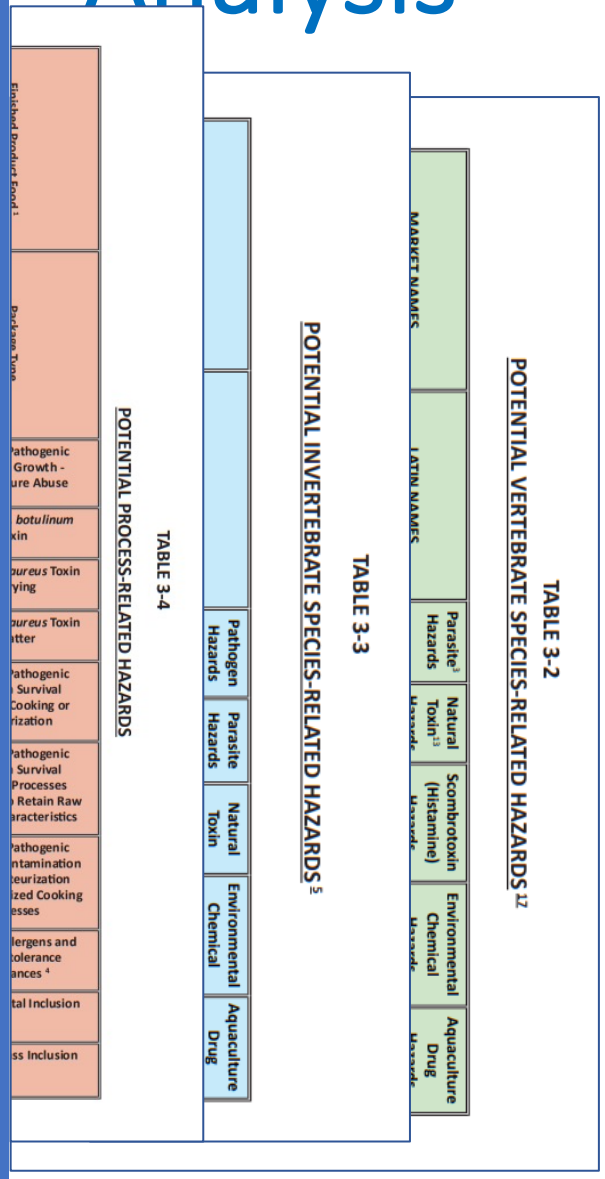
Conduct a Hazard Analysis:

- Principle 1 – Conduct a Hazard Analysis
- Principle 2 – Identify Critical Control Points

Build a HACCP Plan

- Principle 3 – Set Critical Limits
- Principle 4 – Establish Monitoring Procedures
- Principle 5 – Establish Corrective Action Procedures
- Principle 6 – Establish Verification Procedures
- Principle 7 – Establish a Record Keeping System

Principle 1: Conduct a Hazard Analysis



Identify and List all potential food safety hazards associated with the product and process.

Species Hazards

4. Pathogens from Harvest Area
5. Parasites
6. Natural Toxins
7. Scombrotoxin (Histamine)
8. Other Decomposition-related Hazards (Biogenic amines)
9. Environmental Chemicals
10. Methyl Mercury
11. Aquaculture Drugs

CHP 5: 77

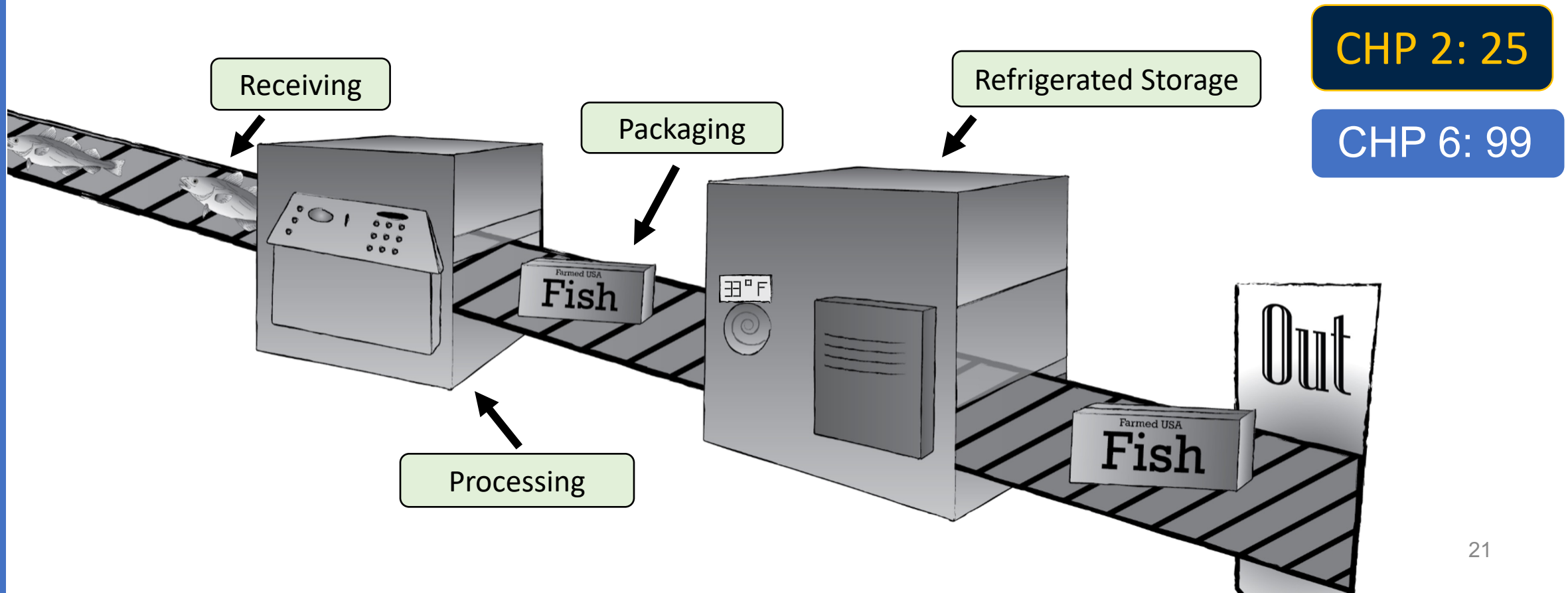
CHP 3: 3-1

Process Hazards

12. Pathogen Growth & Toxin Formation
13. *C. botulinum* Growth & Toxin Formation
14. Pathogen Growth & Toxin Formation inadequate drying.
15. *S. aureus* Toxin Formation in hydrated batters
16. Pathogen Growth & Survival through cooking
17. Pathogen Survival through process designed to retain raw characteristics
18. Intro. of Pathogens after pasteurization and specialized cooking
19. Allergens & Food Intolerance Substances
20. Additives
21. Metal or Glass Inclusion

Principle 2: Identify Critical Control Points (CCPs)

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

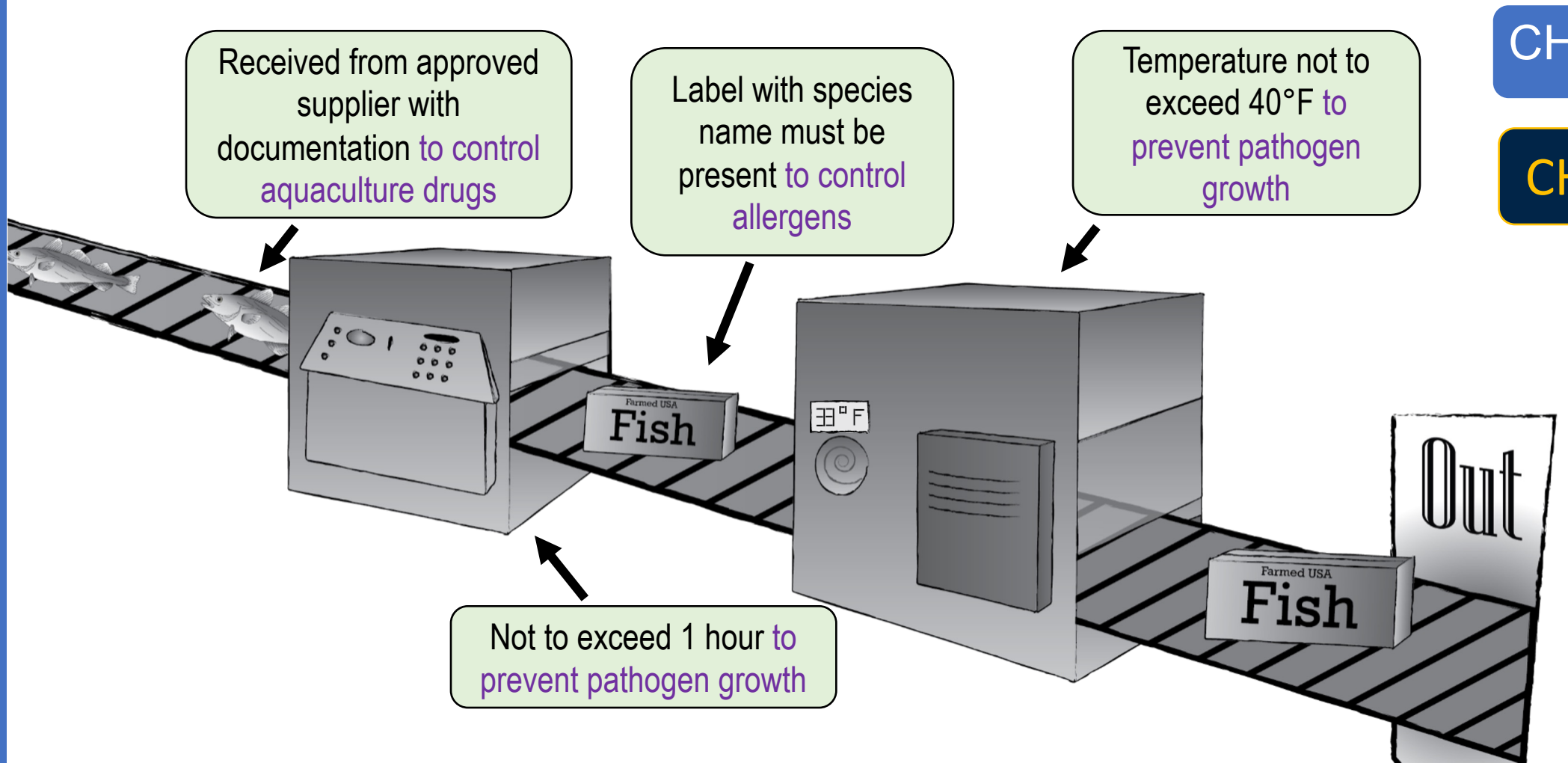


Principle 3: Set Critical Limits

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 Monitoring Procedures

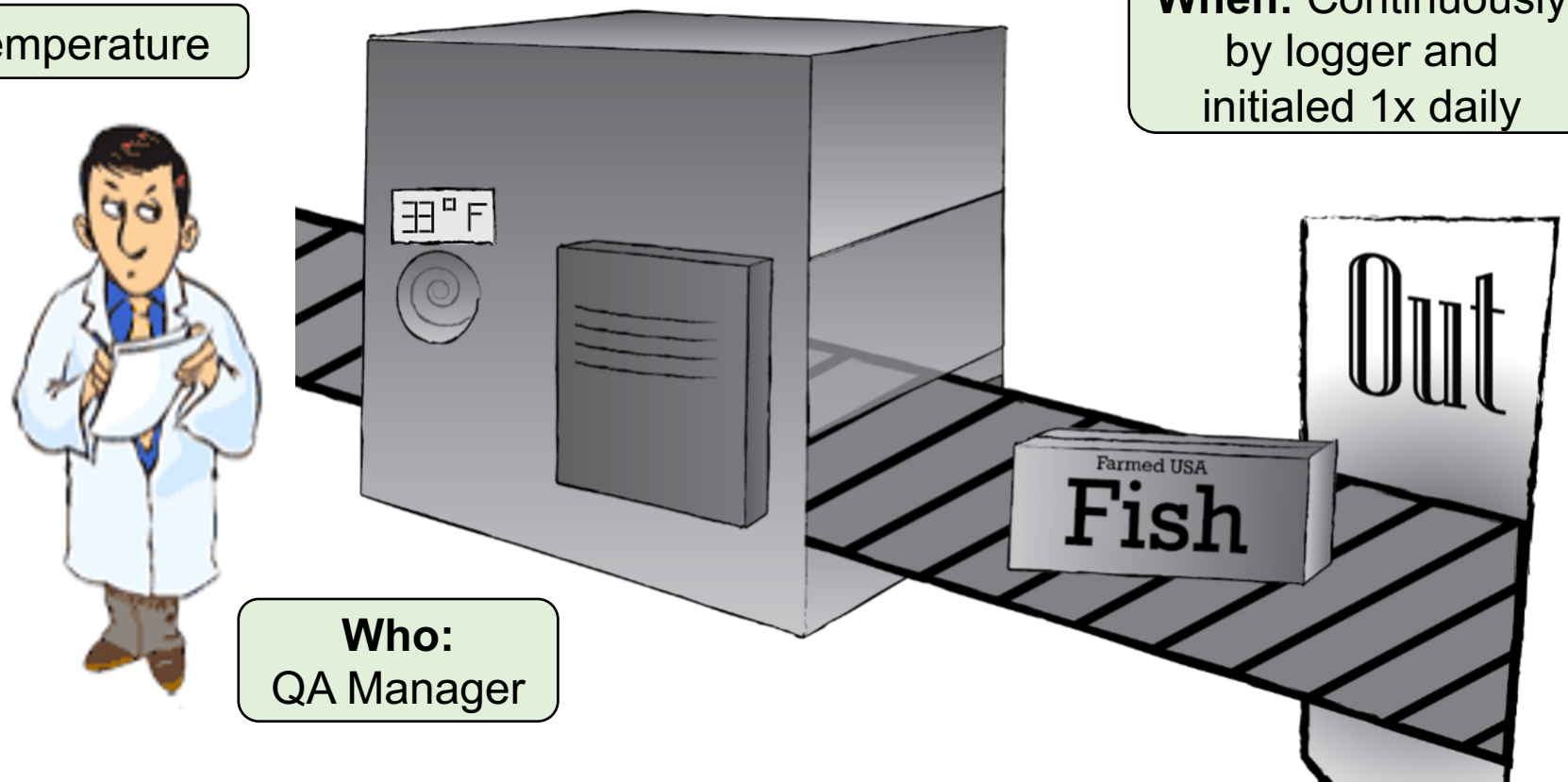
Determine **what** will be monitored, **how** it will be monitored, **when** it will be monitored and by **who**.

What: Temperature

When: Continuously by logger and initialed 1x daily

CHP 8: 119

CHP 2: 26



How: Temperature Logger

Who: QA Manager

Principle 5: Establish Corrective Actions

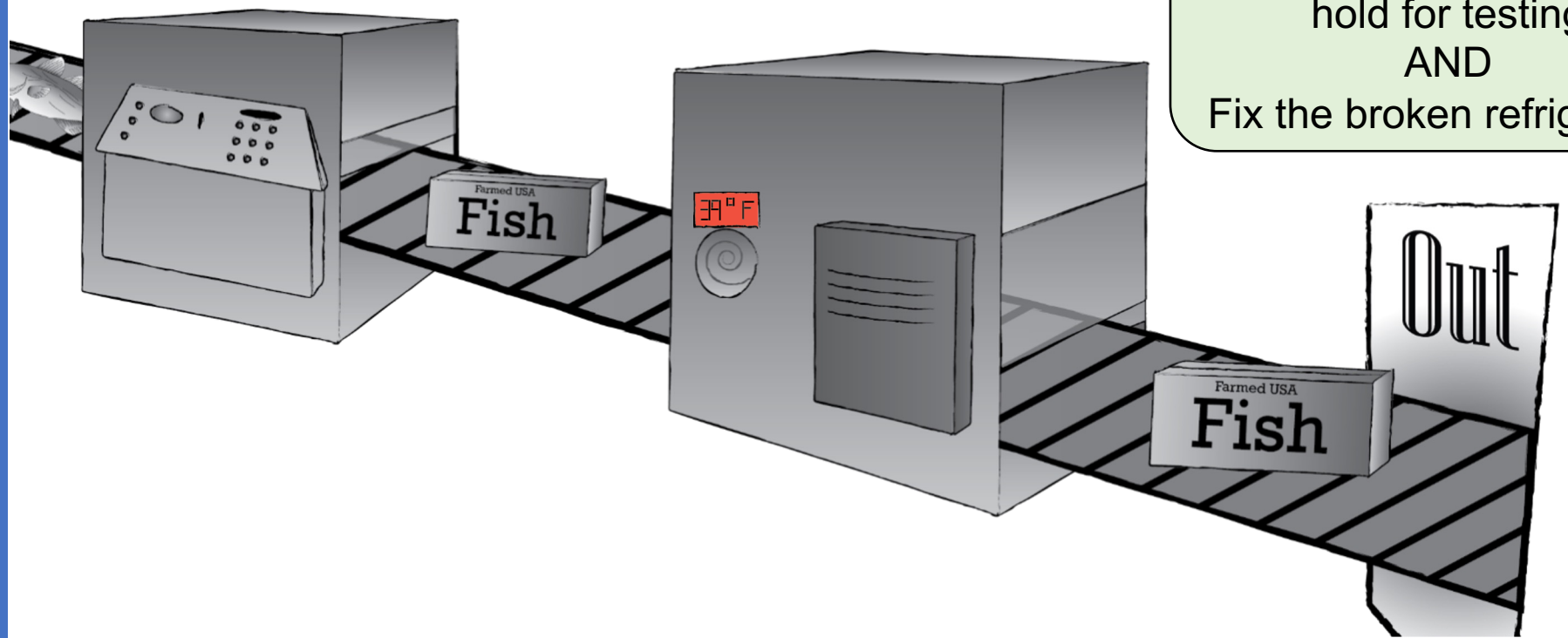
Determine what you will do if your critical limits are not met.

CHP 5: 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

CHP 2: 28

CHP 10: 141

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

- **HACCP Plan Assessment**
- **Process validation**
- **Equipment calibration**
- **Equipment accuracy checks**
- **Targeted sampling and testing for product safety**
- **Review of calibration, monitoring, corrective actions records**

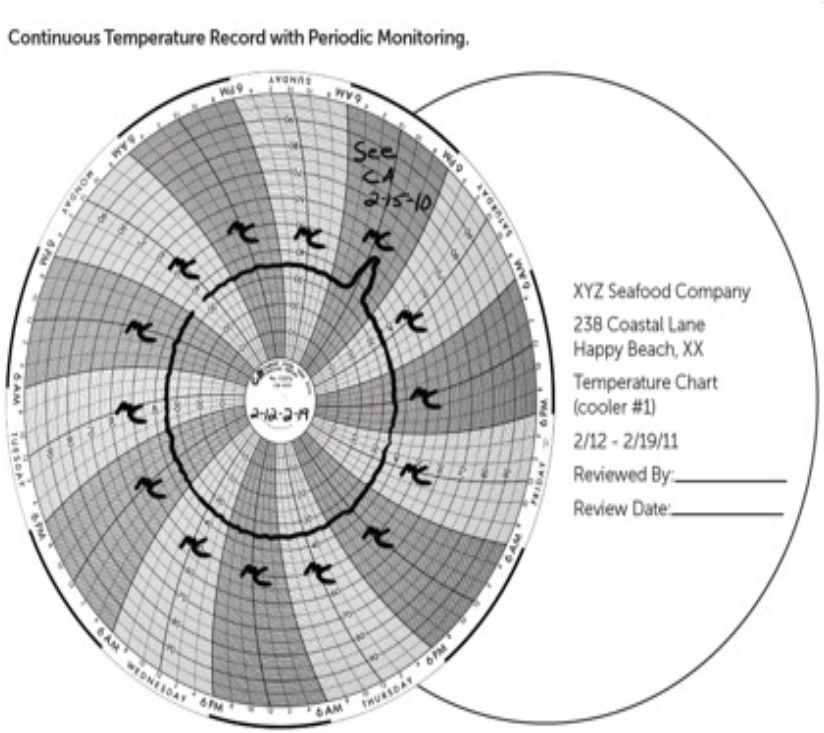
Principle 7: Establish a Record Keeping System

CHP 2: 27

CHP 11: 157

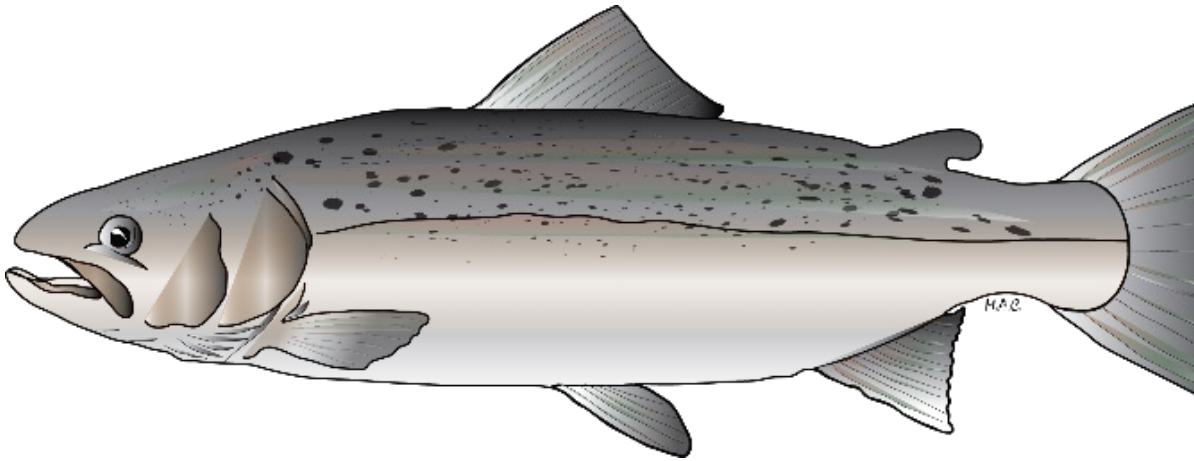
Tracks all monitoring procedures, corrective actions and verifications of your system to ensure standards are met and facility is in compliance.

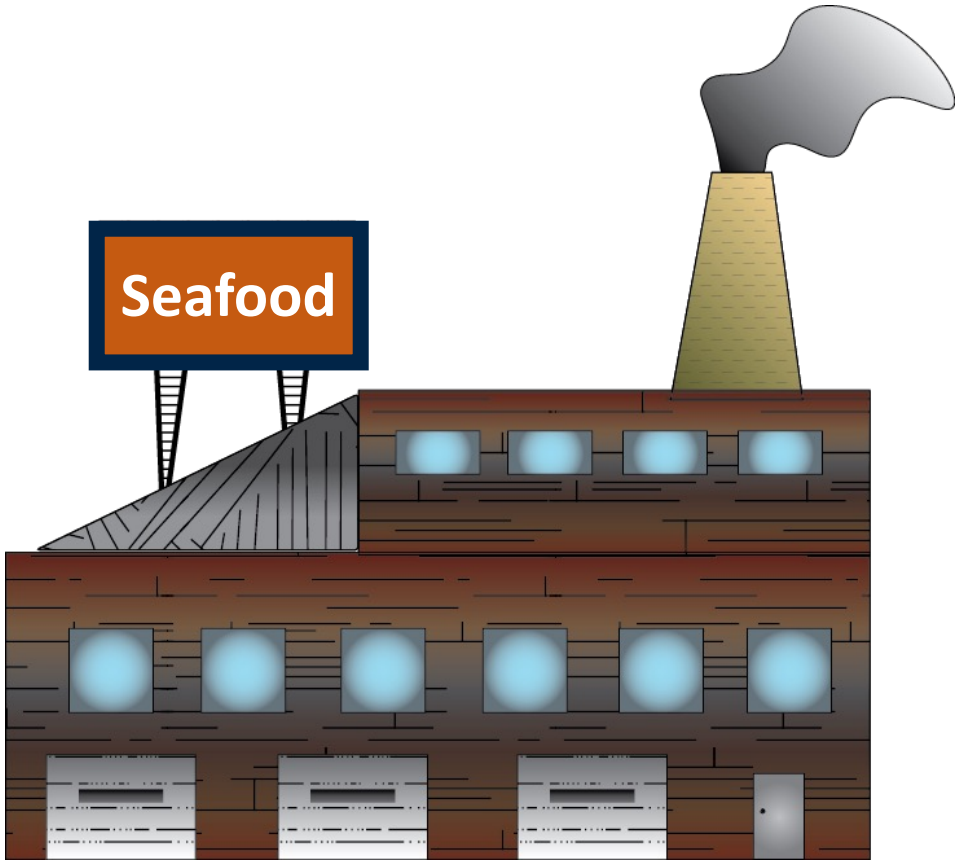
Form Title: Refrigerator Temperature Log (Monitoring Record)					
Firm Name:			**Firm Location:**		
Production Identification:					
Critical Limits:			**Monitoring Activities:**		
Date	Time	Storage Unit #	Refrigerator Temperature	Critical Limit Met (Yes/No)	Line Operator (Initials)
Reviewer Signature: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



Potential Seafood Safety Hazards

Species-Related Hazards





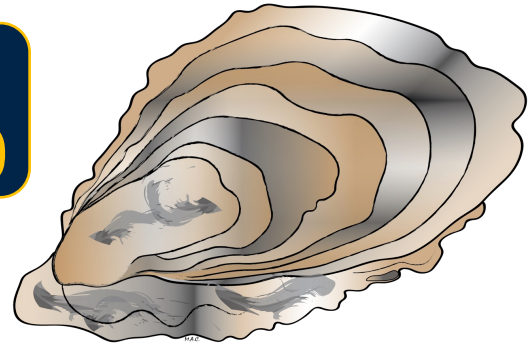
Process-Related Hazards

Potential Seafood Hazards

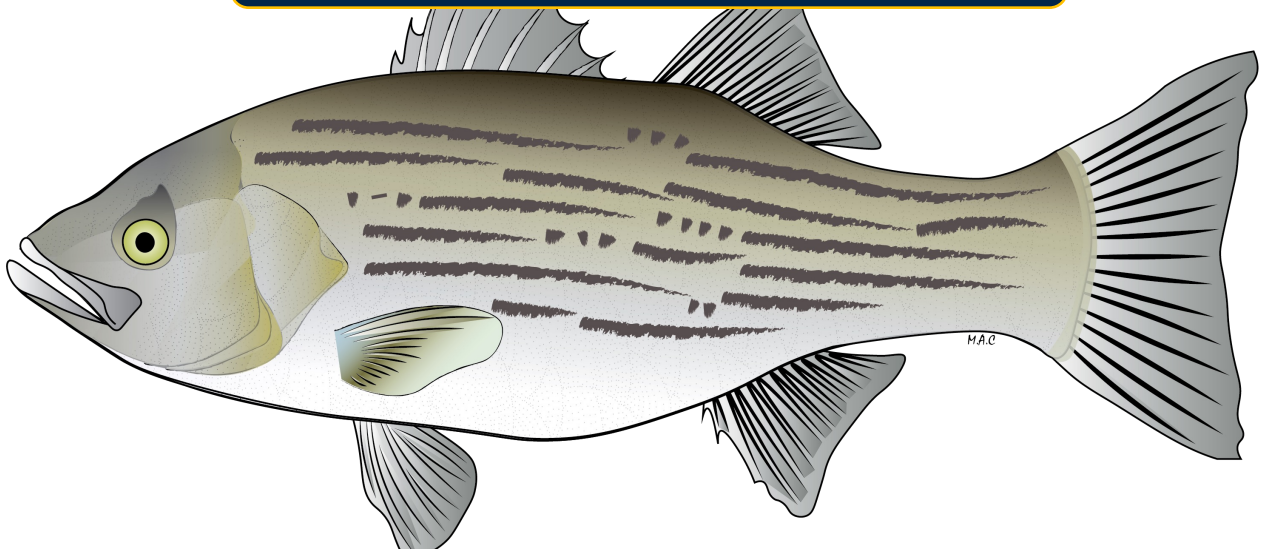
SPECIES-Related Hazards

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

Invertebrate
Table 3-3: 3-40

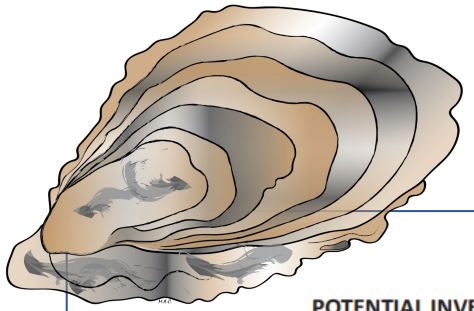


Vertebrate Table 3-2: 3-3



Potential Seafood Hazards

SPECIES-Related Hazards

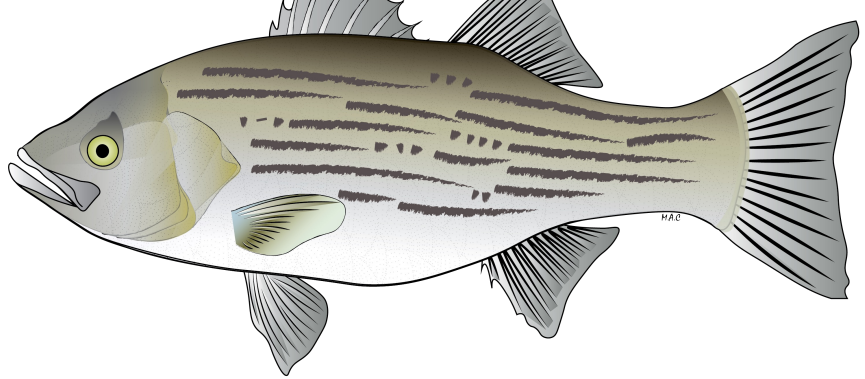


Invertebrate
Table 3-3: 3-40

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
ABALONE	*Haliotis laevigata*			✓	✓	
	H. ruber				✓	
	H. spp.				✓	
	Marinauris roei				✓	
ARKSHELL	*Anadara spp.*	✓		✓	✓	
	Arca spp.	✓		✓	✓	
BARNACLES, GOOSENECK	*Pollicipes polymerus*			✓	✓	
CLAM, BENTNOSE	*Macoma nasuta*	✓		✓	✓	
CLAM BUTTER	*Saxidomus spp.*	✓		✓	✓	
CLAM, CALICO	*Macrocallista maculata*	✓		✓	✓	



Vertebrate Table 3-2: 3-3

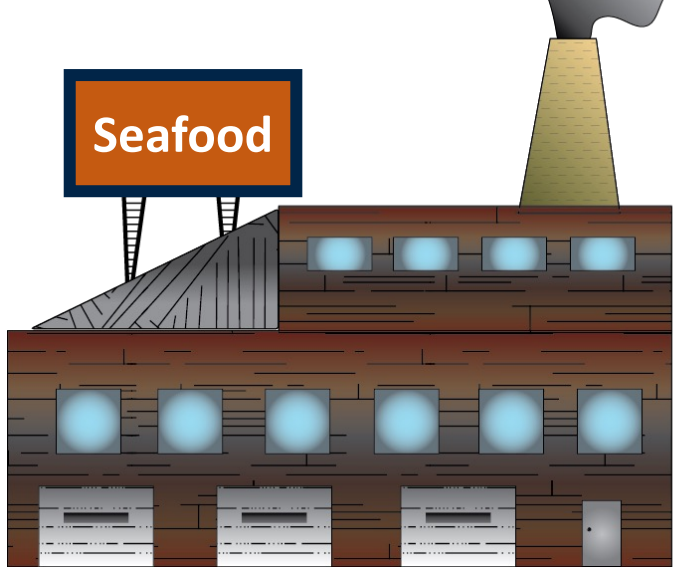
TABLE 3-2

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.*					
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓	✓	
ALFONSINO	*Beryx spp.*					
	Centroberyx spp.					
ALLIGATOR	*Alligator mississipiensis*				✓	
	Alligator sinensis				✓	
ALLIGATOR, aquacultured	*Alligator mississipiensis*				✓	✓
	Alligator sinensis				✓	✓
AMBERJACK	*Seriola dumerili*		CFP	✓		
	S. rivoliana		CFP	✓		
	S. spp.			✓		
AMBERJACK or YELLOWTAIL	*Seriola lalandi*			✓		
AMBERJACK or YELLOWTAIL, aquacultured	*Seriola lalandi*	✓[4]		✓	✓	✓
AMBERJACK or BURI, aquacultured	*Seriola quinqueradiata*			✓	✓	✓
ANCHOVY [12]	*Anchoa spp.*	✓	ASP [5]	✓		
	Anchoviella spp.	✓	ASP [5]	✓		
	Cetengraulis mysticetus	✓	ASP [5]	✓		
	Engraulis spp.	✓	ASP [5]	✓		
	Stolephorus spp.	✓	ASP [5]	✓		

Potential Seafood Hazards

Process-Related Hazards



- Pathogen Bacteria Growth – Temperature Abuse
- *C. botulinum* Toxin
- *S. aureus* Toxin – Drying
- *S. aureus* Toxin – Batter
- Pathogen Bacteria Survival through Cooking and Pasteurization
- Pathogen 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

Potential Seafood Hazards

Process-Related Hazards

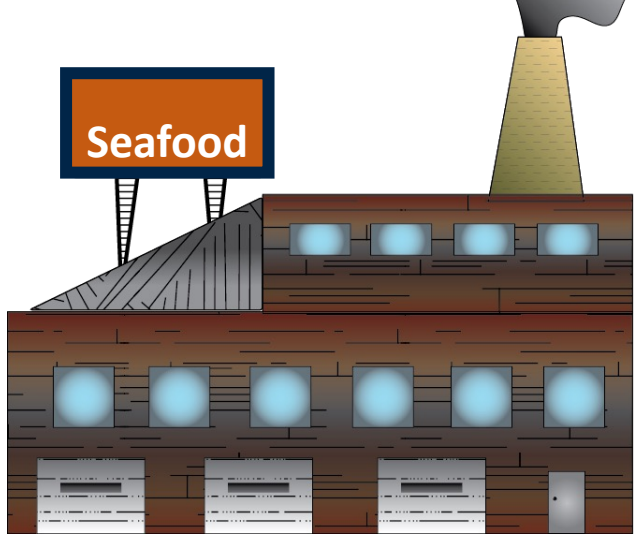


TABLE 3-4

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.	All.	✓	✓[6]	✓					✓	✓	
Fermented, acidified, pickled, salted, and LACFs.	All.	✓	✓[2]						✓	✓	✓
Fish oil.	All.								✓[3]		

Table 3-4: 3-52

Review of Potential Seafood Hazards

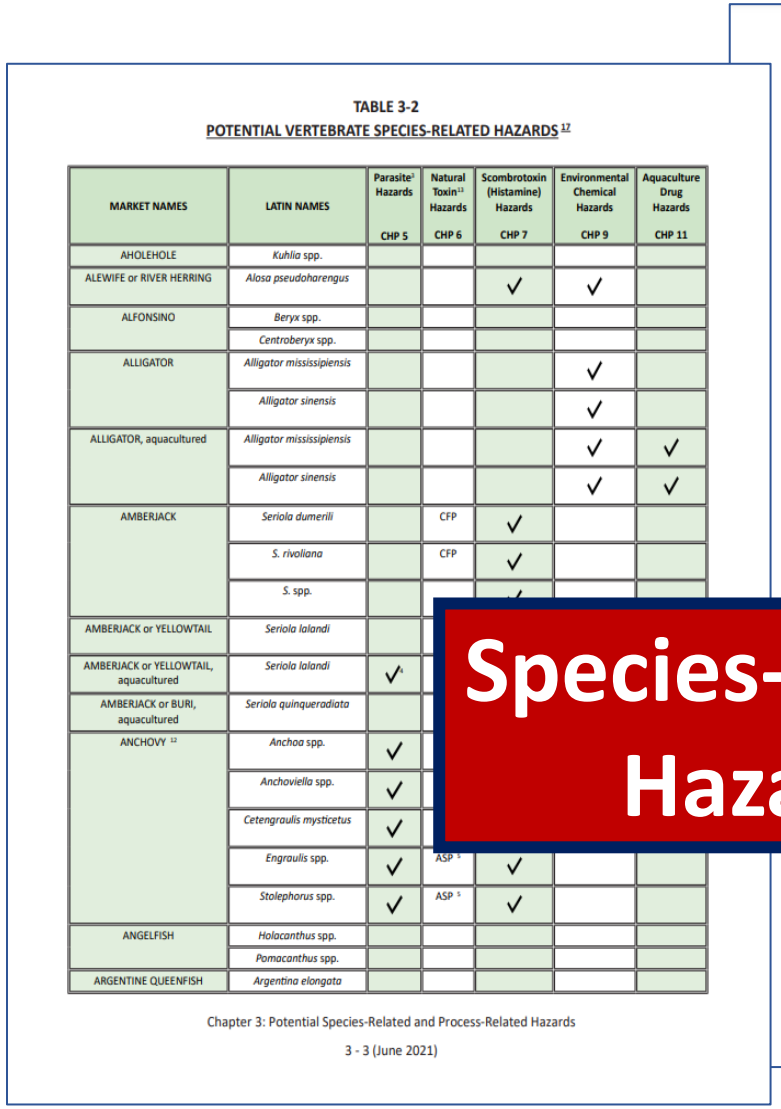


TABLE 3-2

POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

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.					
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓	✓	
ALFONSINO	*Beryx* spp.					
	Centroberyx spp.					
ALLIGATOR	*Alligator mississipiensis*				✓	
	Alligator sinensis				✓	
ALLIGATOR, aquacultured	*Alligator mississipiensis*				✓	✓
	Alligator sinensis				✓	✓
AMBERJACK	*Seriola dumerili*		CFP	✓		
	S. rivoliana		CFP	✓		
	S. spp.			✓		
AMBERJACK or YELLOWTAIL	*Seriola lalandi*					
AMBERJACK or YELLOWTAIL, aquacultured	*Seriola lalandi*	✓[4]				
AMBERJACK or BURI, aquacultured	*Seriola quinqueradiata*					
ANCHOVY [12]	*Anchoa* spp.	✓				
	Anchoviella spp.	✓				
	Cetengraulis mysticetus	✓				
	Engraulis spp.	✓	ASP [5]	✓		
	Stolephorus spp.	✓	ASP [5]	✓		
ANGELFISH	*Holacanthus* spp.					
	Pomacanthus spp.					
ARGENTINE QUEENFISH	*Argentina elongata*					

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
ABALONE	*Haliotis laevigata*			✓
	H. ruber			
	H. spp.			
	Marinauris roei			
ARKSHELL	*Anadara* spp.	✓		✓
	Arca spp.	✓		✓
BARNACLES, GOOSENECK	*Pollicipes polymerus*			✓
CLAM, BENTNOSE	*Macoma nasuta*	✓		✓
CLAM BUTTER	*Saxidomus* spp.	✓		✓
CLAM, CALICO	*Macrocallista maculata*	✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
	Protothaca thaca	✓		✓
CLAM, LITTLENECK	*Protothaca staminea*	✓		✓
	P. tenerrima	✓		✓

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.	All.	✓	✓[2]	✓					✓	✓	
Fermented, a... salted, and LA...										✓	✓
Fish oil.											

Species-Related Hazards

Process-Related Hazards

Species-Related Food Safety Hazards

CHP5: 91

Parasites:

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

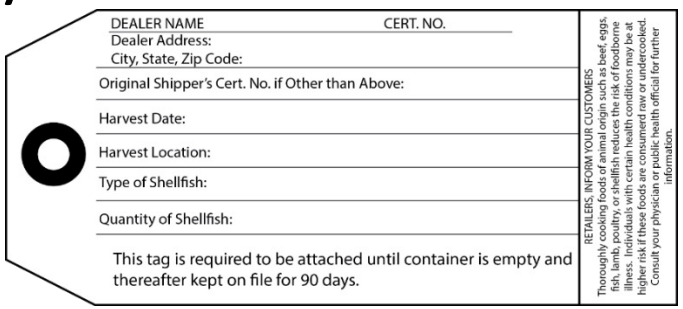
CHP4: 75

Harvest Pathogens:

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 labelled to ensure traceability.

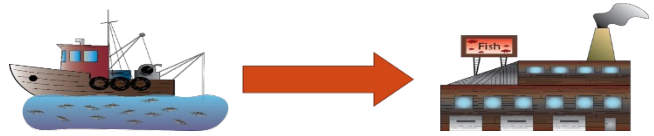

DEALER NAME CERT. NO.
Dealer Address:
City, State, Zip Code:
Original Shipper's Cert. No. if Other than Above:
Harvest Date:
Harvest Location:
Type of Shellfish:
Quantity of Shellfish:
This tag is required to be attached until container is empty and thereafter kept on file for 90 days.
RETAILERS, INFORM YOUR CUSTOMERS:
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.

Species-Related Food Safety Hazards

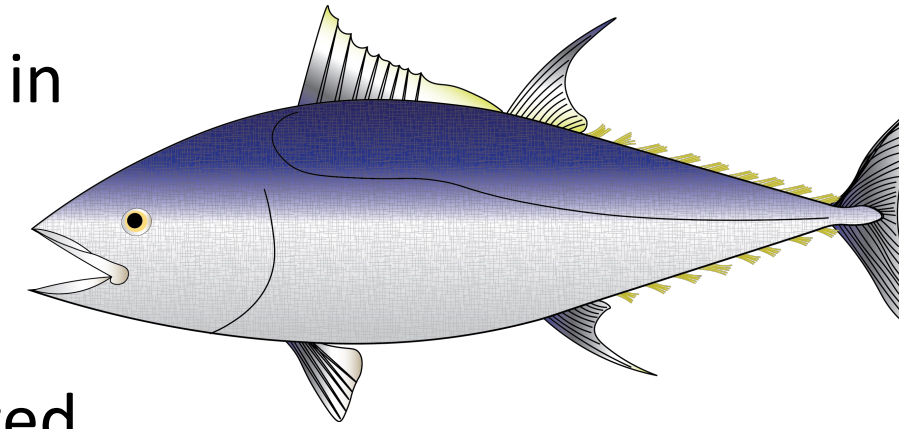
CHP7: 113

Histamine or Scombrotoxin:

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: 155

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 drug usage instructions and FDA requirements.

Potential Seafood Hazards

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

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.					
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓	✓	
ALFONSINO	*Beryx* spp.					
	Centroberyx spp.					
ALLIGATOR	*Alligator mississipiensis*				✓	
	Alligator sinensis				✓	
ALLIGATOR, aquacultured	*Alligator mississipiensis*				✓	✓
	Alligator sinensis				✓	✓
AMBERJACK	*Seriola dumerili*		CFP	✓		
	S. rivoliana		CFP	✓		
	S. spp.			✓		
AMBERJACK or YELLOWTAIL	*Seriola lalandi*					
AMBERJACK or YELLOWTAIL, aquacultured	*Seriola lalandi*	✓[4]				
AMBERJACK or BURI, aquacultured	*Seriola quinqueradiata*					
ANCHOVY [12]	*Anchoa* spp.	✓				
	Anchoviella spp.	✓				
	Cetengraulis mysticetus	✓				
	Engraulis spp.	✓	ASP [5]	✓		
	Stolephorus spp.	✓	ASP [5]	✓		
ANGELFISH	*Holacanthus* spp.					
	Pomacanthus spp.					
ARGENTINE QUEENFISH	*Argentina elongata*					

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
ABALONE	*Haliotis laevigata*			✓
	H. ruber			
	H. spp.			
	Marinauris roei			
ARKSHELL	*Anadara* spp.	✓		✓
	Arca spp.	✓		✓
BARNACLES, GOOSENECK	*Pollicipes polymerus*			✓
CLAM, BENTNOSE	*Macoma nasuta*	✓		✓
CLAM BUTTER	*Saxidomus* spp.	✓		✓
CLAM, CALICO	*Macrocallista maculata*	✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
		✓		✓
	Protothaca thaca	✓		✓
CLAM, LITTLENECK	*Protothaca staminea*	✓		✓
	P. tenerrima	✓		✓

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.	All.	✓	✓[2]	✓					✓	✓	
Fermented, a... salted, and LA...										✓	✓
Fish oil.											

Species-Related Hazards

Process-Related Hazards

Process-Related Food Safety Hazards

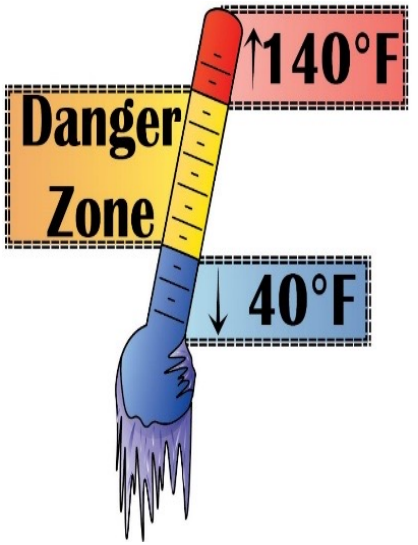
Pathogen Growth caused by time/temperature abuse:

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 Integrators (TTI) when adequate secondary barriers are not in place or when products require more stringent storage controls.

Process-Related Food Safety Hazards

Staph. aureus toxin production:

CHP15: 309

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

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

Undeclared Food Allergens:

CHP19: 19 - 1

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

Controls: Finfish and crustaceans 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:

CHP19: 19 - 3

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


PC # 48908
ICYBAY SURIMI
COOKED IMITATION CRAB CHUNK
VP PASTEURIZED
INGREDIENTS: Fish protein of Alaskan Pollock or Whiting, Water, Wheat Starch, Corn starch, Modified tapioca starch, Egg white, Soybean oil, Sugar, Sorbitol, Salt, Rice wine, Crab extract, Crab flavor, Crab seasoning, Calcium carbonate, Sodium tripolyphosphate, Tetrasodium pyrophosphate, Carmine (E-120) and paprika (E-160c) Color
CONTAINS: Pollock, Whiting, Crab, Soy, Egg, Wheat
Pack 4/2.5 DZ
Product of India
NET WT 10 LB (4.54 kg)
SG PO#
Pack Date:
Not Labeled for Retail Sale
Thaw Instructions: Remove from bag & Thaw under refrigeration
GTIN # 10073129489084
FOR PLACEMENT OF GTIN BARCODE ONLY

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

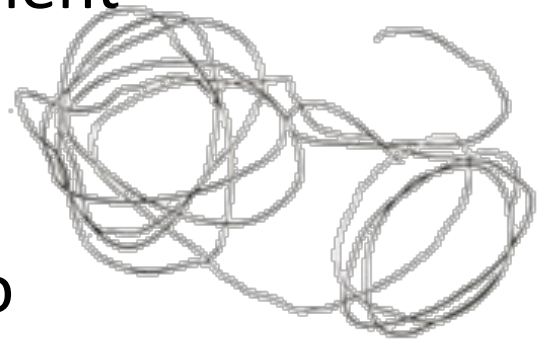
Process-Related Food Safety Hazards

CHP20: 385

Metal Inclusion in finished products:

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

CHP21: 395

Glass inclusion in finished products:

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

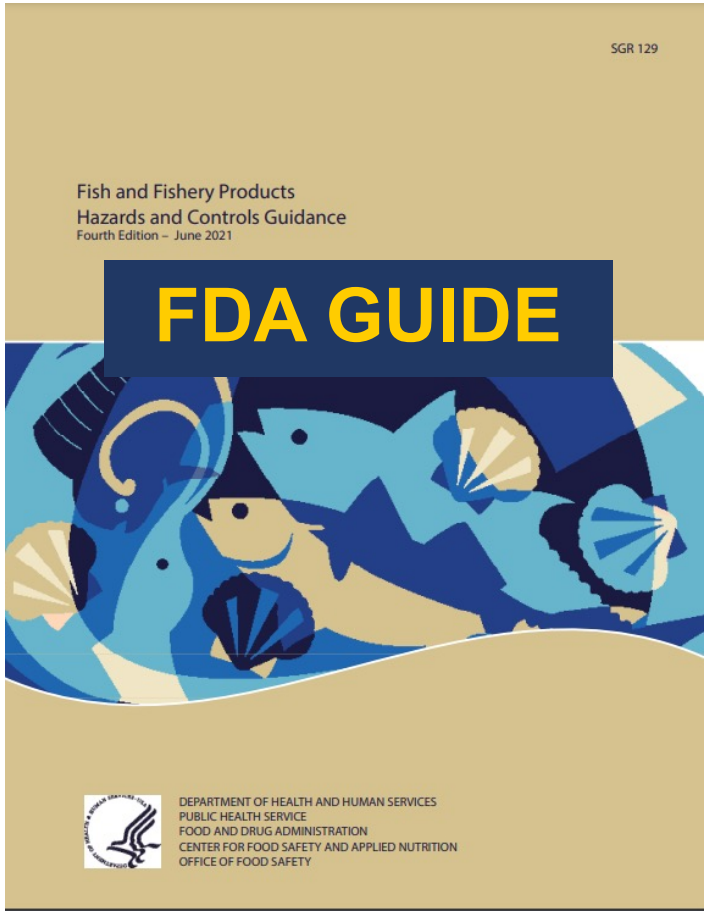
Controls: Glass containers are inspected and cleaned to prevent glass contaminating the food. Or work areas are inspected to identify when glass breakage has occurred.

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.



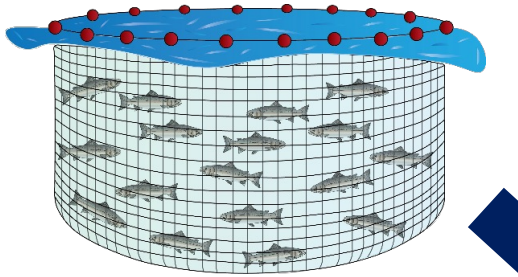
GOLD BOOK

NOTE

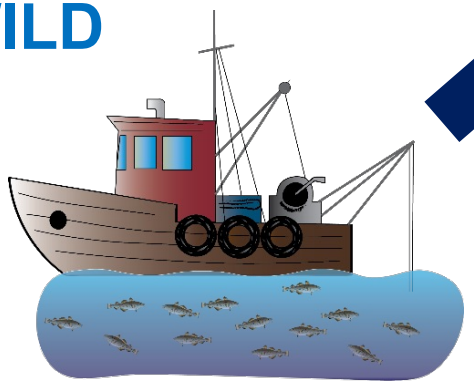
CHP 7: 125

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

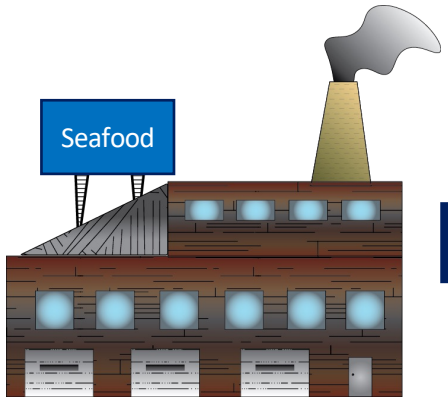
CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Harvest vessel control	✓	
Histamine testing	✓	
Transit control	✓	✓
Processing control	✓	✓
Storage Control	✓	✓

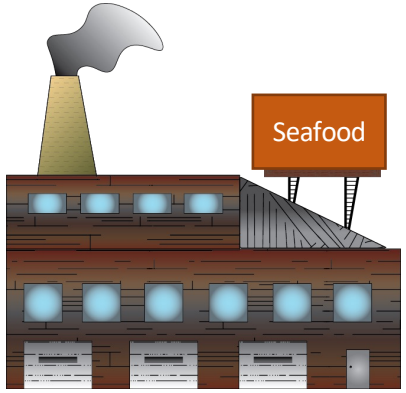


WILD



FARMED





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** - FOURTH EDITION - June 2021

Chapter Structure and Content

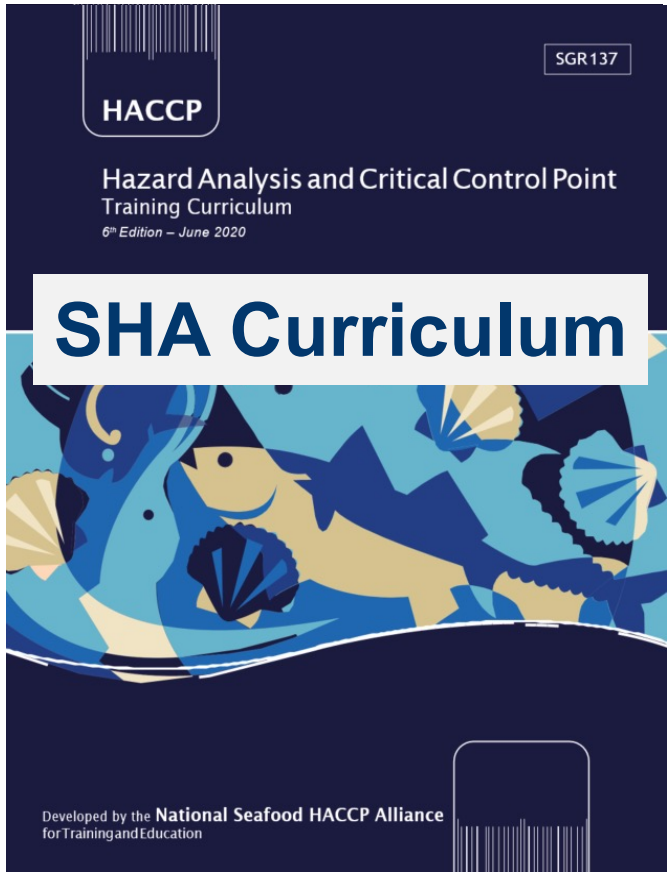
- Understand the Potential Hazard
- Determine whether the hazard is significant
- Identifying CCPs
- Develop a Control Strategy
  - Set Critical Limits
  - Establish Monitoring Procedures
  - Corrective Actions
  - Establish a Recordkeeping System
  - Establish Verification Procedures
- Example HACCP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

Developing a HACCP Program

Hazard Analysis =

HACCP Plan =

Building the HACCP Plan



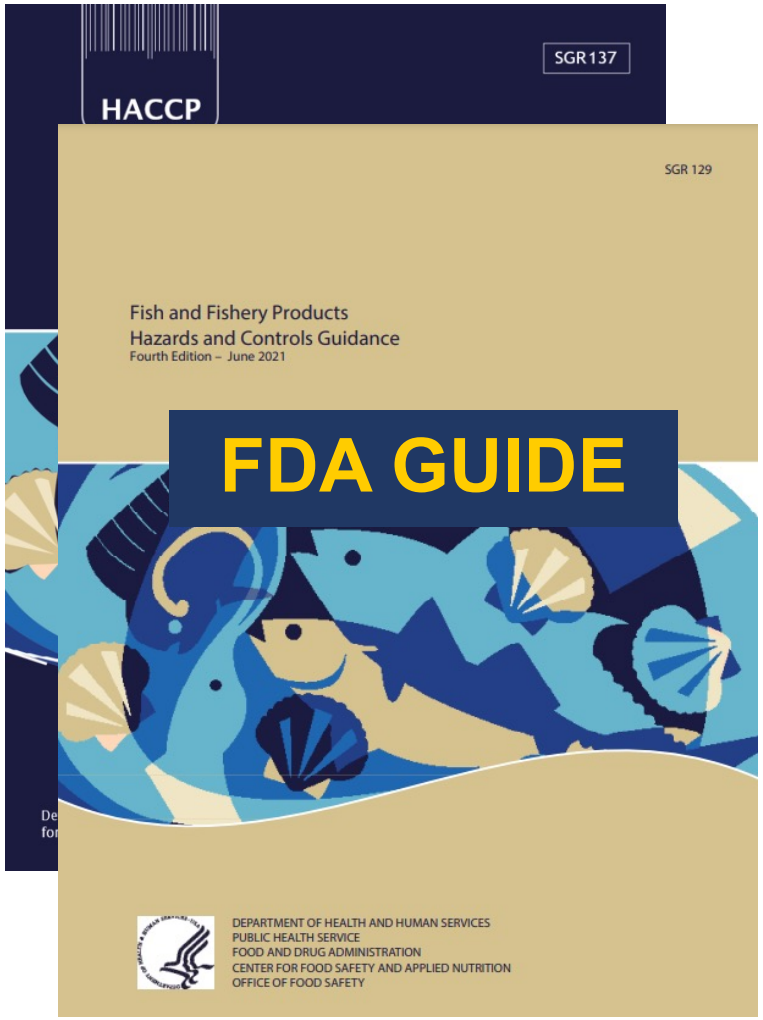
BLUE BOOK

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
1) Assemble HACCP team
2) Describe the product, intended use and consumers
3) Develop a process flow chart and process description

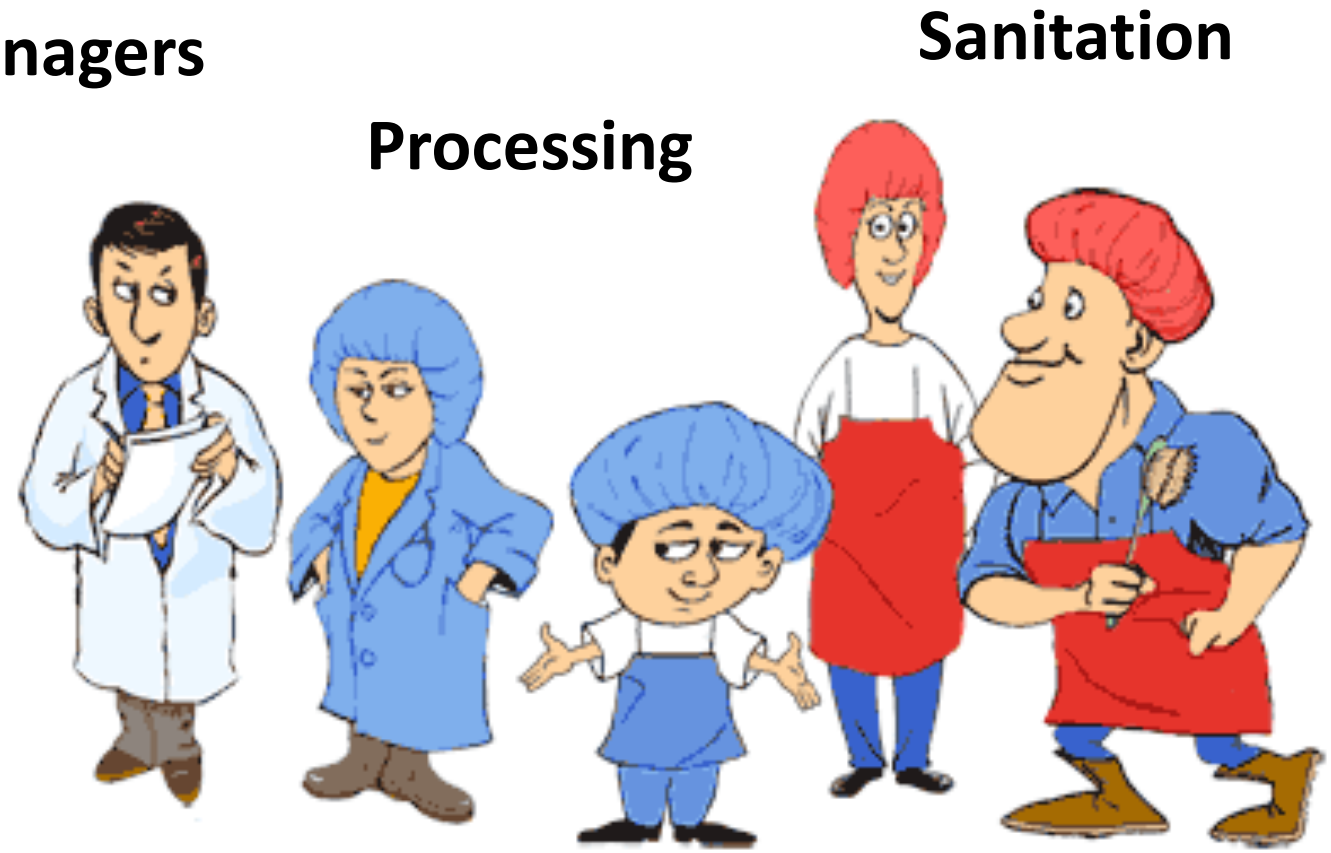
Building the HACCP Plan



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

Preliminary Step 1. Assemble the HACCP Team

CHP4: 74

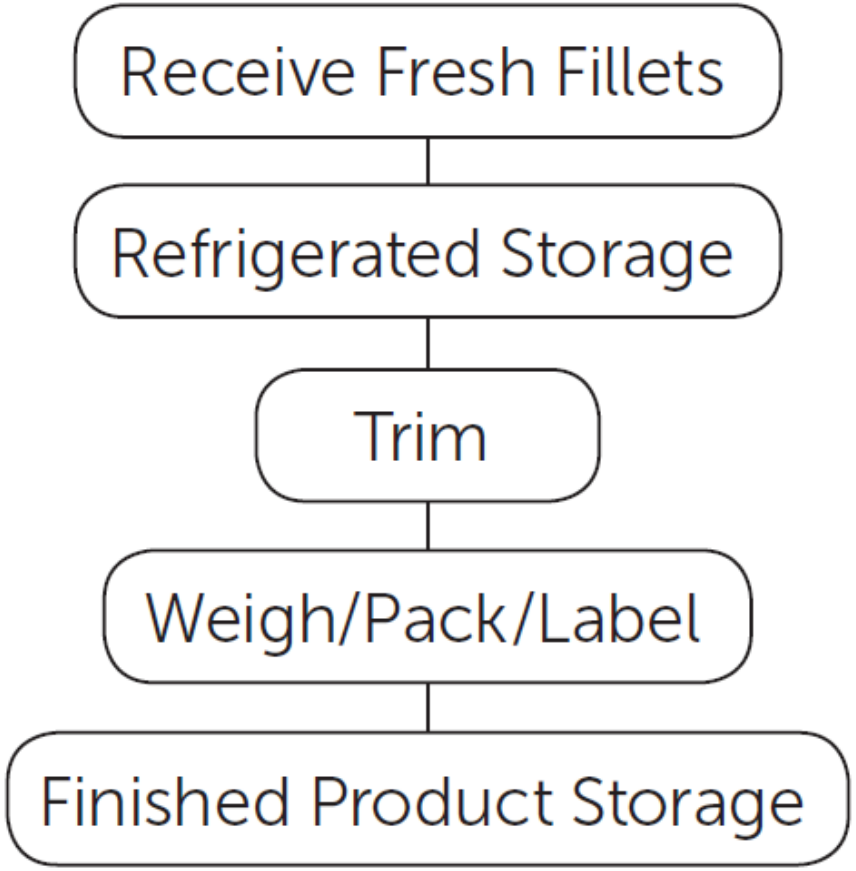


Preliminary Step 2. Process Flow Chart

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

Example: Fresh Mahi-mahi fillets

CHP4: 75



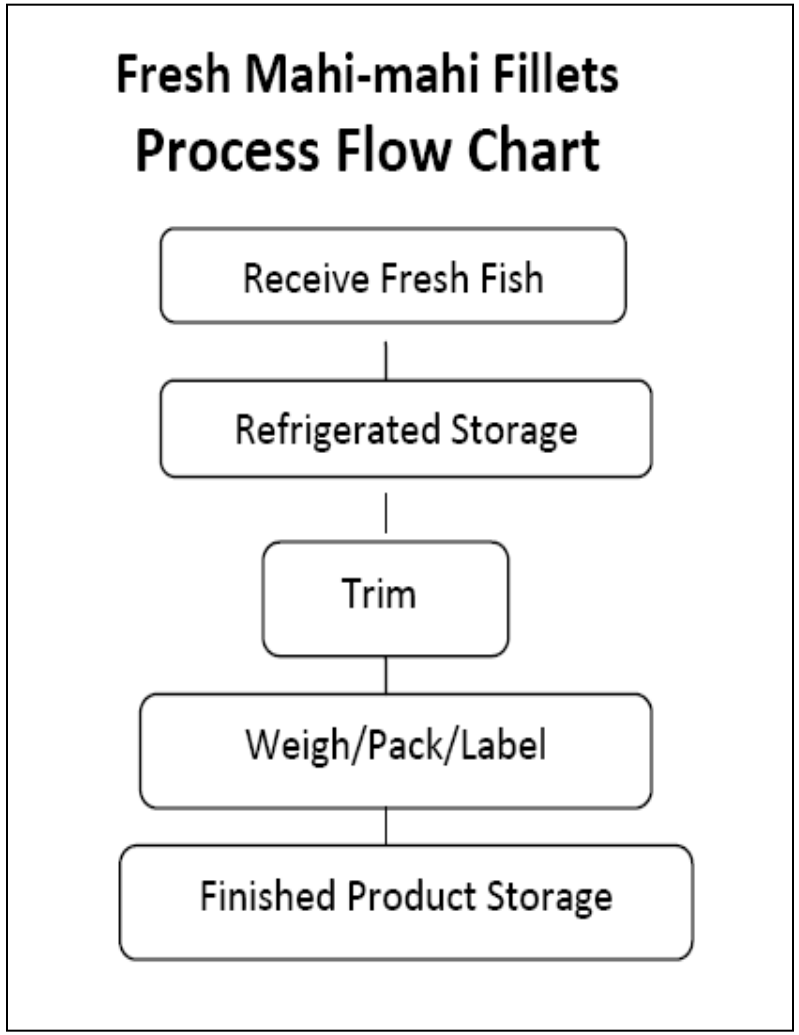
A brief processing narrative can be used to help explain the Processing Flow Chart (1 of 2)

CHP4: 75-76

Receive Fresh Fish – Fresh 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.

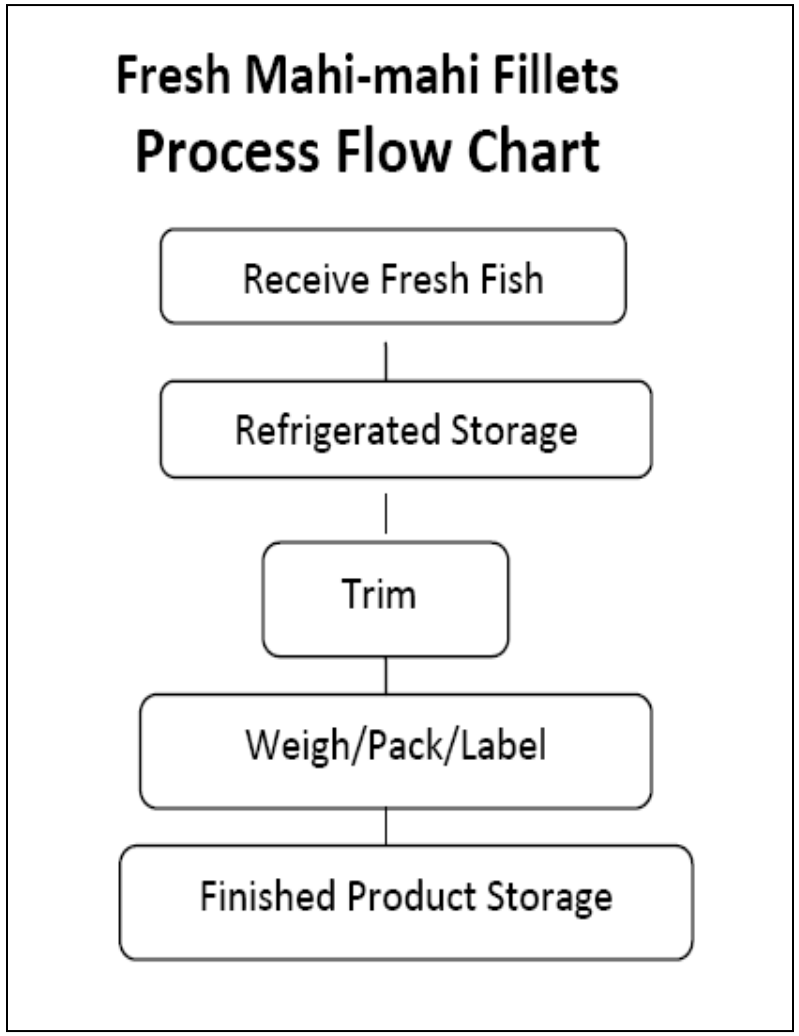


A brief processing narrative can be used to help explain the Processing Flow Chart (2 of 2)

CHP4: 75-76

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.



Preliminary Step 3. Describe Product

CHP4: 74

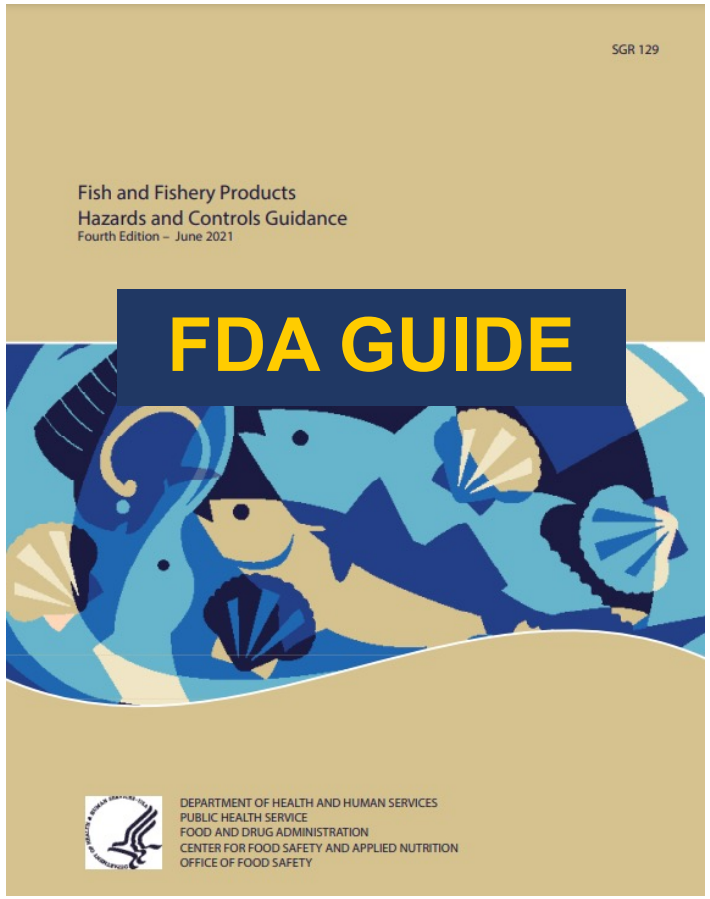
XYZ Seafood Company Product Description Form for Fish and Shellfish Species

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	

Blue Book provides a useful form for preliminary information

Appendix 2

Required Hazard Analysis



GOLD BOOK

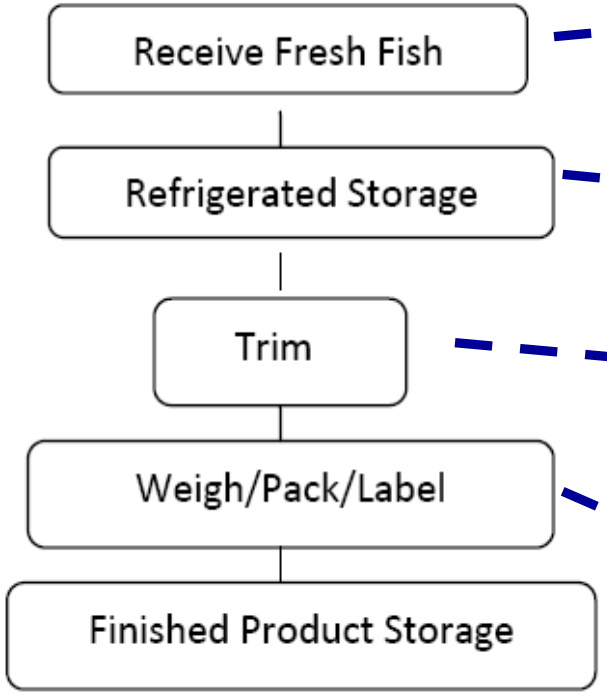
Use the preliminary information

- Process Description
- Processing Flow Chart
- Accompanying process narrative

with recommendations from the **FDA Guide** beginning with a Hazard Analysis Worksheet Appendix 2

Hazard Analysis Worksheet

Fresh Mahi-mahi Fillets Process Flow Chart



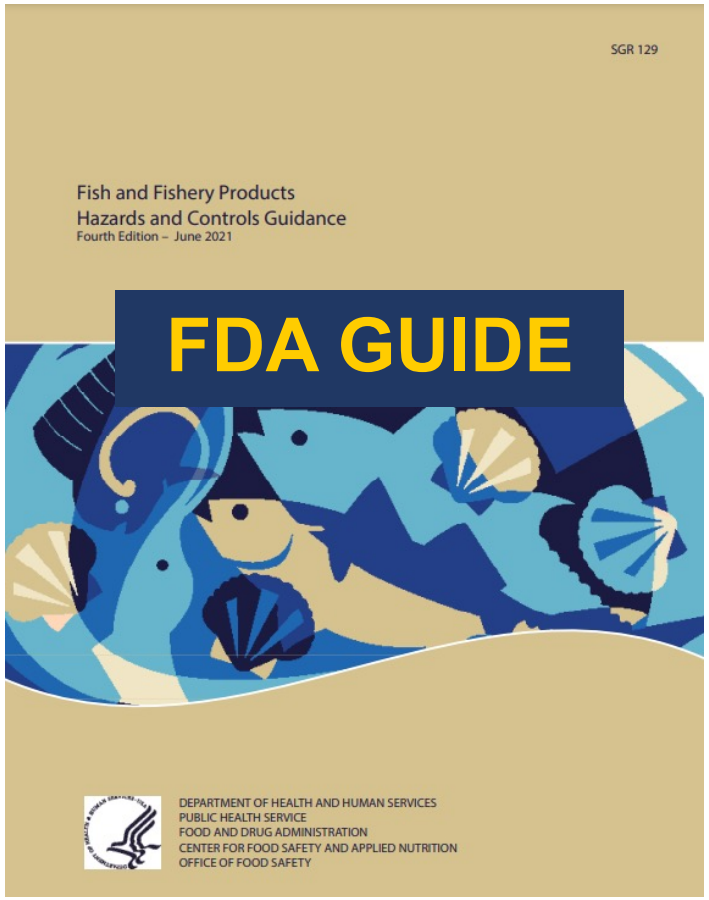
Hazard Analysis Worksheet

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

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

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 'Wild' Mahi-mahi Fillets (XYZ Seafood Company)

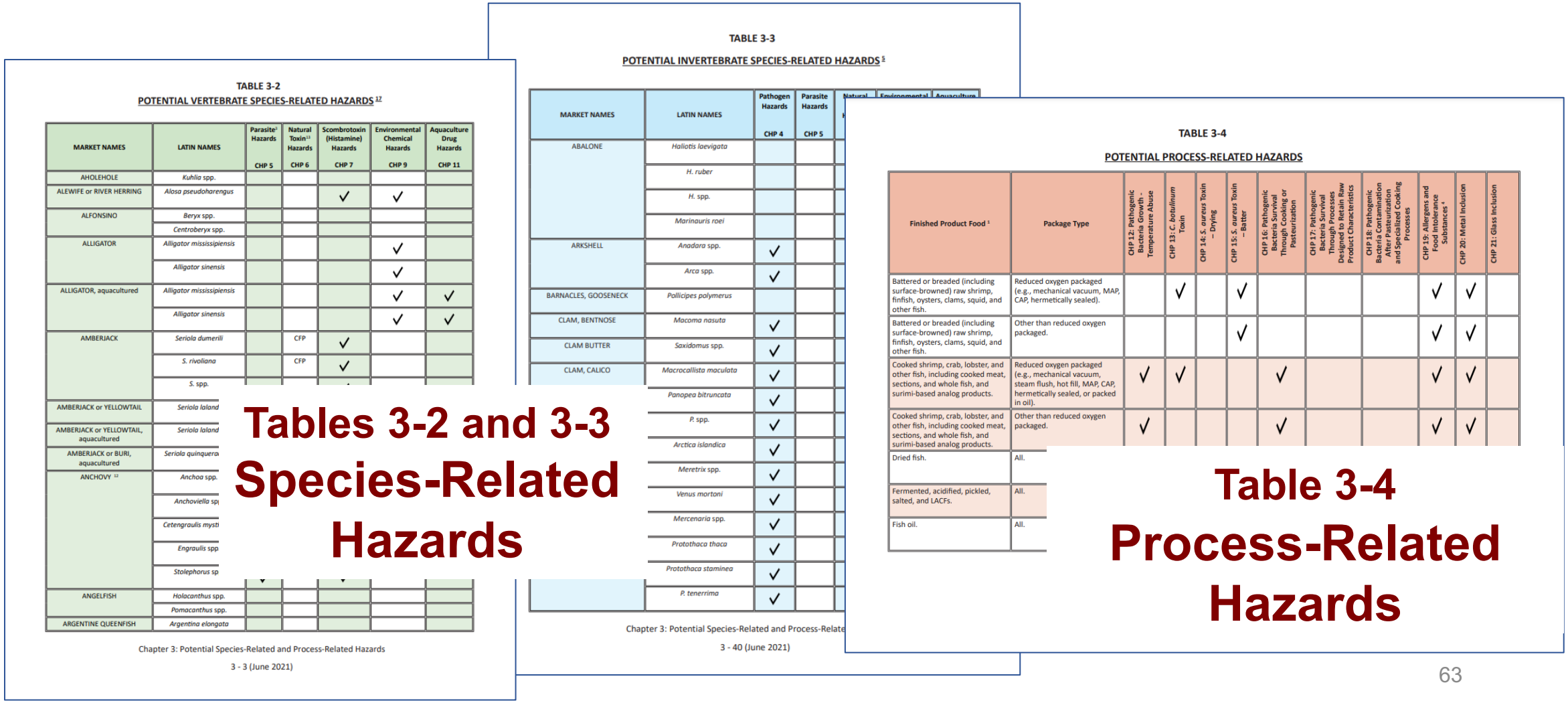


TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[2] 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.					
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓	✓	
ALFONSINO	*Beryx* spp.					
	Centroberyx spp.					
ALLIGATOR	*Alligator mississipiensis*				✓	
	Alligator sinensis				✓	
ALLIGATOR, aquacultured	*Alligator mississipiensis*				✓	✓
	Alligator sinensis				✓	✓
AMBERJACK	*Seriola dumerili*		CFP	✓		
	S. rivoliana		CFP	✓		
	S. spp.					
AMBERJACK or YELLOWTAIL	*Seriola lalandi*					
AMBERJACK or YELLOWTAIL, aquacultured	*Seriola lalandi*					
AMBERJACK or BURI, aquacultured	*Seriola quinqueradiata*					
ANCHOVY [12]	*Anchoa* spp.					
	Anchoviella spp.					
	Cetengraulis mysticetus					
	Engraulis spp.					
	Stolephorus sp.					
ANGELFISH	*Holacanthus* spp.					
	Pomacanthus spp.					
ARGENTINE QUEENFISH	*Argentina elongata*					

Chapter 3: Potential Species-Related and Process-Related Hazards
3 - 3 (June 2021)

TABLE 3-3
POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [6]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5
ABALONE	*Haliotis laevigata*		
	H. ruber		
	H. spp.		
	Marinauris roei		
ARKSHELL	*Anadara* spp.	✓	
	Arca spp.	✓	
BARNACLES, GOOSENECK	*Pollicipes polymerus*		
CLAM, BENTNOSE	*Macoma nasuta*	✓	
CLAM BUTTER	*Saxidomus* spp.	✓	
CLAM, CALICO	*Macrocallista maculata*	✓	
	Panopea bitruncata	✓	
	P. spp.	✓	
	Arctica islandica	✓	
	Meretrix spp.	✓	
	Venus mortoni	✓	
	Mercenaria spp.	✓	
	Protothaca thaca	✓	
	Protothaca staminea	✓	
	P. tenerrima	✓	

Chapter 3: Potential Species-Related and Process-Relate
3 - 40 (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.	All.										
Fermented, acidified, pickled, salted, and LACFs.	All.										
Fish oil.	All.										

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

Table 3-4 Process-Related Hazards

Table 3-2

One Species-related hazard

TABLE 3-2

POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

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
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.			✓	✓	✓

Table 3-4

Four Process-related Hazards

Notice two hazards in Chapter 19

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

Hazard Analysis Worksheet					
Firm Name: XYZ Seafood Company			Product Description: Fresh mahi-mahi fillets		
Firm Address: 238 Coastal Lane, Happy Beach, XX			Method of Storage & Distribution: Stored and distributed on ice		
			Intended Use & Consumer: To be cooked and consumed by the general public		
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process	(3) Is the potential food safety hazard **significant** (introduced, enhanced, eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving	Histamine				
	Pathogen Growth-Temp. Abuse				
	Undeclared Food Allergens				
	Food Intolerance Substances				
	Metal Inclusion				
Refrigerated Storage	Histamine				
	Pathogen Growth-Temp. Abuse				
	Undeclared Food Allergens				
	Food Intolerance Substances				
	Metal Inclusion				

Column 2:

List every potential hazard at each 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, eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving	Histamine				
	Pathogen Growth-Temp. Abuse				
	Undeclared Food Allergens				
	Food Intolerance Substances				
	Metal Inclusion				
Refrigerated Storage	Histamine				
	Pathogen Growth-Temp. Abuse				
	Undeclared Food Allergens				
	Food Intolerance Substances				
	Metal Inclusion				

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 details

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 Fillets	Histamine	Yes CHP7: 121	If the product does not remain sufficiently chilled, histamine could form	Mahi-mahi fillets are shipped in 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 mahi-mahi fillets
Firm Address: 238 Coastal Lane, Happy Beach, XX	Method of Storage & Distribution: Stored and distributed on ice
	Intended Use & Consumer: To be cooked and consumed by the general public

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process	(3) Is the potential food safety hazard **significant** (introduced, enhanced, eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point? (Yes or No)**
Receiving	Histamine	YES	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi fillets are shipped in containers buried in ice (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	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	Not likely to occur at this step		
Refrigerated Storage	Histamine	YES	Time/temp. abuse during transit could cause histamine to form in the fish	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	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	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 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) What	(5) How	(6) Frequency	(7) Who			

Signature:	Date:

Appendix 2

Optional HACCP Plan Forms
(both must contain same information)

Appendix 2

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

Portrait

Set up a HACCP Plan Form for each CCP

Hazard Analysis Worksheet

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

(1) Processing Step	(2) List all potential **food safety hazards** that could be associated with this product and process	(3) Is the potential food safety hazard **significant** (introduced, enhanced, eliminated) at this step? (Yes or No)	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent, eliminate or reduce this significant hazard?	(6) Is this step a **Critical Control Point?** (Yes or No)
Receiving	Histamine	YES	Time/temp. abuse during transit could cause histamine to form in the fish	Mahi-mahi fillets are shipped in containers buried in ice (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	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	Not likely to occur at this step		
Refrigerated Storage	Histamine	YES	Time/temp. abuse during transit could cause histamine to form in the fish	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	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	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

CHP 7: 137

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

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

CHP7: 109 Principle 3: Establish CRITICAL LIMITS

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4)–(7) Monitoring: What	How	Frequency	Who	(8) Corrective Action(s)	(9) Verification	(10) Records
RECEIVING	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt							
REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time							
WEIGH/PACK/ LABEL	Undeclared Food Allergens	All finished product containers will be labeled with the correct market name of the fish							
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time							

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

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

CHP 7: 137-139

CHP8: 119

Principle 4: Establish CCP MONITORING

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4) Monitoring What	(5) How	(6) Frequency	(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
RECEIVING	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt	Adequacy of ice surrounding 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	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each work day	Cooler Manager			
WEIGH/PACK/ LABEL	Undeclared 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 check a representative number of containers and their labels	Each customer order	Packing Manager			
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets ae completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each work day	Cooler Manager			

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

CHP 9: 129 Principle 5: CORRECTIVE ACTIONS (Page 1 of 2)

(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)	(9) Verification	(10) Records
RECEIVING	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt	Adequacy of ice surrounding 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 the supplier until their transport procedures are corrected		
REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and ice and make adjustments to the ice application process		

Example 3
CHP 7: 139

CHP9: 129 Principle 5: CORRECTIVE ACTIONS (Page 2 of 2)

WEIGH/PACK/ LABEL	Undeclared 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 check a representative number of containers and their labels	Each customer order	Packing Manager	**IF** a container is improperly labeled: **THEN** segregate it and properly label it before the customer order is placed in the finished product cooler. Modify labeling procedures and conduct training as necessary to ensure all products are properly labelled		
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and determine and fix icing procedures and cooler problems		

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

CHP10: 141

Principle 6: VERIFICATIONS (Page 1 of 2)

(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)	(9) Verification	(10) Records
RECEIVING	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt	Adequacy of ice surrounding 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 the supplier until their transport procedures are corrected	Weekly review of Receiving Log, Corrective Actions and Verifications. Check internal temp. of fish at delivery for each new supplier and quarterly thereafter to ensure the ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	
REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and ice and make adjustments to the ice application process	Weekly review of Cooler Ice Log, Corrective Actions and Verifications. Check internal temperature of fish quarterly to ensure ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	

Example 3
CHP 7:
139 -140

CHP10:141 Principle 6: VERIFICATIONS (Page 2 of 2)

(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)	(9) Verification	(10) Records
WEIGH/PACK/ LABEL	Undeclared 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 check a representative number of containers and their labels	Each customer order	Packing Manager	**IF** a container is improperly labeled: **THEN** segregate it and properly label it before the customer order is placed in the finished product cooler. Modify labeling procedures and conduct training as necessary to ensure all products are properly labelled	Weekly review of Packing Room Log, Corrective Actions and Verifications	
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and determine and fix icing procedures and cooler problems	Weekly review of Cooler Ice Log, Corrective Actions and Verifications Check internal temperature of fish quarterly to ensure ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	

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

CHP11:157 Principle 7: RECORDS (Page 1 of 2)

Example 3
CHP 7: 139

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventative Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
RECEIVING	Histamine	Mahi-mahi fillets are completely surrounded with ice at receipt	Adequacy of ice surrounding 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 the supplier until their transport procedures are corrected	Weekly review of Receiving Log, Corrective Actions and Verifications. Check internal temp. of fish at delivery for each new supplier and quarterly thereafter to ensure the ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	Receiving Log with the number of containers checked and number of containers in each shipment; and the results of checks for adequacy of ice Corrective Action and Verification Records
REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and ice and make adjustments to the ice application process	Weekly review of Cooler Ice Log, Corrective Actions and Verifications. Check internal temperature of fish quarterly to ensure ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	Cooler Ice Log with number of containers checked, the approx. number of containers in storage, and the results of checks for adequacy of ice. Corrective Action and Verification Records

CHP11:157 Principle 7: RECORDS (Page 2 of 2)

(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)	(9) Verification	(10) Records
WEIGH/PACK/ LABEL	Undeclared 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 check a representative number of containers and their labels	Each customer order	Packing Manager	**IF** a container is improperly labeled: **THEN** segregate it and properly label it before the customer order is placed in the finished product cooler. Modify labeling procedures and conduct training as necessary to ensure all products are properly labelled	Weekly review of Packing Room Log, Corrective Actions and Verifications	Packing Room Log with the number of containers checked, number of containers in the order, and the results from label checks. Corrective Action and Verification Records
FINISHED PRODUCT REFRIGERATED STORAGE	Histamine	Mahi-mahi fillets are completely surrounded with ice throughout storage time	Adequacy of ice surrounding Mahi-mahi fillets	Visual check of adequacy of ice in a representative number of containers in cooler storage	At the beginning and end of each 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 total time and temperature exposure, including exposures during prior processing operations, and determine and fix icing procedures and cooler problems	Weekly review of Cooler Ice Log, Corrective Actions and Verifications Check internal temperature of fish quarterly to ensure ice maintains product temp. Accuracy Check thermometers before use Annually calibrate thermometers	Cooler Ice Log with number of containers checked, the approx. number of containers in storage, and the results of checks for adequacy of ice. Corrective Action and Verification Records

Complete HACCP Plan

CHP11: 179-184

Slide 31

Firm Name: *XYZ Seafood Company*

HACCP Plan Form

Product: Fresh 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	Mahi-mahi fillets are completely surrounded with ice at receipt.	Adequacy of ice surrounding 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 and Verification records. Review of the Verification records within a reasonable time frame. Check internal temperature of fish at delivery for each new supplier and quarterly thereafter to ensure that ice maintains product temperature Check the accuracy of the thermometer before each use. Annual calibration of thermometer used to check internal temp.	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	Mahi-mahi fillets are completely surrounded with ice throughout storage time.	Adequacy of ice surrounding 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 and Verification records. 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

Verification	Records
Weekly review of Packing Room Log (Monitoring record) and Corrective action and Verification records. 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
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

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umed 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 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 a response in Column 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 course discussion

QUESTIONS